May 29, 2019

VIA ELECTRONIC MAIL

Dr. Thomas Armitage, Designated Federal Officer, armitage.thomas@epa.gov
Dr. Michael Honeycutt, Chair
Board Members
Scientific Advisory Board
U.S. Environmental Protection Agency

Re: Comments For the Science Advisory Board's Consideration in Advance of Its June 2019 Meeting: EPA Must Follow the Best Available Science

Dear Dr. Armitage, Dr. Honeycutt, and Members of the Science Advisory Board:

We appreciate the opportunity to comment on five items in advance of the Science Advisory Board's ("SAB's") June 2019 meeting. Earthjustice is a nonprofit environmental law organization that works with a wide array of nonprofit groups, from small grassroots community groups to large national environmental and health organizations. These groups' millions of members and constituents breathe the air, drink the water, eat the food, and work in factories, farms, and elsewhere, and thus have a personal stake in ensuring that EPA implements the laws designed to protect public health and the environment based on the best available science. Earthjustice submits these comments to ensure that the SAB has the information it needs to accurately, fairly, and completely assess the public health effects of proposed rules, plans, and actions.

Unless EPA follows the best available science, its actions – individually and collectively – will severely undermine (or fail to protect) fundamental human health and environmental safeguards. This will leave millions of Americans – particularly children – across the country without a defense against toxic pollutants and chemicals in our air, water, food, workplaces, and communities.

We therefore respectfully request that, when considering what actions to take regarding the matters on its agenda, the SAB advise EPA of the following:

1. EPA's Proposed Rule, "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18,768 (Apr. 30, 2018), is inconsistent with the best available science and methods, and with the Agency's legal responsibility to protect the environment and public health, and should not be finalized. There is no valid scientific basis to ignore epidemiological health studies and other peer-reviewed scientific information that reflect the best-available science when conducting rulemakings.

2. The Agency should not weaken its Guidelines for Carcinogen Risk Assessment or any other risk assessment guidelines ("Guidelines"). Before EPA reviews or

considers updating its Guidelines, EPA should engage the National Academy of Sciences ("NAS"), additional scientific experts without conflicts of interest, and the public, and should follow NAS's prior recommendations on this subject (discussed below). Regarding the substance of any changes, EPA should recognize that there frequently is no threshold for both carcinogens and non-carcinogens — any nonzero level of exposure is associated with a nonzero risk at the population level. EPA should recognize the need to treat many non-carcinogenic risks as low-dose linear, and it should recognize that, like cancer, non-cancer chronic and acute exposures also require strong and cumulative EPA risk assessments and actions to protect public health. EPA should update its approach, as the NAS has directed, to account for missing defaults and exposures, early-life vulnerability and socioeconomic disparities, stressors, and cumulative risks and impacts, through a peer-reviewed process that is free from industry bias and for-profit interests. Following these approaches is especially important for children, infants, pregnant women, and overburdened communities who are among the most vulnerable to harm from toxic exposures. EPA also should recognize that carcinogens frequently are mutagenic and apply age-dependent adjustment factors that account for fetal and early-life exposure for all carcinogens. To follow the best available science, EPA must account for the increased vulnerability and risk due to fetal exposure before birth (*in utero*) and to pregnant women, instead of ignoring this risk completely.

3. EPA's proposal to find that regulation of hazardous air pollutants emitted by coal-fired power plants is not "appropriate" under the Clean Air Act, 84 Fed. Reg. 2670 (February 7, 2019), is seriously flawed and must be withdrawn, and any action EPA takes must follow the best available science. Although the co-benefits of regulating the hazardous air pollution from coal-fired power plants include preventing between 4,000 and 11,000 premature deaths each year, EPA's proposal dismisses them as irrelevant. In addition, the proposal understates the direct benefits of reductions in hazardous air pollution, and overstates the costs.

4. EPA should go back to the drawing board on its Per- and Polyfluoroalkyl Substances (PFAS) Action Plan, which falls short of what is needed to protect communities from a class of chemicals that are polluting drinking water and air, while exposing families – particularly children – to a myriad of health risks, including cancer.

5. EPA should withdraw its Revised Definition of Waters of the United States, 84 Fed. Reg. 4154 (Feb. 14, 2019)). Known as the Dirty Water Rule, this revised definition threatens to remove from America's waters critical protections against pollutants, and will lead to their severe destruction and degradation. And these deleterious effects will disproportionately occur in environmental justice communities across the country.

As additional information in support of this request, we state as follows.

1. SAB Should Advise EPA to Abandon Its Strengthening Transparency in Regulatory Science Proposed Rule Because It Is Scientifically Unsound.

As explained in great detail in the extensive comments Earthjustice previously submitted on behalf of 88 environmental, farmworker, environmental justice, public health, and animal protection organizations, *see* Docket No. EPA-HQ-OA-2018-0259-6137, attached as Attachment 1,[1] the Proposed Rule does not strengthen science at all, as its misleading name suggests. Instead, its intent and effect is to exclude from consideration scientific studies that examine the health impacts of environmental contamination and toxic chemicals that meet all standards of scientific validity and rigor simply because they rely upon non-public data such as confidential medical information. The devastating effect this will have on public health cannot be overstated.

Epidemiological studies are foundational to understanding critical connections between exposure to toxic chemicals and public health harms. These studies are possible because the researchers promise to protect the medical or other sensitive or identifying information of its participants.[2] Under the Proposed Rule, EPA could not consider these studies despite their scientific integrity, eliminating valid scientific information critical to understanding environmental and occupational exposures to toxic chemicals simply because the studies depend upon non-public data. For example:

- Epidemiological studies have been crucial to understanding toxic harms stemming from exposure to airborne lead. One of the key studies – known as the Miranda study – found a significant correlation between living near a general aviation airport where leaded aviation fuel is used and elevated blood lead levels in children. M.L. Miranda et al., *A Geospatial Analysis of the Effects of Aviation Gasoline on Childhood Blood Lead Levels*, Envtl. Health Persp. 119(10): 1513-1516 (Oct. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3230438/. Because the study relied on blood lead level surveillance data for over 125,000 children between the ages of 9 months and 7 years in specific counties in North

[1] In response to the Proposed Rule, 597,082 individuals and organizations submitted comments, most of which were critical of the Proposed Rule's outright and unjustified rejection of sound science. And 91 individuals and organizations testified at the hearing, the majority of whom expressed strong opposition to the Proposed Rule. *See* Public Hearing Transcript on the Proposed Rule Titled, "Strengthening Transparency in Regulatory Science," (July 17, 2018), Docket No. EPA-HQ-OA-2018-0259-8281, attached as Attachment 2.

[2] Recognizing the importance of public participation in health studies and the need to protect confidential information of human subjects, in 1981 the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research recommended that all federal agencies adopt uniform regulations concerning the protection of human research subjects. *See* 47 Fed. Reg. 13,272 (March 29, 1982). In response, EPA and 14 other federal agencies and departments adopted uniform regulations on this issue (the "Common Rule"), *see* 56 Fed. Reg. 28,003 (June 18, 1991), which prohibits EPA from relying on research that is "deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm . . . or impaired their informed consent." 40 C.F.R. §§ 26.1704(b)(2), 26.1705(b). The Common Rule recognizes that the protection of private information of the human subject is central to its ability to provide informed consent. *See generally id.* § 26.116.

Carolina that has been kept confidential to protect the privacy of the child participants, EPA could refuse to consider the results of this landmark study when taking regulatory action on lead. Ignoring this information could have grave public health consequences.

- Researchers have conducted extensive epidemiological studies on exposure and health risks related to perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonate ("PFOS"), working with nearly 70,000 participants to examine health impacts from exposure to these chemicals. These studies -- which found probable links between exposure to PFOA and PFOS and incidence of six specific diseases (diagnosed high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer, and pregnancy-induced hypertension) – depend upon confidential and sensitive medical and demographic data. As a result, under EPA's Proposed Rule, this scientifically sound research would not be considered when determining health-based standards for these toxic chemicals.

- Alaska Community Action on Toxics has been conducting rigorous, peer-reviewed, multi-year research into "exposure pathways, body burdens, and health outcomes associated with chemicals, including PCBs, PBDEs and other flame retardants, and PFAS, in homes, in air, water, traditional foods, and in the blood serum of the Yupik people of St. Lawrence Island" in Alaska. *See* Comments Prepared By Pamela Miller, Executive Director, Alaska Community Action on Toxics, July 17, 2018, Docket No. EPA-HQ-OA-2018-0259-6123, attached as Attachment 3. These studies "have shown elevated body burdens, as well as disruption of thyroid function associated with exposures to certain PBDEs and PFAS chemicals." *Id*. To conduct these studies, the team "gather[s] detailed information about peoples' health and occupational histories, practices in their homes and communities that might relate to chemical exposures," and participants depend on promises of privacy when deciding to engage in the studies. *Id*. Under the Proposed Rule, because of the confidential nature of the underlying data, "studies such as these" – which are "rigorous[ly] review[ed]" and "published . . . in eleven peer-reviewed journal articles" – "would not be considered by EPA when it makes decisions about chemicals and pollutants that are poisoning the people of the Arctic." *Id*.; *see also* Public Hearing Transcript at 228-33.

- The Farmworker Association of Florida conducts scientific research to better understand the "health and safety risks to farmworkers from the conditions of their employment, including pesticide exposure." *See* Comments Prepared By Jeannie Economos, The Farmworker Association of Florida, Aug. 16, 2018, Docket No. EPA-HQ-OA-2018-0259-6884, attached as Attachment 4. Farmworkers risk exposure to toxic chemicals every day, as they work in the fields where pesticides are applied, and live in communities where the water is affected by pesticide run-off and homes are subject to pesticide residue carried on clothing and shoes. *Id*. Studies on farmworker communities are critical to understanding the health impacts of pesticide exposure, and are only possible because of guarantees that confidential information will remain private "so that

> [farmworkers] do not risk retaliation for participating" in the studies. *Id.*; *see also* Public Hearing Transcript at 80-84. Under the Proposed Rule, EPA will not consider these critical studies on health and safety risks to farmworker communities when evaluating risks associated with pesticide exposure.

Many other studies would likewise be excluded from consideration under the Proposed Rule either because the data is confidential and not publicly available, or because the data is old and thus the results can no longer be replicated as required by the Proposed Rule. This includes, but is not limited to: early studies on the neurological effects of low-dose lead exposure on children's health, which have been foundational to setting lead levels for air and water, as well as for certain products such as paint,[3] where the underlying data is confidential and not subject to public exposure; studies demonstrating the link between exposure to arsenic and developing cancer that depend upon confidential clinical examinations of the patients that served as research subjects,[4] and thus where the sensitive health data underlying the studies cannot be publicly exposed; and studies on the impact of air pollution and mortality rates that have been used by EPA for decades to set air quality standards that rely on confidential data that may not be lawfully disclosed.[5] In addition, foundational research and toxicology relying on peer-reviewed, epidemiological studies by EPA's IRIS program and other agency scientists, and by independent scientists on PM2.5, lead, and other toxicants, have saved lives by providing regulatory safeguards against unhealthy air. EPA's longstanding use and reliance on this scientific information has prevented and reduced asthma, heart attacks, and early death, and has led to stronger health protections against cancer, neurological, and other harms affecting children and other vulnerable populations.[6] Under the Proposed Rule, EPA could no longer use this critical information because of the confidential nature of the underlying data.

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[3] Herbert L. Needleman et al., *Deficits in Psychologic and Classroom Performance of Children with Elevated Dentine Lead Levels*, 300 New England J. Medicine 689 (1979); EPA, Air Quality Criteria for Lead 12-86 to 12-88, 12-95 (1986), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=32647; Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper, 56 Fed. Reg. 26,460, 26,468–69 (June 7, 1991); Lead; Identification of Dangerous Levels of Lead, 63 Fed. Reg. 30,302, 30,316–30,317 (June 3, 1998). The final rule was published at 66 Fed. Reg. 1206 (Jan. 5, 2001); National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 66,964 (Nov. 12, 2008).

[4] National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 65 Fed. Reg. 38,888, 38,902 (June 22, 2000).

[5] Douglas W. Dockery et al., *An Association between Air Pollution and Mortality in Six U.S. Cities*, 329 New England J. Med. 1753 (1993), http://www.scientificintegrityinstitute.org/Dockery1993.pdf.

[6] As the D.C. Circuit explained when upholding the last PM NAAQS against a polluter challenger, "In the 2013 Rule, EPA lowered the level of the particulate matter NAAQS from 15.0 µ/m3 to 12.0 µ/m3. EPA did so after it considered a broad array of scientific sources, as well as the views of EPA staff and the Clean Air Scientific Advisory Committee. *See* National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3086, 3106-21 (Jan. 15, 2013); Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee, to Lisa P. Jackson, EPA Administrator i-ii (Sept. 10, 2010). EPA selected the 12.0 µ/m3 level because it was somewhat below the long-term mean concentration shown by certain key epidemiologic studies to cause adverse health effects. *See* 78 Fed. Reg. at 3158-59, 3161." *Nat'l Ass'n of Mfrs. v. EPA*, 750 F.3d 921, 924 (D.C. Cir. 2014).

Each and every one of these epidemiological studies has played a pivotal role in protecting millions of Americans from pollutants and toxic chemical exposure. Yet under the Proposed Rule, EPA could not consider this science when issuing regulations that have a direct impact on public health. EPA's proposal to ignore health-based science would hurt children the most, especially in communities experiencing a multitude of toxic exposures. As the SAB previously recognized when considering the Proposed Rule,

> For studies published many years ago, it may not be feasible to deliver public access to data and analytic methods. There are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate.
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> Furthermore, the rule could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts. The proposed rule does not acknowledge that the epidemiologic science community, for example, has been making significant efforts to make data available where possible and to develop studies based on publicly available data where appropriate.

See Memorandum from Alison Cullen, Chair, SAB Work Group, to Members of the Chartered SAB and SAB Liaisons, "Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)," 3 (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf ("SAB Comment"). And as the SAB also explained, release of confidential information is not the only or even best way to validate a study:

> The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies ***without public access to data and analytic methods***. For example, the Health Effects Institute (HEI) conducted a re-analysis of the influential Harvard Six Cities and American Cancer Society (ACS) epidemiologic studies and was able to replicate its findings and to assess the robustness of the findings via sensitivity analysis.

SAB Comment at 4 (emphasis added). The Proposed Rule provides no justification for limiting science the way that it does.

Overall, the Proposed Rule does not strengthen science at all, but instead aims to restrict EPA's use of the types of human health studies that have been instrumental in setting pollution limits that save hundreds of thousands of lives and prevent millions of diseases each year, and that protect against harmful and sometimes lethal exposure to toxic chemicals. Given the multitude of ways the Proposed Rule undermines the use of sound science, EPA's Proposal

would weaken, not improve, its decision-making on critical public health issues. The SAB should therefore advise EPA to abandon the Proposed Rule and instead continue to consider the epidemiological studies that have been and will continue to be so critical to protecting public health.[7]

2. The SAB Should Advise EPA to Strengthen – Not Weaken – Its Guidelines on Carcinogenicity Assessment.

Given EPA's approach to science under the Proposed Rule, we have serious concerns that any updates to the Guidelines for Carcinogen Risk Assessment and the creation of guidelines for non-carcinogen risk assessment will be used to further diminish the role of science in Agency decision-making. Any proposed changes to risk assessment guidelines should be subject to public comment and external peer review. All experts who participate in peer review should be free of financial conflicts of interest, including any employment or consulting relationship with a regulated industry. However, we emphasize the conclusion of EPA's Office of Inspector General that receipt of a federal grant is *not* a financial conflict of interest.[8]

If EPA does create or update risk assessment guidelines, the SAB should advise the Agency to ensure that all changes reflect the best available science. Specifically, EPA should consider the following principles:

First, if EPA updates the Guidelines, the SAB should advise EPA to state clearly that *all* carcinogens should be presumed mutagenic, and age-dependent adjustment factors should be applied, unless reliable data allow the Agency to establish a non-mutagenic mode of action. Since their creation in 2005, the Guidelines have advanced cancer risk assessment at EPA and the many other agencies that utilize them. However, EPA still fails to fully account for cancer risk when conducting analyses to support rulemaking. For example, EPA has restricted its application of age-dependent adjustment factors recommended by the Guidelines and Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens to carcinogens that act by a mutagenic mode of action. Thus, the SAB should advise EPA to evaluate and revise this approach to assure consideration of the additional health risks caused by children's exposure to carcinogens.[9]

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[7] Not only is the Proposed Rule scientifically unsound, but it is also unlawful for myriad reasons described in detail in Earthjustice's comments. *See* Docket No. EPA-HQ-OA-2018-0259-6137.

[8] EPA, OIG, "EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees" at 9 (2013), attached as Attachment 5, https://www.epa.gov/sites/production/files/2015-09/documents/20130911-13-p-0387.pdf.

[9] For additional information on this issue, *see* Attachment 6, Earthjustice *et al.* Comments on EPA's Request for Information on Cumulative Risk Assessment at 22, https://www.regulations.gov/document?D=EPA-HQ-ORD-2013-0292-0133; *see also* Cal. EPA, OEHHA, "Technical Support Document for Cancer Potency Factors: Methodologies for Derivation, Listing of Available Values, and Adjustments to Allow for Early Life Stage Exposures" 3-4, 50-51 (May 2009), http://www.oehha.ca.gov/air/hot_spots/2009/TSDCancerPotency.pdf, and http://oehha.ca.gov/air/hot_spots/tsd052909.html; Earthjustice *et al.* Comments on Draft Guidelines for Human Exposure Assessment, https://www.regulations.gov/document?D=EPA-HQ-ORD-2015-0684-0024, attached as Attachment 9.

Second, if EPA updates the Guidelines, the SAB should advise EPA to apply adjustment factors or other appropriate methods to account for *pre-natal* exposures. While the Supplemental Guidance recommends the application of age-dependent adjustment factors to account for increased susceptibility to *post*-natal exposures, it does not recommend methods to account for heightened vulnerability during the *pre*-natal period. The NAS has noted that "EPA treats the prenatal period as devoid of sensitivity to carcinogenicity" despite the Agency's clear statement in the Guidelines that "exposures that are of concern extend from conception through adolescence."[10] EPA has no valid scientific basis to refuse to account for the additional cancer risks caused by exposure to the developing fetus and pregnant women. Thus, the SAB should recommend that EPA revise its approach. For example, there is strong scientific support for adding a safety factor of at least 10X to account for pre-natal exposure.[11]

Third, any guidelines for non-carcinogen risk assessment should recognize that many chemicals and pollutants that can cause severe chronic and acute harm to public health have no threshold or "safe" level of exposure. For example, EPA has concluded there is no threshold for lead or PM2.5.[12] Furthermore, NAS has concluded that, due to the variability in susceptibility and exposures to other stressors within populations, non-carcinogens may lack thresholds in *populations* even when these effects have thresholds in *individuals* who are less susceptible or have lower background exposures.[13] NAS concluded that no-threshold models should be applied to *both* carcinogens and non-carcinogens with few exceptions.[14] Therefore, the SAB should advise EPA to apply a no-threshold default to dose-response assessment for non-carcinogens as well as carcinogens.[15]

Finally, all risk assessment guidelines need to account for the *cumulative* impacts of chemical and non-chemical stressors. EPA must fully account for the fact that some people are more vulnerable to chemicals and pollutants than others due to various physiological, societal, demographic, and exposure history differences, and these people may experience greater health

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[10] NAS, Science and Decisions: Advancing Risk Assessment 112 (2009), https://www.nap.edu/read/12209/chapter/6#112, attached as Attachment 7.

[11] *See, e.g.*, Earthjustice *et al.* CRA Comments (Attachment 6), *supra* note 9, at 23-24; *see also* American College of Obstetricians and Gynecologists Committee on Health Care for Underserved Women, American Society for Reproductive Medicine Practice Committee, Committee Opinion No. 575, Exposure to Toxic Environmental Agents (Oct. 2013, reaffirmed 2018), http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Exposure-to-Toxic-Environmental-Agents.

[12] EPA, *Integrated Science Assessment for Lead* at lxxxviii (2013), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=518908 ("[T]here is no evidence of a threshold below which there are no harmful effects on cognition from [lead] exposure."). EPA, *Integrated Science Assessment for Particulate Matter* at 2-25 (Dec. 2009), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=494959 ("Overall, the studies evaluated further support the use of a no-threshold log-linear model[.]").

[13] Institute of Medicine of the National Academies, Identifying and Reducing Environmental Health Risks of Chemicals in Our Society: Workshop Summary 55 (2014), attached as Attachment 8.

[14] NAS, *supra* note 10, at 148.

[15] *See* Earthjustice *et al.* Comments (Attachment 1) at 82-84, EPA-HQ-OA-2018-0259-6137.

risk from the same level of exposure to a toxic chemical. As the NAS has observed, performing risk assessment that is meaningful for communities that already face a significant amount of pollution and for communities concerned about environmental justice "requires an ability to evaluate multiple agents or stressors simultaneously—to consider exposures not in isolation but in the context of other community exposures and risk factors."[16] In addition to recognizing unique environmental justice concerns, the NAS and the National Environmental Justice Advisory Committee have acknowledged the importance of stakeholder involvement throughout the risk assessment process.[17] Development of any risk assessment guidelines must involve meaningful community engagement and participation to ensure all stakeholders have an equal opportunity to participate in the process. Therefore, the SAB should advise EPA to ensure that risk assessment guidelines developed or updated by the Agency fully reflect NAS conclusions with respect to cumulative risk.[18]

3. The SAB Should Advise EPA That Its Proposal to Find That Regulating the Hazardous Air Pollutants Emitted By Coal-Fired Power Plants Is Not "Appropriate" Under the Clean Air Act, 84 Fed. Reg. 2670 (February 7, 2019), Is Seriously Flawed And Must Be Withdrawn, And That Any Further Action Must Follow the Best Available Science.

In its Supplemental Finding That It Is Appropriate and Necessary To Regulate Hazardous Air Pollutants from Coal- and Oil-Fired Electric Utility Steam Generating Units, EPA found that the value of reducing power plants' fine particulate matter emissions along with their hazardous air pollutant emissions is between $37 billion and $90 billion per year.[19] Comparing that figure to a "projected $9.6 billion" in cost confirmed the Agency's conclusion that regulating power plants' hazardous emissions is appropriate.[20] In this year's proposal to find that such regulation is not appropriate, EPA finds fault with its purported previous decision to give "equal" weight to these co-benefits.[21] The SAB should advise EPA to withdraw its proposal because co-benefits are just as real as other benefits and, accordingly, should be given equal weight. That is especially true here, where the co-benefits of reducing fine particulate matter – including the

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[16] NAS, *supra* note 10, at 215.
[17] National Environmental Justice Advisory Council, *Ensuring Risk Reduction in Communities with Multiple Stressors: Environmental Justice and Cumulative Risks/Impacts* (2004), https://www.epa.gov/sites/production/files/2015-04/documents/ensuringriskreducationnejac.pdf; NAS, *supra* note 10, at 234.
[18] *See, e.g.*, Earthjustice CRA Comments (Attachment 6). For additional information on each issue discussed above regarding EPA's guidelines, *see also* Earthjustice Human Exposure Guidelines Comments (Attachment 9), https://www.regulations.gov/document?D=EPA-HQ-ORD-2015-0684-0024; Scientists' Human Exposure Guidelines Comments (Attachment 10), https://www.regulations.gov/document?D=EPA-HQ-ORD-2015-0684-0027.
[19] 81 Fed. Reg. 24,420, 24,425 (April 25, 2016).
[20] *Id.*
[21] 84 Fed. Reg. 2670, 2675-76 (Feb. 7, 2019).

prevention of between 4,000 and 11,000 unnecessary premature deaths each year – are well supported and undisputed.[22]

Even if only half of the actual value of these co-benefits is recognized – i.e., between $18.5 billion and $45 billion – it is far greater than the projected costs of $9.6 billion. The SAB should advise EPA that, assuming it can and should give less-than-equal weight to co-benefits, it must come up with a scientifically valid method to determine that less-than-equal weight. Instead, having found fault with its purported prior decision to give "equal" weight to them, EPA effectively gives them no weight at all. Without providing any explanation for how it values co-benefits, EPA accords them no significance in its proposed finding that regulating power plants' hazardous air emissions is not appropriate.

The SAB's April 25, 2019 Memorandum, Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2018 Regulatory Agenda, recognizes the need to review EPA's findings regarding both the benefits and the costs of regulating power plants' hazardous air emissions.[23] With regard to benefits, the SAB should review EPA's assessment of the direct benefits of the reductions in hazardous air pollutants. Information that EPA did not consider indicates that the benefits of reducing mercury emissions from power plants are approximately $3.7 billion per year[24] rather than the $4-$6 million estimated by EPA. Further, although EPA purports to "acknowledge[] the importance of the[] benefits"[25] of reducing hazardous air pollutants other than mercury, such as arsenic, chromium, and lead, the Agency gives no weight at all to these benefits in its cost-benefit analysis. Nor does EPA provide any support for its apparent conclusion that these direct benefits – which it has not attempted to monetize, quantify, or even estimate – are outweighed by the costs of regulation. The SAB should advise EPA that it must give proper weight to all benefits.

Finally, EPA's proposed finding rests on grossly overstated estimates of the costs of regulating power plants' hazardous air pollutant emissions. It is now clear that the actual costs of such regulation are far lower than the $9.6 billion EPA projected.[26]

For all of these reasons, the SAB should advise EPA that its proposal is seriously flawed and should be withdrawn or replaced with a scientifically and methodologically sound proposal.

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[22] Comments of Environmental, Public Health, and Civil Rights Organizations at 8, attached as Attachment 11, https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0794-3364; *see also* Anderko *et al.*, MATS Comments , attached as Attachment 12, https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0794-1679.

[23] Memorandum To Members of the Chartered SAB and SAB Liaisons re Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2018 Regulatory Agenda , April 25, 2019, at 4-5.

[24] Comments of Giang, *et al.*), attached as Attachment 13, https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0794-1188. *See also* Comments of Scientists and the Emmett Environmental Law & Policy Clinic, at 3-13, attached as Attachment 14, https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0794-1665.

[25] 84 Fed. Reg. at 2677.

[26] Comments of Scientists and the Emmett Environmental Law & Policy Clinic, *supra* note 24, at 13-15.

4. The SAB Should Advise EPA to Revise its PFAS Action Plan.

Per- and polyfluoroalkyl substances ("PFAS") are a "large, complex, and ever-expanding" family of approximately 5,000 man-made fluorinated organic chemicals characterized by the strong bond between fluorine and carbon.[27] Some 110 million Americans have been exposed to PFAS through drinking tainted water, and many more are exposed daily from household consumer products, food packaging, food, and airborne dust.[28] Specific medical harms associated with PFAS include: kidney cancer, testicular cancer, bladder cancer, liver function impairment, impaired fetal development, chronic intestinal inflammation, disruption of critical thyroid hormones, weakened immune system, and high cholesterol.[29] Studies in humans with PFAS exposure show that PFAS may also affect growth, learning and behavior of infants and older children as well. More than 95 percent of the U.S. population has PFAS in their bodies, according to the Centers for Disease Control and Prevention.[30]

According to a senior CDC official, the presence and concentrations of PFAS chemicals in U.S. drinking water is "one of the most seminal public health challenges for the next decades."[31] Yet, PFAS are currently highly *unregulated*. In the face of the serious concerns PFAS present, EPA issued its PFAS Action Plan in February 2019. Yet this Plan lacks concrete and immediate steps needed to protect the health and well-being of affected communities across this country. Rather, the Plan largely announces steps it will consider and study.

As the government's own scientists have recognized, the entire class of PFAS is comprised of structurally similar compounds that scientists can "reasonably expect to act through the same pathways and have similar effects."[32] Thus, "[a]pproaching PFAS as a class for

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[27] *Hearing on "Examining the Federal response to the risks associated with per- and polyfluoroalkyl substances (PFAS)" Before the S. Comm. on Env't & Pub. Works*, 1 (2019) (Testimony of Linda S. Birnbaum, Director, Nat'l Inst. Envtl. Health Sci. & Nat'l Toxicology Program Nat'l Ins. Health)

[28] *See* Abrahm Lustgarten, *How the EPA and the Pentagon Downplayed a Growing Toxic Threat*, ProPublica (July 9, 2018), https://www.propublica.org/article/how-the-epa-and-the-pentagon-downplayed-toxic-pfas-chemicals, *see also* Elsie M. Sunderland et al., *A Review of the Pathways of Human Exposure to Poly-and perfluoroalkyl Substances (PFASs) and Present Understanding of Health Effects*, 29 J. Exposure Sci. & Envtl. Epidemiology 1 (2018)

[29] *See, e.g.*, C8 Science Panel, *C8 Probable Link Reports*, http://www.c8sciencepanel.org/prob_link.html (last updated Oct. 29, 2012).

[30] *See* CDC, Agency for Toxic Substances and Disease Registry, *An Overview of Perfluoroalkyl and Polyfluoroalkyl Substances and Interim Guidance for Clinicians Responding to Patient Exposure Concerns* (2017), https://www.atsdr.cdc.gov/pfc/docs/pfas_clinician_fact_sheet_508.pdf

[31] Pat Rizzuto et al., *CDC Sounds Alarm on Chemical Contamination in Drinking Water*, Bloomberg Env't. (Oct. 17, 2017, 4:23 PM), https://news.bloombergenvironment.com/environment-and-energy/cdc-sounds-alarm-on-chemical-contamination-in-drinking-water

[32] Testimony of Linda S. Birnbaum, *supra* note 1 at 4.

assessing exposure and biological impact is the most prudent approach to protect public health."[33] EPA's Plan, however, fails to take the necessary comprehensive approach either for ensuring our drinking water is safe or allowing new PFAS to enter commerce.

For example, the Plan discusses potential binding water regulations for only two PFAS. And even for those PFAS, EPA has committed only to beginning the multi-year process for establishing maximum contaminant levels ("MCLs"), a process that will not even necessarily result in the setting of an MCL. With respect to the other thousands of PFAS, the Plan states only that it will continue to gather information to "inform the development of a national drinking water regulation for a broader class of PFAS in the future."[34] EPA's Plan also fails to indicate how it will limit the flow of new PFAS into commerce. EPA has approved hundreds of new PFAS under the Toxic Substances Control Act over the last decade, several of which have already been associated with health effects.[35] Indeed, since 2012, EPA has approved at least 75 PFAS chemicals despite concluding that those substances "may present an unreasonable risk of injury to human health and the environment."[36]

Finally, EPA's Plan does not commit to ensuring that communities learn when PFAS are released in their backyards. The Toxics Release Inventory ("TRI") is the primary federal law designed to alert communities to toxic contamination. EPA has recognized the importance of adding PFAS to the TRI, having committed in 2006 to "to add PFOA and related chemicals" to it.[37] Yet, as of now, not a single PFAS is listed on the TRI. Rather than commit to this common sense step, the Plan states only that "the EPA is considering whether to add PFAS chemicals" to the TRI.[38]

We ask the SAB to urge EPA to revise its PFAS Action Plan so that it includes genuine commitments to meaningful action that reduces exposures and increases the flow of information

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[33] *Id*. at 13.

[34] EPA, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan*, 22 (2019), https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf

[35] For example, EPA recently reported that exposure to GenX, a PFAS chemical used to replace PFOA, was associated with liver toxicity, kidney toxicity, immune and developmental effects, and cancer in animal studies. *See, e.g.*, EPA, *Draft for Public Comment: Human Health Toxicity Values for Hexfluoropropylene (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known as "GenX Chemicals,"* (2018), https://www.epa.gov/sites/production/files/2018-11/documents/genx_public_comment_draft_toxicity_assessment_nov2018-508.pdf.

[36] EPA, Consent Order issued for chemical P-16-0157, "fluorinated polyurethane," (Aug. 18, 2017), https://chemview.epa.gov/chemview/proxy?filename=sanitized_consent_order_p_16_0157.pdf

[37] EPA, Press Release, *100 percent Participation and Commitment in EPA's PFOA Stewardship Program*, EPA (Mar. 2, 2006), https://archive.epa.gov/epapages/newsroom_archive/newsreleases/95de36c6115a523a8525712500693772.html.

[38] EPA, *supra* note 8 at 19.

to the public. Attached hereto are comments we submitted to EPA last September on behalf of dozens of organizations, which outline the actions EPA should commit to taking in a true action plan. *See* Attachment 15.

5. SAB Should Urge EPA to Withdraw Its Proposed Revision to the Definition of Waters of the United States.

SAB should also urge EPA to withdraw its proposed Revised Definition of Waters of the United States, referred to as the Dirty Water Rule. The proposed definition is contrary to law, contrary to science, and contrary to the overwhelming evidence in the rulemaking record that shows that this rule will leave America's waters unprotected from pollution and subject to destruction and degradation. Among other problems, the Dirty Water Rule casually disregards the conclusions of the SAB's analysis of the underlying 2015 definition, yet EPA points to no new scientific facts, no mistakes, and no considerations EPA or the SAB neglected to include in the prior analysis. The proposed definition would also have a disproportionate adverse effect on environmental justice populations, which EPA has not analyzed as required by Executive Order 12898. *See* Comments of Earthjustice *et al.*, on the Revised Definition of "Waters of the United States;" Docket No. EPA-HQ-OW-2018-0149, April 2019, attached as Attachment 16.

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Commenters appreciate EPA and members of the SAB's time and consideration of these comments. For additional information, please contact Carrie Apfel at capfel@earthjustice.org, (202) 797-4310, or Michelle Mabson at mmabson@earthjustice.org, (202) 797-5254 or any of the below-listed Commenters.

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Attachments:

1. Earthjustice *et al.* Comments on Proposed Rule (2018)
2. Public Hearing Transcript on Proposed Rule (2018)
3. Pam Miller Comments on Proposed Rule (2018)
4. Jeannie Economos Comments on Proposed Rule (2018)
5. OIG 2013 Report
6. Earthjustice *et al.*, RFI on Cumulative Risk Assessment (CRA) Comments (06-28-13)
7. Nat'l Acad. Of Sci., Science & Decisions (2009)
8. IOM Report (2014)
9. Earthjustice, Human Exposure Guidelines Comments (2016)
10. Singla *et al.*, Scientists' Comments on Human Exposure Guidelines (2016)
11. Comments of Envtl Health Civil Rights Orgs. MATS (2019)
12. Anderko *et al.* Scientists Comments on MATS (2019)
13. Giang et al. MATS comments (2019)
14. Emmett Clinic Comments MATS 2019
15. Earthjustice *et al.* Comments to EPA on PFAS (2018)
16. Earthjustice *et al.* Comments to EPA on WOTUS Rule (2019)

Attachment 1

August 15, 2018

Acting Administrator Andrew Wheeler
& Office of the Science Advisor
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

RE: Comments of 88 Environmental, Farmworker, Environmental Justice, Public Health, and Animal Protection Organizations on Proposed Regulations on "Transparency" in Regulatory Science, 83 Fed. Reg. 18,768 (April 30, 2018), Docket ID No. EPA-HQ-OA-2018-0259.

Earthjustice submits these Comments on behalf of the 88 undersigned environmental, farmworker, environmental justice, public health, and animal protection organizations that represent millions of people who live and work in this country. We breathe the air, drink the water, eat the food, and work in the factories, farms, and elsewhere. In every way, we depend on public health safeguards established by the U.S. Environmental Protection Agency ("EPA" or "Agency"). Our lives and our health depend on EPA's limiting pollution and toxic chemical exposure to amounts that will not cause harm. We strongly oppose the Proposed Rule, "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18,768 (Apr. 30, 2018) ("Proposed Rule" or "Proposal") because of its clear intent and impact to weaken, or prevent the necessary strengthening of, these vital public health safeguards.

I. INTRODUCTION AND SUMMARY

Though EPA, former Administrator Scott Pruitt, and industry supporters of the Proposed Rule present it as one that will strengthen public confidence in science by insisting that the data underlying scientific studies are available to the public, as well as to industry itself, this superficial gloss conceals the pernicious purpose and impact of the Proposal. As demonstrated below, the true intent and effect of the Proposed Rule are not to strengthen science, but to exclude critical public health scientific studies – the very studies that have been instrumental in setting pollution limits that save hundreds of thousands of lives and prevent millions of diseases each year, and that protect against harmful and sometimes lethal exposure to toxic chemicals. Even EPA's own Scientific Advisory Board ("SAB") has expressed its concern with and opposition to this Proposal for this very reason. By excluding scientific studies that examine the health impacts of environmental contamination and toxic chemicals that meet all standards of scientific validity and rigor simply because they rely upon non-public data such as confidential medical information, EPA's Proposal would weaken, not improve, its decision-making. Analysis of the actual text, the preamble, and history of the Proposed Rule make clear that this exclusion of important sound public health science is indeed the intent of the Proposed Rule. It is not an incidental consequence of some other laudable goal, but rather is, in fact, the goal itself.

EPA did not arrive at this Proposal on science following careful analysis and discussion with scientific bodies. Rather, this Proposal follows numerous meetings between EPA staff and representatives of industries that sought to weaken rules and regulations necessary to protect public health. In fact, the text of the Proposed Rule comes not from any scientific source or career or expert staff within EPA, but rather from partisan bill language introduced years ago by members of Congress. *See infra* at Section II.C. And although the preamble to the Proposed Rule asserts that it was "informed" by the policies of major scientific journals, the policy is counter to sound scientific review policies and has been expressly repudiated by many of those journals. *See infra*, Section VI.B.1. Instead, the Proposal follows the tobacco industry playbook, using as a defense against limitations on harmful chemicals an attack on the science on process grounds. And, lest there be doubt about the true intent of the Proposed Rule, the fact that it does not act even-handedly but rather would favor inaction or removing protections over imposing or strengthening safeguards makes eminently clear the intent to protect polluters and not the public.

The problems with EPA's Proposal are put in stark relief when compared to basic principles of scientific and health-based decision-making. Indeed, if the restrictions EPA proposes here were applied to the Food and Drug Administration ("FDA") or the Centers for Disease Control and Prevention ("CDC"), it is unclear how many pharmaceuticals, vaccinations, or cures for diseases would ever have been approved or used as drug trial information, as underlying data frequently relies on epidemiological evidence and private medical information that cannot be released.[1] Even if EPA had authority to restrict the consideration of health-based information otherwise, it could have no scientific or rational basis to ignore health information that health professionals recognize is both relevant and often essential to consider when determining what health protections are needed.

Not only does the Proposed Rule threaten both public health and the integrity of decision-making, but it likewise is illegal, for many reasons.

- ***First***, EPA lacks the authority to issue the rule. EPA asserts authority under the Clean Air Act ("CAA"), Clean Water Act ("CWA"), Safe Drinking Water Act ("SDWA"), Comprehensive Environmental Response Compensation and Liability Act ("CERCLA"), Emergency Planning and Community Right to Know Act ("EPCRA"), Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), Toxic Substances Control Act ("TSCA"), and the Resource Conservation and Control Act ("RCRA"). Yet in virtually every case, EPA refers to sections that authorize or mandate the Agency to undertake research, not to impose unfounded limitations on the scientific information that informs public health decisions. EPA also cites provisions authorizing it to promulgate rules "necessary" to achieve the goals of the statute, but restricting sound science is neither

[1] *See, e.g.*, FDA, *Step 3: Clinical Research*, (last updated Jan. 4, 2018), https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm; Nat'l Institutes of Health, *Finding a Clinical Trial* (last updated on Mar. 13, 2017), https://www.nih.gov/health-information/nih-clinical-research-trials-you/finding-clinical-trial; CDC, *Clinical Trials* (last updated Nov. 29, 2017), https://www.cdc.gov/epilepsy/managing-epilepsy/clinical_trials.htm.

necessary nor consistent with the statutory goals – as EPA has previously determined – for moving the country toward clean air, water, workplaces, farms, and the environment.

- ***Second***, not only is the Proposed Rule not authorized by law, but it directly contravenes the specific mandate of numerous statutes, such as the SDWA and TSCA, that require EPA to use the "best available" science or all "reasonably available" science and information. It also undermines the public health objectives of the very statutes upon which EPA mistakenly relies as authority for the rule. A rule that deliberately excludes this best science cannot be reconciled with these firm Congressional mandates and public health purposes.

- ***Third***, EPA's process in proposing this rule, to date, violates procedural requirements of the Administrative Procedure Act ("APA"), as well as of the CAA, FIFRA, and TSCA. These requirements are designed to promote reasoned decision-making by ensuring the relevant documents underlying the decision are in the record and that the Proposal has sufficient specificity to permit a sound response. The Proposal does not meet those requirements. In addition, the Proposal also fails to comply with the procedures required by a number of Executive Orders, particularly the performance of an environmental justice analysis.

- ***Fourth***, EPA's Proposed Rule is arbitrary and capricious for a farrago of reasons. The Proposal is irrational and unsupported by facts, reason, history, scientific evidence, or even any reasoned explanation. EPA has failed to show that the purported benefits of the Proposed Rule – which are largely inflated or imagined – justify the burdens imposed on public health and the environment. The Proposal represents a significant change in a long-standing EPA policy without the requisite acknowledgment or justification for such a departure. Many definitions are vague and can easily be implemented in arbitrary or politically driven ways. And the Proposed Rule would allow the Administrator to make an exception for any of a wide variety of reasons, again, not cabining at all the exercise of discretion. Any one of these failures would render the rule fatally arbitrary and thus invalid; together they demonstrate that it would be extreme arrogance for EPA to continue this rulemaking to conclusion.

- ***Fifth***, in addition to its overall effect, many specific provisions of the Proposed Rule are independently illegal or improper. Among other things, as currently designed, the rule would likely apply in an uneven manner, for example, only to a decision to restrict the use of a pesticide, not to allow the use of such a chemical. It is a one-way street. Yet sound science must be followed wherever it leads. This rule puts a thumb on the scale toward regulation that ignores evidence of harm to human health. In addition, the Proposed Rule aims to undermine certain peer-reviewed science by injecting industry-manufactured uncertainty regarding science into the rulemaking process. The Proposal would cast doubt on science that has gone through independent peer-review by adding a second round of agency-required peer-review. And by injecting a mandate to "minimize

costs" into the rule, even where Congress has specifically forbidden consideration of costs in determining health standards, the Proposed Rule sows confusion, doubt, and delay, and weakens our public health.

- ***Finally***, EPA seeks comment on a number of ways it might make this rule even more destructive and deadly through possibilities like retroactive application or application in enforcement or permitting decisions. There is no reasoned or scientific basis for the Proposed Rule and certainly no such basis to extend it further.

EPA should end this rulemaking promptly, withdraw this Proposal, and base its decisions on the best science available. The lives and health of millions of people living in America depend on this and deserve nothing less.

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II. THE PROPOSED RULE WOULD EXCLUDE CRITICAL SCIENTIFIC STUDIES, HARMING THE PUBLIC SIMPLY TO FURTHER A POLITCAL AGENDA

A. The Proposed Rule Would Exclude Critical Scientific Studies.

Although the Proposed Rule is couched in terms of increasing transparency, its effect – and indeed its true purpose as made evident by emails, press statements, and other documents – would be to "preclude" EPA from using critical human health studies that rely on confidential medical information. 83 Fed. Reg. at 18,769, n.3. The rule would require that "the regulatory science underlying [a proposed EPA action] is publicly available in a manner sufficient for independent validation." *Id*. at 18,773 (proposed 40 C.F.R. § 30.1). Using terms that are vague, unsupported, and easily susceptible of manipulation, the Proposal would apply this public availability requirement to the "dose response data and models" underlying "pivotal regulatory science" used to justify "significant" "regulatory decisions." *Id*. (proposed 40 C.F.R. §§ 30.2, 30.3, 30.5).

In practice, the "data" underlying studies used to set quantitative limits and tolerances to protect public health and the environment often consists of confidential medical or other personal data gathered in epidemiological studies. Both the law and medical research ethics prohibit the disclosure of this data.[2] As EPA's own Science Advisory Board ("SAB") warned:

> For studies published many years ago, it may not be feasible to deliver public access to data and analytic methods. There are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate.
>
> Furthermore, the rule could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts. The proposed rule does not acknowledge that the epidemiologic science community, for example, has been making significant efforts to make data available where possible and to develop studies based on publicly available data where appropriate.

See Memorandum from Alison Cullen, Chair, SAB Work Group, to Members of the Chartered SAB and SAB Liaisons, "Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)," 3 (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/W

[2] For example, as discussed *infra*, Section IV.E, under the Common Rule For Research Involving Human Subjects, 45 C.F.R. Part 46, in order to gain approval from an Institutional Research Board to conduct federally funded research, "when appropriate, there [must be] adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." 45 C.F.R. § 46.111(a)(7). This usually requires obtaining informed consent from the research subjects, including a description of how the researchers will preserve the confidentiality of identifiable records. *Id.* § 46.116(a)(5).

kGrp_memo_2080-AA14_final_05132018.pdf ("SAB Comment").[3] Thus, by imposing a requirement that certain data that cannot legally or ethically be made public be disclosed for the study to be used, EPA is effectively preventing the use of such studies.

In an effort to minimize the effect of the Proposed Rule, EPA asserts that "concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government." 83 Fed. Reg. at 18,770. As support for this assertion, EPA merely says, "[s]ee examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau." *Id*. n.16. But EPA ignores the fact that removing confidential information from the underlying data in such studies is impractical, ineffective, and unnecessary. For example, in the last ozone NAAQS review, EPA reviewed more than 4,000 studies and references, and cited more than 2,200 in the final Integrated Science Assessment. Anonymizing the confidential information in all of the data underlying over 2,000 studies would be overly burdensome in terms of effort and cost.[4]

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[3] Given these potential impacts, at its May 31, 2018, meeting, the SAB voted to independently review this rule. *See* Doug Obey, "SAB Votes To Review EPA's Science, Emissions Rules In Sign Of 'Rebuke,'" *Inside EPA* (May 31, 2018), https://insideepa.com/daily-news/sab-votes-review-epas-science-emissions-rules-sign-rebuke. At this meeting, several members of the scientific and medical communities testified about the deleterious impact of the Proposed Rule. EPA, Meeting: Chartered Science Advisory Board (May 31 to June 1, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/7D239353BCECF85B852582600058B716?OpenDocument; Written Statement from Ms. Genna Reed, Union of Concerned Scientists, https://yosemite.epa.gov/sab/sabproduct.nsf/3B1AE8935A26E56C852582940075D516/$File/UCS+SAB+written+comment+5.31+v2.pdf; Written Statement from Dr. David McCabe, Clean Air Task Force, https://yosemite.epa.gov/sab/sabproduct.nsf/A4979E2FDC1153A7852582A600787981/$File/34697863.pdf; Written Statement from Lynn Goldman, The George Washington University, https://yosemite.epa.gov/sab/sabproduct.nsf/112CC313B0FB652D852582A6007BA0DA/$File/Goldman+Oral.pdf; Written Statement from Mary Rice, American Thoracic Society, https://yosemite.epa.gov/sab/sabproduct.nsf/6E8D2B56375A3FE5852582A600781D7E/$File/70258076.pdf; Written Statement from Liz Borkowski, Jacobs Institute of Women's Health, https://yosemite.epa.gov/sab/sabproduct.nsf/69E37E4047D5208A8525829E00601B26/$File/26246226.pdf; Written Statement from Dr. George Thurston, NYU School of Medicine, https://yosemite.epa.gov/sab/sabproduct.nsf/1A46C31B5E4BFFBF852582A60078E00A/$File/89488078.pdf.

[4] For example, in response to proposed legislation that would have required removal of all confidential information in all studies used by EPA, the Congressional Budget Office ("CBO") stated: "If the EPA continued to rely on as many scientific studies as it has used in recent years to support its covered actions, then CBO estimates that the agency would need to spend at least $100 million dollars per year to upgrade the format and availability of those studies' data to the level required by H.R. 1430." CBO, *Cost Estimate: H.R. 1430 Honest and Open New EPA Science Treatment (HONEST) Act of 2017* at 3 (Mar. 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.

Moreover, de-identifying personal information has thus far proven to be ineffective.[5] In 2000, the U.S. Department of Health and Human Services adopted Standards for the Privacy of Individually Identifiable Health Information (commonly known as the "Privacy Rule"), pursuant to its authority under HIPAA. *See* 45 C.F.R. Pts. 160 and 164. The Privacy Rule protects all individually identifiable health information held or transmitted by certain covered entities – that is, health plans, health care clearinghouses, or health care providers – and their business associates. *Id.* §§ 160.103, 164.502(a). Under the Privacy Rule, two methods have been used to de-identify individually identifiable health information so that the data may be disclosed. *First*, the entity may rely on the judgment of a qualified individual who determines, with documentation, "that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information." *Id.* § 164.514(b)(1). *Second*, the entity may remove multiple enumerated categories of information, including patient names, social security numbers, full face photographs, and biometric identifiers (such as fingerprints). *Id.* § 164.514(b)(2). An entity following this approach must generalize each patient's birth date to the relevant year and may include only the first three digits of a patient's zip code. *Id.* § 164.514(b)(2)(i)(B), (C). Despite these seemingly thorough requirements for de-identification, the Privacy Rule is significantly less protective than it appears. In the years since its adoption, publicly available personal information has proliferated, and new databases are created every day.[6] To "reidentify" de-identified data, an adversary need only discover an individual's "data fingerprint"—that is, the combination of values shared by nobody else in an anonymized data set.[7] The adversary can then link this fingerprint to publicly available, non-anonymized information to discover the individual's identity.[8]

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[5] Even if it were effective – which it is not – as the Seventh Circuit has explained, people may have privacy interests in unidentifiable personal information: "Imagine if nude pictures of a woman, uploaded to the Internet without her consent though without identifying her by name, were downloaded in a foreign country by people who will never meet her. She would still feel her privacy had been invaded." *Nw. Mem'l Hosp. v. Ashcroft*, 362 F.3d 923, 929 (7th Cir. 2004). Indeed, according to a 1993 study, more than 60 percent of Americans want hospitals, pharmaceutical companies, and researchers to obtain patient consent before using medical information—even if that information has been de-identified. N. Nina Zivanovic, *Medical Information as a Hot Commodity: The Need for Stronger Protection of Patient Health Information*, 19 Intell. Prop. L. Bull. 183, 201 (2015).

[6] Zivanovic at 201; Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. Rev. 1701, 1724 (2010).

[7] Ohm at 1723. Indeed, 87 percent of the population can be identified based only on their 5-digit ZIP code, gender, and date of birth. Latanya Sweeney, *Simple Demographics Often Identify People Uniquely*, Carnegie Mellon University, Date Privacy Working Paper 3 at 2 (2000), https://dataprivacylab.org/projects/identifiability/paper1.pdf. More than half the population can be identified by their gender, data of birth, and city, town, or municipality, while nearly 20 percent can be identified by their gender, date of birth, and county. *Id.*

[8] Ohm at 1724. Of course, adversaries need not resort to such sophisticated methods. As the Seventh Circuit explained in the context of medical records relating to abortion, once a patients' de-identified records are made available, "persons of their acquaintance, or skillful 'Googlers,' sifting the information

Removing confidential information so that it can be publicly disclosed is also wholly unnecessary, as studies can be validated without demanding access to confidential data. As the SAB explained,

> The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies ***without public access to data and analytic methods***. For example, the Health Effects Institute (HEI) conducted a re-analysis of the influential Harvard Six Cities and American Cancer Society (ACS) epidemiologic studies and was able to replicate its findings and to assess the robustness of the findings via sensitivity analysis.

SAB Comment at 4 (emphasis added). Yet these are some of the very studies EPA would exclude under the Proposed Rule. 83 Fed. Reg. at 18,769, n.3.

EPA then claims that the Proposal would not "compel[] the disclosure of any confidential or private information." *Id.* at 18,770–71. While technically, true, this is misleading, because the Proposal would force decision-makers to ignore important and relevant science precisely to avoid unnecessary and illegal disclosure.[9]

The exclusionary intent of the Proposed Rule is likewise demonstrated by proposed 40 C.F.R. § 30.8, which requires that the rule be implemented so as to "minimize costs." As the SAB explained, "[i]n addition, there are considerations associated with the cost and effort that would be involved in making large and complex existing datasets available within Institutional Review Board requirements, including the issue of who would be responsible for shouldering this burden." SAB Comment at 3. In other words, if EPA must minimize costs, the exclusion of science, rather than taking complicated and expensive steps to hide confidential medical data, is likely to be the approach followed.

B. EPA Inexcusably Ignores the Fact that by Excluding Critical Human Health Studies, the Proposed Rule Significantly Harms Public Health.

The harm this Proposed Rule is likely to cause cannot be overstated. Restricting science in the manner proposed by EPA would result in significant public health failures.

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contained in the medical records concerning each patient's medical and sex history, will put two and two together, 'out' the . . . women, and thereby expose them to threats, humiliation, and obloquy." *Nw. Mem'l Hosp.* 362 F.3d. at 929.

[9] In his testimony before the House of Representatives Subcommittee on Environment, Committee on Energy and Commerce, former Administrator Pruitt expressly stated that EPA would only consider studies where the underlying data and methodology were made public. *See* U.S. House of Representatives, Transcript of Hearing: The Fiscal Year 2019 Environmental Protection Agency Budget (Apr. 26, 2018), https://docs.house.gov/meetings/IF/IF18/20180426/108218/HHRG-115-IF18-Transcript-20180426.pdf.

Epidemiological studies have been foundational to understanding critical connections between exposure to toxic chemicals and public health harms — connections that will be severed under EPA's Proposed Rule. For example, links between certain occupations and incidences of cancer were discovered through the precursors to epidemiological studies.[10] "Historically, much of what was known about the causes of cancer was derived from studies of workers," as the work environment offered critical characteristics allowing for the occurrence of cancer to be studied, namely "well-defined populations that are exposed, often at high levels, to agents that can be quantitatively characterized."[11] The methods used in these studies linking exposure to chemicals to the risk of disease "contributed importantly to the development of modern epidemiology."[12] Just as "[i[dentifying occupational carcinogens is an important research endeavor with broad relevance to science and public health," with "[k]nowledge of cancer hazards from occupational exposure support[ing] prevention and surveillance activities, as well as compensation of exposed workers,"[13] so too are epidemiological studies critical to protecting the public health from exposure to toxins in our air, water, and food. EPA's Proposal – which would remove most of these crucial studies from consideration when setting safety standards – poses a clear and present danger to our health and the environment.

Another example of toxic harm documented through epidemiological studies is airborne lead. General aviation aircraft emit the majority of airborne lead in the nation. Multiple studies have found an association between airborne lead exposure and elevated blood lead levels in children. But the Proposed Rule would, in effect, prohibit EPA from considering one of the key studies that directly links high childhood blood lead levels and living in proximity to general aviation airports. This study, M.L. Miranda et al., *A Geospatial Analysis of the Effects of Aviation Gasoline on Childhood Blood Lead Levels*, Envtl. Health Persp. 119(10): 1513–1516 (Oct. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3230438/ ("Miranda Study"), a copy of which is submitted herewith, found a significant association between living in close proximity to a general aviation airport where non-commercial piston jets that use leaded aviation fuel (or "leaded avgas") are common, and elevated blood lead levels in children. The Miranda Study relies on state blood lead surveillance data for over 125,000 children between the ages of 9 months and 7 years in six North Carolina counties who had been tested for lead between 1995 and 2003, as well as GIS mapping of the locations of the children's homes relative to the locations of airports where aircraft use avgas, and estimates of lead emissions from aircraft. The data relied on by the Miranda Study would likely be characterized as "dose response data and models" under the Proposed Rule as the study links exposure to nearby emissions of lead with blood lead levels. Thus, EPA could refuse to rely on the Miranda Study in taking a significant regulatory action – such as regulating the use of leaded avgas – unless obvious personal identifiers of the 125,000 children whose blood lead levels were studied were made publicly available. Because North Carolina collected that data as part of a mandatory statewide registry

[10] Dana Loomis et al., *Identifying occupational carcinogens: an update from the IARC Monographs*, Occup. & Envtl. Med. (2018), http://oem.bmj.com/content/early/2018/05/16/oemed-2017-104944.
[11] *Id*.
[12] *Id*.
[13] *Id*.

of blood lead surveillance data – undoubtedly with assurances of strict confidentiality to the participants – it would be impossible for the Miranda Study authors to make these "dose response data and models" "publicly available in a manner sufficient for independent validation," as section 30.5 of the Proposed Rule would require as a condition for relying on the study. Moreover, the location data are fundamental to the analysis, and these data could not be redacted in a way that still permits reproduction of the results. The authors took special care when presenting their results to preserve the privacy of the child participants, as required by their institutional review board.

The Miranda Study found that living within 1,000 meters of an airport where avgas is used may have a significant effect on blood lead levels in children, and that the impacts of avgas are highest among those children living closest to the airport. Excluding the Miranda Study from consideration of the impact of the ongoing use of leaded avgas could lead EPA to underestimate the risks posed by leaded avgas by ignoring the association found in the Miranda Study between continued use of leaded avgas and children's exposure to lead. This could result in EPA's wrongly deciding that leaded avgas does not endanger public health, undercutting the basis for moving forward with a ban on leaded avgas despite the fact that leaded automobile gas was banned as a danger to public health decades ago.

EPA's exclusionary rule would also gravely limit EPA's ability to protect the public from the health hazards associated with perfluorooctanoic acid ("PFOA," also known as "C8") and perfluorooctane sulfonate ("PFOS"). As the result of a settlement of a lawsuit brought against a DuPont Washington Works facility near Parkersburg, West Virginia, related to contamination of drinking water, researchers conducted exposure and health epidemiological studies consisting of nearly 70,000 participants to examine the health impacts of exposure to these chemicals. These studies looked at "demographic data, medical diagnoses (both self-report and medical records review), clinical laboratory testing, and determination of serum concentrations of 10 perfluorocarbons (PFCs),"[14] information that is both sensitive and confidential. Through this work, the researchers identified probable links between exposure to these chemicals and six specific diseases: diagnosed high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer, and pregnancy-induced hypertension.[15] The results of these studies have been published in numerous articles in scientific journals. Yet, under EPA's Proposed Rule, this research would be excluded from consideration when determining health-based standards for PFOA under a number of environmental statutes, despite the clear evidence of harm these chemicals pose. Turning a blind eye to this data would have dramatic public health consequences, as it would preclude evaluation of valuable evidence of harm from exposure that could and should form the foundation of protections under the statutes EPA is charged with executing for the benefit of the public and the environment.

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[14] Stephanie J. Frisbee et al., *The C8 Health Project: Design, Methods, and Participants*, Envtl. Health Persp 117:1873, 1873 (2009), https://ehp.niehs.nih.gov/wp-content/uploads/117/12/ehp.0800379.pdf.
[15] C8 Science Panel, *The Science Panel Website* (last updated Jan. 4, 2017), http://www.c8sciencepanel.org/index.html.

Many other studies would likewise be excluded from consideration under the Proposed Rule either because the data is confidential and not publicly available, or because the data is old and thus the results can no longer be replicated as required by the Proposed Rule. This includes, but is not limited to, the following:

- Early studies on the neurological effects of low-dose lead exposure on children's health have been foundational to setting lead levels for air and water, as well as for certain products such as paint.[16] The underlying data is confidential and not subject to public exposure. And it is likewise nearly 40 years old and thus likely no longer available.

- Studies demonstrating the link between exposure to arsenic and developing cancer depend upon confidential clinical examinations of the patients that served as research subjects,[17] and thus the sensitive health data underlying the studies cannot be publicly exposed.

- Studies on the impact of air pollution and mortality rates that have been used by EPA for decades to set air quality standards rely on confidential data that may not be lawfully disclosed.[18]

- EPA's toxicological reports in its Integrated Risk Information System ("IRIS") program, which create health reference values that the Agency uses under various statutes to assess health risks from different chemicals.[19]

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[16] Herbert L. Needleman et al., *Deficits in Psychologic and Classroom Performance of Children with Elevated Dentine Lead Levels*, 300 New England J. Medicine 689 (1979); EPA, Air Quality Criteria for Lead 12-86 to 12-88, 12-95 (1986), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=32647; Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper, 56 Fed. Reg. 26,460, 26,468–69 (June 7, 1991); Lead; Identification of Dangerous Levels of Lead, 63 Fed. Reg. 30,302, 30,316–30,317 (June 3, 1998). The final rule was published at 66 Fed. Reg. 1206 (Jan. 5, 2001); National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 66,964 (Nov. 12, 2008).

[17] National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 65 Fed. Reg. 38,888, 38,902 (June 22, 2000).

[18] Douglas W. Dockery et al., *An Association between Air Pollution and Mortality in Six U.S. Cities*, 329 New England J. Med. 1753 (1993).

[19] Industry has sought to stall and undermine these assessments using language strikingly similar to what is in the Proposed Rule. *See, e.g.*, Valerie Volcovici, "Pressured by industry, U.S. EPA slows formaldehyde study release: documents," *Reuters* (May 24, 2018), https://www.reuters.com/article/us-usa-epa-formaldehyde/pressured-by-industry-u-s-epa-slows-formaldehyde-study-release-documents-idUSKCN1IP3EX; *see also* Jennifer Sass, "Toxic Chemical Industry and House R's Attack on Science," NRDC (Sept. 27, 2017), https://www.nrdc.org/experts/jennifer-sass/toxic-chemical-industry-and-house-rs-attack-science; Written Testimony of Kenneth A. Mundt, Ramboll Environ, *The Iris Review Process: Chloroprene and the criticality of good science*, https://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-115-SY18-WState-KMundt-20170906.pdf; Oral Presentation of James S. Bus, Exponent, Inc. (support provided by the

EPA's Proposal would exclude these pivotal epidemiological studies and IRIS assessments that rely on such studies, as well as other critical research merely because the underlying data cannot be made public.

Compounding this problem, many public health protections are predicated upon coincidental benefits – or "co-benefits" – defined as "favorable impact[s] of [a rule] . . . that [are] typically unrelated or secondary to the purpose of the action."[20] It has long been the practice of federal agencies to include co-benefits of regulatory action when studying a proposed rule.[21] For example, EPA includes PM2.5 reductions as a co-benefit for additional regulations, including, but not limited to, the National Emissions Standards for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers and Process Heaters,[22] and the Petroleum Refinery NSPS.[23] In light of the interconnectedness of many of EPA's rules, a restriction on the science supporting one will have a domino effect, weakening support for all rules that rely on the undermined rule. By way of illustration, should the Proposed Rule's restriction on the science EPA can consider in its rulemaking processes impact the PM2.5 reductions, it will, in turn, severely undercut the support provided for all other environmental programs for which PM2.5 reductions serve as a co-benefit.[24]

American Chemistry Council), https://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-115-SY18-WState-JBus-2070906.pdf; Am. Chemistry Council, https://www.americanchemistry.com/Policy/Regulatory-Reform/ACC-CEO-Makes-the-Case-for-Fixing-EPAs-IRIS-Program-Improved-Risk-Assessments.pdf. A repeated industry criticism of IRIS assessments focuses on "transparency," as a code to try to attack science (just as this Proposed Rule does) even though IRIS follows peer-reviewed, scientific protocols affirmed by the National Academies of Sciences. *See, e.g.*, "ACC: National Academies Missed a Critical Opportunity with IRIS Review," Am. Chemistry Council (Apr. 13, 2018), https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/National-Academies-Missed-Critical-Opportunity-With-IRIS-Review.html.

[20] OIRA, OMB, Exec. Office of the President, *Regulatory Impact Analysis: A Primer* at 7 (Aug. 15, 2011), https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf.

[21] *See, e.g.*, *The Case for Co-Benefits: Regulatory Impact Analyses, Michigan v. EPA, and the Environmental Protection Agency's Mercury and Air Toxic Standards* (Feb. 2016), https://www-cdn.law.stanford.edu/wp-content/uploads/2016/09/The-Case-for-Co-Benefits-Regulatory-Impact-Analyses-Michigan-v.-EPA-and-the-Environmental-Protection-Agencys-Mercury-and-Air-Toxics-Standards.pdf.

[22] EPA, *Regulatory Impact Analysis: National Emissions Standards for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers and Process Heaters* at 1-2 (Feb. 2011), https://www.regulations.gov/document?D=EPA-HQ-OAR-2002-0058-3290.

[23] EPA, *Regulatory Impact Analysis for the Petroleum Refineries NSPS* at 7-1, EPA-452/R-08-002, (Apr. 2008), https://www3.epa.gov/ttnecas1/docs/ria/refineries_ria_final-nsps_2008-04.pdf.

[24] Simultaneous with the Proposed Rule's attack on science, EPA issued an Advanced Notice of Proposed Rulemaking that aims to eliminate its ability to rely on co-benefits in the public health rulemaking process. *See* Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process, 83 Fed. Reg. 27,524 (June 13, 2018).

For all of these reasons, the Proposed Rule will have far-reaching and damaging consequences on public health protections. In a world in which EPA cannot consider critical studies demonstrating the deleterious impacts of toxic chemicals, pollutants, and pesticides when developing rules governing exposure levels, acceptable uses, and safety measures, there will be little to no available evidence to support the imposition of public health protections. Absent such evidence, EPA will be unable to implement rules that protect our air and water from harmful pollution, our farmworkers from toxic pesticides, and the public from overall exposure to chemicals, as EPA will have no science to point to as justification for such measures. Simply put, removal of this science from consideration in the rulemaking process will cause the very foundation upon which many of our public health standards depend to crumble.

C. The Proposed Rule Results Not from Any Scientific Principles or Justification but Rather from Industry Pressure to Weaken Public Health Protections and Follows the Tobacco Playbook.

While described as a measure to "better inform[] the public," "enhance[] the public's ability to understand and meaningfully participate in the regulatory process," and to ensure that "[t]he best available science must serve as the foundation of EPA's regulatory actions," 83 Fed. Reg. at 18,769, the Proposed Rule does nothing of the sort. Indeed, it was not intended to do so. Multiple documents indicate that the true purpose of this rule is to restrict EPA's ability to use relevant and credible – and frequently the best available – science that underlies strict and fully protective public health protections.

The genesis of the Proposed Rule is politically-driven legislation previously introduced by the House that would prohibit EPA from relying in its rulemaking on any science where the underlying research is not made publicly available.[25] Industry lobbied Congress in an effort to gut environmental and health laws by attacking the science upon which they are based. For example, both the Secret Science Reform Act of 2014 and the Secret Science Reform Act of 2015 provided that EPA may not take action "unless all scientific and technical information relied on to support such covered action is . . . ***publicly available online in a manner that is sufficient for independent analysis and substantial reproduction of research results.***"[26] Two years later, after its prior unsuccessful attempts, the House passed the HONEST Act in March 2017, which again would have limited EPA's ability to perform any assessment or analysis based

[25] *See, e.g.*, Juliet Eilperin and Brady Dennis, "Pruitt unveils controversial 'transparency' rule limiting what research EPA can use," *Washington Post* (Apr. 24, 2018), https://www.washingtonpost.com/news/energy-environment/wp/2018/04/24/pruitt-to-unveil-controversial-transparency-rule-limiting-what-research-epa-can-use/ (noting that, during a meeting between the then-EPA Administrator and Representative Lamar Smith, who introduced the House legislation, "Smith made 'his pitch that EPA internally implement the HONEST Act [so that] no regulation can go into effect unless the scientific data is publicly available for review.'").

[26] H.R. 4012, Secret Science Reform Act of 2014 (introduced Feb. 6, 2014), https://www.congress.gov/bill/113th-congress/house-bill/4012/text; H.R. 1030 - Secret Science Reform Act (introduced Feb. 24, 2015), https://www.congress.gov/bill/114th-congress/house-bill/1030/text.

on science if the public does not have complete access to the underlying data.[27] When these bills did not succeed, industry looked to a new audience to try put in place what Congress failed to enact: a ban on consideration of science when making regulatory decisions critical to public health and the environment if the underlying data is not made publicly available.

Industry pitched EPA hard, and found a willing ear, complaining that air pollution limits and toxin tolerances were being set at levels that were too stringent. Given that the strong Congressional mandate expressed in numerous statutes for strict health protections would require EPA to act if the science demonstrated a risk to public health, industry saw that their best bet was to knock out the science, this time through EPA itself.[28] Industry groups, including the National Association of Manufacturers and American Petroleum Institute, "pitched EPA a Proposal last spring that closely resembled what became Administrator Scott Pruitt's 'secret science' plan," according to EPA internal documents.[29] This plan closely tracks the longstanding attacks on EPA science from these groups.[30] EPA was responsive to the industry pitch and met with industry groups dozens of time, while repeatedly canceling the few scheduled meetings with public health advocates.[31]

Similarly, pesticide manufacturers, such as Dow Chemical Company, have long opposed the use of epidemiological studies that collect human health data that must be kept confidential. For example, they vigorously challenged EPA's proposal to revoke tolerances for chlorpyrifos, one of the country's most widely used pesticides, which in effect would have prohibited the use of chlorpyrifos on food crops. EPA had found that it could not conclude that exposure to this pesticide in food and drinking water was safe based on a risk assessment that included a safety factor mandated under the Food Quality Protection Act to protect the health of infants and children whose developing bodies are uniquely vulnerable to toxic pesticides. *See* 80 Fed. Reg. 69,079, 69,090 (Nov. 6, 2015); *see also* National Academy of Science ("NAS"), *Pesticides in the*

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[27] *See also* H.R. 1430 - Honest and Open New EPA Science Treatment Act (introduced Mar. 8, 2017), https://www.congress.gov/bill/115th-congress/house-bill/1430/text; *see also*, Brian Resnick, "The House Just Passed Two Bills That Would Stifle Science at the EPA," *Vox* (Mar. 30, 2017), https://www.vox.com/science-and-health/2017/3/30/15112704/transparency-epa-bills-not. Also in March 2017, Republicans on the Senate Committee on Environmental and Public Works ("EPW") "made transparency, including data access, a priority" throughout the confirmation process for Gina McCarthy. *See* U.S. Senate Comm. on Env't and Pub. Works, *Minority Staff Rep., EPA's Playbook Unveiled: A Story of Fraud, Deceit, and Secret Science* at v, 48, 55 (2014) (*hereinafter* "Minority Staff Report"), https://www.epw.senate.gov/public/_cache/files/2d30f39e-2fde-4b37-8810-32fa21b6e6bd/epaplaybookunveiled.pdf (describing how the "EPW Republicans sought the Agency's secret science used to justify nearly all regulations issued under the Clean Air Act," and they "boycotted the Committee nomination vote of McCarthy" in protest of "the lack of transparency at" EPA).

[28] *See, e.g.*, Maxine Joselow, "Emails: EPA All Ears as Industry Pitched 'Secret Science,'" *E&E News* (May 17, 2018), https://www.eenews.net/stories/1060081997.

[29] *Id.*

[30] *See, e.g.*, Minority Staff Report.

[31] *See id.*; *see also* Sharon Lerner, "Scott Pruitt's Policy Director at EPA Met with Hundreds of Industry Representatives, Emails Show," *The Intercept* (May 16, 2018), https://theintercept.com/2018/05/16/scott-pruitt-epa-industry-lobbyists/.

Diets of Infants and Children (1993). EPA retained the safety factor over industry objections because epidemiologic studies indicate that prenatal exposure to chlorpyrifos can harm the developing nervous system. So the industry attacked those studies, claiming they needed to see the underlying medical information[32], even though the studies – conducted by highly reputable institutions including Columbia University, University of California-Berkeley, and Mt. Sinai School of Medicine – were all published peer-reviewed articles in scientific journals. While the Columbia scientists who authored the study have allowed EPA scientists to analyze the data in a secure setting on Columbia's campus, they have refused to make the raw data publicly available in order to protect the privacy of the mothers and children who participated in the research.[33] Not satisfied, the pesticide industry is pressing EPA to exclude the study so that it can continue to sell a pesticide known to cause severe harm to children. And EPA is playing along.

This attack on supposedly "secret science" is not new or unique to this EPA and cannot be viewed in a vacuum. Attacking the underlying science has been a key strategy for decades, most notably in the tobacco industry's effort to limit evidence of the enormous public health harms caused by tobacco. After EPA published its final Risk Assessment for Environmental Tobacco Smoke (secondhand smoke) in 1992, which concluded that secondhand smoke "is a human carcinogen, responsible for approximately 3,000 lung cancer deaths annually in U.S. nonsmokers,"[34] the tobacco industry went on the attack. The Risk Assessment had been based in part on a meta-analysis of "31 epidemiologic studies from 8 different countries" which showed a significant risk of harm.[35] Recognizing that "[v]igorous denial is not a satisfactory defensive strategy" and that "the most significant [secondhand smoke] problem facing the Industry is the result of epidemiological studies which indicate" a risk from exposure, the tobacco industry decided to attack epidemiological science.[36] Industry lawyers candidly noted that "there is virtually no chance of affecting change on this issue if the focus is" secondhand smoke so "our approach is one of addressing process as opposed to scientific substance, and global applicability

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[32] CropLife, *Petition EPA to halt regulatory decisions that are highly influenced/determined by results of epidemiological studies that do not meet well-defined data quality standards, and that are not integrated into the health risk assessment in a transparent, well-defined manner* (Nov. 29, 2016), http://191hmt1pr08amfq62276etw2.wpengine.netdna-cdn.com/wp-content/uploads/2016/01/FINAL-CLA-Petition-Regulatory-Decision-Making-11-29-16.pdf; CropLife, Comments *Re: Chlorpyrifos; Tolerance Revocations; 80 FR 69080, November 6, 2015; Docket ID: EPA-HQ-OPP-2015-0653* (Jan. 25, 2015), https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0653-0342.

[33] Letter from Linda P. Fried, Columbia University Medical Center, to Jack E. Housenger, EPA OPP Director, *Re: Columbia Center for Children's Environmental Health Epidemiology Study Data* (May 18, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0928.

[34] EPA, *Respiratory Health Effects of Passive Smoking (Also Known As Exposure to Secondhand Smoke or Environmental Tobacco Smoke – ETS)* – Overview (last updated Jan. 4, 2010), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2835.

[35] EPA, *Respiratory Health Effects of Passive Smoking (Also Known As Exposure to Secondhand Smoke or Environmental Tobacco Smoke – ETS)*, EPA/600/6-90/006F at 1-9, 2-8 (1992).

[36] Amended Final Opinion, *United States of America et al. v. Phillip Morris USA, Inc., et al*., Civ. Action No. 99-2496 at 185-86 (D.D.C. Aug. 17, 2006), http://www.publichealthlawcenter.org/sites/default/files/resources/doj-final-opinion.pdf.

to industry rather than focusing on any single industrial sector."[37] Shortly thereafter, one of RJ Reynolds' lobbying firms organized a "Secret Science" Work Group to "[f]ocus public attention on the importance of requiring disclosure of taxpayer-funded analytical data."[38]

This Proposed Rule follows suit. It is just another effort to hide evidence of the public health harm of toxic chemicals, given that there is no way to change the research results showing the deleterious effects.[39] And this time, the effort is much broader, as it is not hiding evidence related to just one industry or one product. Indeed, when describing the hearing on the Secret Science Reform Act of 2015 – a predecessor of the Proposed Rule – Representative Eddie Bernice Johnson noted that "[w]hen the Majority held a hearing on this legislation last Congress, every Majority witness at the hearing had significant ties to the tobacco industry. . .. Judging from the groups that have endorsed this bill, it might be more accurate to state that H.R. 1030 is the polluting industries' attempt to prevent EPA from using the best available science." *See* Minority Staff Report at 48. The same holds true for the Proposed Rule. EPA should not be permitted to "deliberately misle[a]d the public about the risks of" certain pollutants or other chemicals by hiding evidence of their harms.[40] As several courts have found, the best available ***politics*** does not equate to the "***best available science***,"[41] so while this Proposed Rule may serve EPA's political ends, it does not meet the mandates of sound science.

III. EPA LACKS LEGAL AUTHORITY TO ADOPT THE PROPOSED RULE, AND THEREFORE THE RULE IS UNLAWFUL

EPA has no authority to limit what scientific information may be considered in making regulatory decisions. No statute authorizes this rule, and EPA lacks any inherent authority to regulate absent a statutory basis. Thus, should EPA proceed to promulgate the Proposed Rule or otherwise limit what science can be considered in regulatory decisions, it will be acting in violation of the law. *See* 5 U.S.C. § 706(2)(C) (requiring a reviewing court to "hold unlawful and set aside agency action . . . found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.").

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[37] Memorandum re Background and Proposed Program to Address Federal Agency Science from Christopher C. Horner, Bracewell & Patterson LLP, to Tim Hyde and Randy Johnson, RJ Reynolds Tobacco Company (Dec. 23, 1996), https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=jfww0019.

[38] Memorandum re Tasks to "Secret Science" Work Group from Leslie Gianelli, Powell Tate (April 10, 1998), https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=klyc0069.

[39] *See* Sharon Lerner, "Republicans Are Using Big Tobacco's Secret Science Playbook to Gut Health Rules," *The Intercept* (Feb. 5, 2017), https://theintercept.com/2017/02/05/republicans-want-to-make-the-epa-great-again-by-gutting-health-regulations/.

[40] *Id.*

[41] *Ecology Ctr., Inc. v. U.S. Forest Serv.*, 451 F.3d 1183, 1194 n.4 (10th Cir. 2006) (emphasis added).

A. The Stated Statutory Provisions Upon Which EPA Relies Do Not Provide Authority for the Proposed Rule.

EPA lists a number of statutes it administers as purported authority for this rule, including "provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conducting of and reliance on scientific activity to inform those functions." *See* 83 Fed. Reg. 18,769. As discussed in detail below, none of the statutes cited by EPA authorizes this proposed action.[42] EPA thus lacks authority to promulgate this rule under any statutory regime administered by the Agency, rendering the rule invalid.

i. Clean Air Act ("CAA")

EPA cites two provisions of the Clean Air Act ("CAA") as authority for the Proposed Rule. As further detailed below, neither provision provides such authority.

First, EPA cites Clean Air Act § 103, 42 U.S.C. § 7403, as authority for the Proposed Rule. 83 Fed. Reg. at 18,769. However, this section provides no authority for such a rule. Instead, the section requires EPA to create a research and development program for prevention and control of air pollution and to conduct research on health effects, among other issues. Specifically:

- Section 7403(a) requires EPA to "establish a national research and development program for the prevention and control of air pollution," which includes funding or conducting studies, establishing technical advisory committees, and related activities.

- Section 7403(b) provides a list of specific "[a]uthorized activities" that EPA may take in establishing the "research and development program" under subsection (a), including, for example, collecting and making available information pertaining to the program, cooperating with other agencies, and making grants and contracts for research. *Id.* § 7403(b)(6).

- Section 7403(c) requires EPA to "conduct a program of research, testing, and development of methods for sampling, measurement, monitoring, analysis, and modeling of air pollutants."

- Section 7403(d) requires EPA to "conduct a research program on the short-term and long-term effects of air pollutants, including wood smoke, on human health."

- Section 7403(e) requires EPA to conduct ecosystem research.

[42] Even assuming any of the statutory provisions upon which EPA relies provided authority to restrict science – which they do not – at best, the provisions could authorize EPA's proposed policy only with respect to activities under the particular statute. The provisions could not authorize an across-the-board restriction on science for rulemakings under all statutes.

- Section 7403(f) requires EPA to oversee an "experimental and analytical research effort, with the experimental research to be carried out at the Liquefied Gaseous Fuels Spill Test Facility."

- Section 7403(g) requires that, in carrying out purpose of subsection (a), EPA shall "conduct a basic engineering research and technology program to develop, evaluate, and demonstrate nonregulatory strategies and technologies for air pollution prevention."

- Section 7403(h) authorizes certain research by the National Institute of Environmental Health Sciences.

- Section 7403(i) discusses coordination of research with "other Federal ecological and air pollution research efforts."

- Section 7403(j) discusses acid rain research.

- Section 7403(k) discusses air pollution conferences.

Notably absent from this long list of explicit requirements and responsibilities is rulemaking authority, much less authority to exclude scientific studies from consideration by EPA in any "regulatory decisions" for any reason, including whether or not the underlying data is, or can be made publicly available. *See* 83 Fed. Reg. at 18,773-74 (proposed 40 C.F.R. §§ 30.2, 30.3, 30.5) (indicating application of Proposed Rule only to use of studies and data in "significant regulatory decisions"). Indeed, the authorized activities included in Section 7403(b) are quite specific, including actions such as collecting and disseminating information, making grants and contracts, and even "construct[ing] facilities, provid[ing] equipment, and employ[ing] staff as necessary to carry out this chapter."

Congress knew how to authorize EPA rulemaking activities elsewhere in the Clean Air Act. That § 7403 does not include such authority, much less authority to restrict science in particular, shows a clear intent not to grant such authority. *Meghrig v. KFC W., Inc.*, 516 U.S. 479, 485 (1996). Rather, the purpose of § 7403 is plainly to promote research and to advance and increase the use and consideration of data, not to restrict it.[43]

Equally problematic, EPA's proposed action serves none of the goals and meets none of the requirements of § 7403. The Proposed Rule is not a "research and development program" and does not include the requisite components of such a program necessary for EPA to act pursuant to its authority under this provision. EPA is not proposing any grants or research fellowships, *see* § 7403(b), or any air pollutant monitoring, analysis, modeling, and inventory

[43] *See, e.g.*, § 7403(b), (c)(2), (d)(1)(A) ("collect and make available, through publications and other appropriate means . . . information . . . pertaining to [EPA's] research and other activities"; "collect and disseminate . . . basic data on chemical, physical, and biological effects of varying air quality . . ."; "establish[] a national network to monitor, collect, and compile data . . . of air emissions, deposition, air quality . . ."; "conduct studies, including epidemiological, clinical, and laboratory and field studies, as necessary to identify and evaluate exposure to and effects of air pollutants on human health").

research, *see* § 7403(c), or any "basic engineering research and technology program to develop, evaluate, and demonstrate nonregulatory strategies and technologies for air pollution prevention," *see* § 7403(g). Nor is EPA proposing to conduct any epidemiological studies on air pollution or to develop any methods or techniques for human health risk assessment, *see* § 7403(d).[44]

In addition, even if EPA could otherwise act pursuant to this provision, EPA may not develop health risk assessment methods and techniques applicable to air pollutants without including the following requisite statutory elements:

- The creation of an Interagency Task Force, *id*. § 7403(d)(2)(A);

- An evaluation of each of the listed hazardous air pollutants ("HAPs") under § 7412(b)(1) "based on reasonably anticipated toxicity to humans and exposure factors" listed therein, and which "shall be reviewed by the Interagency Task Force," *id*. § 7403(d)(2)(B);

- Preparation of environmental health assessments for each of the HAPs, with specific deadlines, that "shall be prepared in accordance with guidelines developed by the Administrator in consultation with the Interagency Task Force and the Science Advisory Board," including a specific list of scientific elements that includes "available toxicological and epidemiological information," "a determination of gaps in available information," and "where appropriate, an identification of additional activities . . . needed to identify the types or levels of exposure which may present significant risk of adverse health effects in humans." *Id*. § 7403(d)(2)(C).

EPA's Proposal does not include any, much less each, of these required components for an exercise of § 7403 authority. Thus, even if EPA otherwise had authority to act pursuant to this provision, the Proposed Rule is inconsistent with and contravenes the very provision which EPA itself cites.

For each and all of these reasons, § 7403 does not give EPA authority to regulate science or to exclude from EPA regulatory decisions the consideration of a subset of scientific studies.

Second, EPA cites section 301(a) of the Clean Air Act, 42 U.S.C. § 7601(a), as authority for the Proposed Rule. 83 Fed. Reg. at 18,769. This section of the Clean Air Act authorizes only "such regulations as are necessary to carry out [the Administrator's] functions under [the Clean Air Act]." 42 U.S.C. § 7601(a)(1). As discussed below, this provision does not authorize the Proposed Rule.

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[44] Moreover, and as discussed in great detail *infra*, Section V, for EPA to perform any of these tasks, it would have to meet the procedural requirements constraining its research and development authority. For example, 42 U.S.C. § 7403(d) sets specific directions that ensure that EPA may not conduct a research program on the effects of air pollution on its own pursuant to this provision, but rather, for such "environmental health effects research," EPA must consult with the Secretary of Health and Human Services, generally. *Id*. § 7403(d)(1). EPA failed to follow these requisite procedures.

It is beyond cavil that general rulemaking provisions do not "'provide [EPA] Carte blanche authority to promulgate any rules, on any matter relating to the Clean Air Act, in any manner that the [EPA] wishes.'" *North Carolina v. EPA* 531 F.3d 896, 922 (D.C. Cir. 2008), *on reh'g in part*, 550 F.3d 1176 (D.C. Cir. 2008) (citing *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 873 (D.C. Cir. 1979)). Rather, such regulations must be "necessary" to carry out another statutory duty. *See, e.g., id.* ("EPA cannot claim retiring excess Title IV allowances is 'necessary' for EPA to ensure SIPs comply with section 110(a)(2)(D)(i)(I)."); 42 U.S.C. § 7601(a). And "'EPA cannot rely on its gap-filling authority to supplement the Clean Air Act's provisions when Congress has not left the agency a gap to fill'—i.e., 'when there is statutory language on point.'" *WildEarth Guardians v. EPA*, 830 F.3d 529, 539 (D.C. Cir. 2016) (citing *Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063–64 (D.C. Cir. 2014)); *see also Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063–64 (D.C. Cir. 2014) ("[W]e have consistently held that EPA's authority to issue ancillary regulations is not open-ended, particularly when there is statutory language on point." (citing *Am. Petroleum Inst. v. EPA*, 52 F.3d 1113, 1119 (D.C. Cir. 1995))).[45]

EPA has not argued, nor could it, that the Proposed Rule is "necessary" for fulfilling the agency's rulemaking duties under the CAA. Rather, as discussed *infra*, Section IV.A, EPA's proposed exclusion of scientific data that is not publicly available is antithetical to the purposes of the CAA. Moreover, EPA itself has repeatedly determined, and the D.C. Circuit has affirmed, that disclosure of the data underlying studies on which the agency relies is ***not*** necessary to fulfill the Agency's transparency and public comment obligations under the Clean Air Act, 42 U.S.C. § 7607(d).

For example, when EPA set the 1997 Particulate Matter National Ambient Air Quality Standards ("NAAQS"), "[s]everal commenters questioned EPA's ability to rely on studies demonstrating an association between PM and excess mortality without obtaining and disclosing the raw 'data' underlying these studies for public review and comment." 62 Fed. Reg. 38,652, 38,689 (July 18, 1997); *see also* EPA, *Responses to Comments on the 1996 Proposed Rule on the Nat'l Ambient Air Quality Standards for Particulate Matter* (July 1997), https://www3.epa.gov/ttn/naaqs/standards/pm/data/rtc_pm.pdf. EPA responded that "[i]t would be impractical and unnecessary for EPA to review underlying data for every study upon which it relies as support for every proposed rule or standard." 62 Fed. at 38,689. EPA made clear that disclosing such data was not its general practice, in part because EPA was not relying on the underlying data but rather on the study results themselves. *Id*. EPA recognized that "[i]f EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment." *Id*. EPA explained:

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[45] *See also Nat. Res. Def. Council v. Reilly*, 976 F.2d 36, 41 (D.C. Cir. 1992) (EPA cannot use its general rulemaking authority as justification for adding to a statutorily specified list); *Sierra Club v. EPA*, 719 F.2d 436, 453 (D.C. Cir.1983) (same); *see also Gonzales v. Oregon*, 546 U.S. 243, 264–65 (2006) ("It would go . . . against the plain language of the text to treat a delegation for the 'execution' of [the Attorney General's] functions as a further delegation to define other functions well beyond the statute's specific grants of authority.").

> [S]uch data are often the property of scientific investigators and are often not readily available because of the proprietary interests of the investigators or because of arrangements made to maintain confidentiality regarding personal health status and lifestyle information of individuals included in such data. Without provisions of confidentiality, the possibility of conducting such studies could be severely compromised.

Id. And when the 1997 PM NAAQS was challenged, the D.C. Circuit affirmed EPA's consideration of relevant scientific epidemiological evidence without disclosure of all of the raw data. *See Am. Trucking Ass'ns. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002) (The court "agree[d] with EPA that requiring agencies to obtain and publicize the data underlying all studies on which they rely 'would be ***impractical and unnecessary***.'" (quoting 62 Fed. Reg. at 38,689) (emphasis added)).

In *Coalition of Battery Recyclers Association v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010), petitioners again challenged EPA's failure to disclose underlying data for a study on the health effects of lead exposure, on which it relied to issue the 2008 Lead NAAQS. Specifically, the petitioners contended "the *Lanphear* study [on which EPA relied] contained such errors that EPA acted arbitrarily and capriciously in relying on results from the study without first obtaining and making public the underlying data for the study." *Battery Recyclers*, 604 F.3d at 622-23. EPA reiterated in its briefing that it would be "***impractical and unnecessary***" to disclose such data. *See* EPA Respondent Brief (Doc. No. 1230237) at 47 (Feb. 16, 2010) (citation and quotation marks omitted; emphasis added), *Battery Recyclers*, 604 F.3d at 623. The D.C. Circuit again agreed with and upheld EPA's determination that disclosure of underlying data is not necessary to consider the results of a health study to be relevant to a clean air rulemaking pursuant to 42 U.S.C. § 7607(d). The court applied its prior holding in *American Trucking*, that "'[t]he Clean Air Act imposes no such obligation' and that 'requiring agencies to obtain and publicize the data underlying all studies on which they rely would be impractical and unnecessary.'" *Battery Recyclers*, 604 F.3d at 623 (quoting *American Trucking*, 283 F.3d at 372). Though petitioners "attempt[ed] to distinguish their request on the ground that in *American Trucking* the court was addressing requests for data underlying several studies, while they request only that EPA obtain and make public the data underlying the Lanphear study," *id.* at 623, the court found that argument unpersuasive, again "noting that raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants." *Id.* at 623 (citing *American Trucking*, 283 F.3d at 372).

EPA also cannot argue that excluding studies from the Agency's consideration when the underlying data cannot be publicly disclosed is "necessary" for ensuring the Agency relies on the best available science. As an initial matter, nowhere in the Proposed Rule does EPA find that particular studies, much less all studies that rely in part on the collection of confidential raw data (such as people's names and health records), are bad science, or even less reliable science. Nowhere does EPA show how health studies that rely in part on confidential personal information can never be relevant in any way to CAA rulemakings. Nor could it, as EPA has found such studies relevant and has relied on such studies for decades, and they are commonly accepted and valued as important scientific information of health effects within the scientific community. *See* Section IV.A. EPA cites no examples of situations where unsound, unlawful or

arbitrary decision-making resulted from an agency's reliance on studies that do not fit its newfound notions of "transparency" and "integrity." Rather, courts have repeatedly upheld actions that have relied on such studies, as cited above.

Moreover, EPA has not demonstrated that it is consistent with scientific principles to categorically ***exclude*** peer-reviewed scientific information from all consideration in a rulemaking, as EPA proposes to do. If EPA has any doubts or concerns regarding the merits of a particular study, it must address those doubts or concerns for that particular study in the context of a given rulemaking, where agency staff, internal scientific experts, scientific advisory committees, or commenters contend that study is relevant. EPA has provided no scientific justification for ignoring an entire class of health science simply because the underlying data has not been disclosed. Whether underlying data on which a study relies is made public or not simply has no bearing on whether a scientific study is good science, is accurate, is reliable, and is relevant to a scientific question (such as the health effects of air pollution). And to the extent EPA requires additional verification of a study, there are myriad ways it can do so without disclosing confidential data (for example, requesting an independent scientific body to conduct a confidential review). *See* Section IV.A, *infra*.

Furthermore, there is no statutory gap with respect to what studies EPA should consider (nor does EPA attempt to identify any). As further discussed below, sections of the Clean Air Act that govern air standards and rulemakings specify the applicable standards and generally require consideration of all available science. EPA has been adopting rules under most of these provisions for decades without finding any need for restrictions of the sort EPA proposes here. The Agency provides no explanation, and none exists, for suddenly finding "gaps" in these provisions.

Finally, EPA fails to acknowledge that it has had a longstanding policy of considering health studies without requiring disclosure of all underlying raw data. Indeed, it tries to minimize its prior position in a footnote, stating that: "Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use [of] non-public data in support of its regulatory actions." 83 Fed. Reg. at 18,769, n.3. It ignores the fact that EPA itself has ***consistently*** considered and used health studies dependent on non-public information for clean air rulemakings. Further, the Agency's longstanding policy has been that "EPA does not generally undertake evaluations of raw, unanalyzed scientific data as part of its public health standard setting process." 62 Fed. Reg. at 38,689. Only in "extreme cases – for example where there are credible allegations of fraud, abuse or misconduct – would a review of raw data be warranted." *Id*. That EPA now finds this data so important that it must be publicly disclosed before the Agency will even consider a study represents a monumental shift in course.

EPA is not working on a blank slate. Therefore, it must do more than just explain the change. Rather, EPA must provide "a more detailed justification," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41-42 (1983), because its new policy directly contradicts the Agency's prior findings that such studies are relevant to clean air rulemakings and provide evidence of health effects that the Agency can and must consider. EPA has not provided any reasoned explanation for its departure, much less an explanation with the requisite detail to justify its about-face.

ii. Clean Water Act ("CWA")

EPA cites sections 104 and 501 of the Clean Water Act, 33 U.S.C. §§ 1254, 1361, as statutory authority for its Proposed Rule. Upon examination, these sections do not provide the authority EPA suggests.

Section 104, 33 U.S.C. § 1254, entitled "Research, investigations, training, and information," addresses the Administrator's authority as it relates to the establishment of national programs, cooperation, investigations, water quality surveillance system, and reports. It requires the Administrator to, among other things: "conduct and promote the coordination and acceleration of, research, investigations, experiments, training, demonstrations, surveys, and studies relating to the causes, effects, extent, prevention, reduction, and elimination of pollution"; and to "initiate and promote the coordination and acceleration of research designed to develop the most effective practicable tools and techniques for measuring the social and economic costs and benefits of activities which are subject to regulation under this chapter." 33 U.S.C. § 1254(a)(1), (6).

Toward that end, the provision authorizes the Administrator to: "collect and make available, through publications and other appropriate means, the results of and other information, including appropriate recommendations by him in connection therewith, pertaining to such research and other activities referred to in" 1254(a)(1); and "cooperate with other Federal departments and agencies, State water pollution control agencies, interstate agencies, other public and private agencies, institutions, organizations, industries involved, and individuals, in the preparation and conduct of such research and other activities referred to in" 1254(a)(1). *Id.* § 1254(b)(1), (2). It also requires the Administrator to "conduct research on, and survey the results of other scientific studies on, the harmful effects on the health or welfare of persons caused by pollutants." *Id*. § 1254(c). And it requires the Administrator to conduct and update a variety of studies, including, but not limited to, studies on oil pollution controls, *id*. § 1254(i), effects and control of pesticides in water, *id.* § 1254(l), waste oil disposal, *id*. § 1254(m), effects of pollution on estuaries and estuarine zones, *id*. § 1254(n), pollution from agriculture, *id*. § 1254(p), and effects and methods of controlling thermal discharges, *id*. § 1254(t).

Thus, section 1254 discusses research and studies in great detail, but it does so by setting forth requirements for ***cooperation and promotion of research***. This section does not grant EPA any rulemaking authority at all, nor does it say anything about the Administrator's ability to screen or otherwise define the parameters for research that EPA can rely on for regulatory purposes. Instead, it describes the different areas for research and study and requires the Administrator to conduct research and studies in these areas.

The second CWA provision upon which EPA relies fares no better. EPA cites to section 501, 33 U.S.C. § 1361, as additional statutory authority for this rule. This is the provision generally authorizing the Administrator to "prescribe such regulations ***as are necessary to carry out his functions under this chapter***." 33 U.S.C. § 1361(a) (emphasis added). Such authority only exists if the regulation is, in fact, "necessary to carry out" the provisions under the CWA. *Mourning v. Family Publ'n Serv., Inc.*, 411 U.S. 356, 369 (1973) ("[w]here the

empowering provision of a statute states simply that the agency may 'make . . . such rules and regulations as may be necessary to carry out the provisions of [an] Act,' . . . the validity of a regulation promulgated thereunder will be sustained [only] so long as it is 'reasonably related to the purposes of the enabling legislation.'" (citation omitted)). The Proposed Rule is decidedly not necessary at all. As with the CAA discussed *supra*, the CWA regulatory authority enables the Agency to carry out its functions and fill any statutory gaps. The Proposed Rule is not needed to fill any "gaps" in the CWA, as Congress has already provided – in great detail – the Administrator's regulatory authority as it relates to research, emphasizing the need for the use and promotion of inclusive research. *See* § 1254. Moreover, a rule "devised pursuant to Congress' directive to issue regulations 'necessary to carry out' [an] Act . . . cannot stand if it is 'arbitrary, capricious, or manifestly contrary to the statute.'" *Ragsdale v. Wolverine World Wide, Inc*., 535 U.S. 81, 86 (2002) (citations omitted); *see also Am. Petroleum Inst.*, 52 F.3d at 1119 ("EPA cannot rely on its general authority to make rules necessary to carry out its functions when a specific statutory directive defines the relevant functions of EPA in a particular area."). As discussed below in Section IV.A and elsewhere herein, not only is the regulation unnecessary to carry out EPA's functions under the CWA or to fill any gaps, but it is arbitrary and antithetical to the objectives of the CWA. Thus, the Proposed Rule is not authorized under this general rulemaking provision.

iii. Safe Drinking Water Act ("SWDA")

Despite EPA's contrary contentions, the Safe Drinking Water Act ("SDWA"), 42 U.S.C. § 300f *et seq*., does not provide any authority for the adoption of a policy that would "preclude" EPA from considering all relevant scientific evidence in carrying out its duty to protect the quality of drinking water in the United States. *See* 83 Fed. Reg. at 18,769, n.3. In the Proposal, EPA points to two specific provisions of the SDWA as authorizing the rule, neither of which provides the necessary authority.

First, EPA points to 42 U.S.C. § 300j-1, but its reliance on this section is misplaced. Rather than authorizing the Administrator's selective exclusion of science and research, this section simply describes the Agency's responsibility to gather information—that is, "[to] conduct research, studies, and demonstrations relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments of man resulting directly or indirectly from contaminants in water, or to the provision of a dependably safe supply of drinking water." 42 U.S.C. § 300j-1(a)(1). This section also directs EPA to study certain serious threats to drinking water, including "polychlorinated biphenyl contamination," "disposal of waste (including residential waste)," "surface spills of contaminants," "virus contamination," "abandoned injection or extraction wells," "intensive application of pesticides and fertilizers in underground water recharge areas," "surface disposal of contaminants in underground water recharge areas," and "the nature, extent, sources of and means of control of contamination by chemicals or other substances suspected of being carcinogenic." *Id*. § 300j-1(a)(3)–(9). It therefore provides no legitimate basis for a rule that aims to limit the data that EPA can consider in executing the purposes of the SDWA.

Second, EPA cites the general grant of rulemaking authority in 42 U.S.C. § 300j-9(a)(1) as authorizing the Proposed Rule. However, this section likewise does not offer authorization. While this section empowers EPA "to prescribe such regulations as are necessary or appropriate to carry out [its] functions under this subchapter," the Proposed Rule is neither necessary nor appropriate to effectuate the SDWA.

The SDWA requires EPA to protect the public by limiting contaminants in public water systems. Specifically, the Act directs EPA to establish a "maximum contaminant level goal" for each contaminant "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." 42 U.S.C. § 300g-1(b)(4)(A). EPA must then set an enforceable "maximum contaminant level" as close to this goal as is feasible. *Id*. § 300g-1(b)(4).

To accomplish these goals, in 1996, Congress amended the SDWA to ensure that EPA's regulatory decisions were scientifically sound and adequately protective of public health. As amended, the SDWA directs EPA to base its determination about whether to regulate any particular contaminant "on the ***best available public health information***." *Id*. § 300g-1(b)(1)(B)(ii)(II) (emphasis added). In addition, the amended SDWA expressly requires that, "to the degree that an Agency action is based on science, [EPA] shall use . . . ***the best available, peer-reviewed science and supporting studies*** conducted in accordance with sound and objective scientific practices[] and . . . data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." *Id.* § 300g-1(b)(3)(A) (emphasis added). "Best available" means precisely what it says – the best of all that is available, not the best of some subset of what is available. The only qualifiers the SDWA places on what is "best available" are that the science be "peer-reviewed," and that the "supporting studies" be "conducted in accordance with sound and objective scientific practices." *Id*. Disclosure of confidential data underlying the studies plays no role in determining whether the science is the best available and is in no way required by the rule (but rather is expressly rejected by the scientific community, *see infra*). Any rule proposing to disregard reliable scientific information relevant to the regulation of drinking water contaminants directly conflicts with the SDWA's sound science mandate.

Given that the Proposed Rule is manifestly contrary to the SDWA, which expressly requires use of the best science available, it is not authorized by the general rulemaking authority in § 300j-9(a)(1). *Mourning*, 411 U.S. at 369; *Ragsdale*, 535 U.S. at 86. EPA is thus left without an appropriate authorizing provision under the SDWA.

iv. Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA")

EPA also cites to provisions under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") as authority for its Proposed Rule. However, upon examination, these provisions likewise provide no legal support for the Proposal.

The first provision upon which EPA relies – Section 115 – is inapposite. It merely sets out goal dates for EPA to begin assessment and remediation of facilities on the National

Priorities List, and is entirely irrelevant to the issues of the Proposed Rule. *See* 42 U.S.C. § 9616. While the second provision upon which EPA relies – Section 311 – is at least relevant to the issues of the Proposed Rule, it nonetheless conflicts with the proposition that the Proposed Rule espouses. It requires the Department of Health and Human Services, in consultation with EPA, to establish and support a research program consisting of:

> Basic research (including epidemiologic and ecologic studies) which may include each of the following:
>
> > (i) Advanced techniques for the detection, assessment, and evaluation of the effects on human health of hazardous substances.
> >
> > (ii) Methods to assess the risks to human health presented by hazardous substances.
> >
> > (iii) Methods and technologies to detect hazardous substances in the environment and basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances.

42 U.S.C. § 9660(a)(1)(A); *see also id.* § 9660(c) (authorizing EPA to conduct research on the "detection, assessment, and evaluation of the effects on and risks to human health of hazardous substances and detection of hazardous substances in the environment"). These provisions say nothing about authorizing EPA to adopt rules at all, much less rules limiting reliance on studies that do not meet the criteria of the Proposed Rule. Section 311(a) merely provides for the Department of Health and Human Services to establish and support certain research programs. It does not give EPA any authority at all, much less authority to limit the type of studies that can be relied upon for purposes of implementing CERCLA's operative provisions. Accordingly, CERCLA provides no support for EPA's actions here.

v. Emergency Planning and Community Right to Know Act ("EPCRA")

EPA likewise relies upon a provision in the Emergency Planning and Community Right to Know Act ("EPCRA") that in no way authorizes this Proposed Rule. Specifically, Section 328 of EPCRA – upon which EPA relies – merely authorizes EPA to "prescribe such regulations as may be necessary to carry out" the statute. 42 U.S.C. § 11048. But this provision does not "empower[] [EPA] to establish regulations which run far afield from the substance of the Act." *Kaw Valley, Inc. v. EPA* 844 F. Supp. 705, 708 (D. Kan. 1994) (citing *Central Forwarding, Inc. v. Interstate Commerce Comm'n*, 698 F.2d 1266, 1277 (5th Cir. 1983)). Given that the Proposed Rule is contrary to the purposes of EPCRA, *see infra*, Section IV.A, this general rulemaking provision cannot be considered "necessary," and thus does not do the work that EPA ascribes to it. *See Mourning*, 411 U.S. at 369; *Ragsdale*, 535 U.S. at 86.

vi. Federal Insecticide, Fungicide, Rodenticide Act ("FIFRA")

EPA also cites to two specific provisions in the Federal Insecticide, Fungicide, Rodenticide Act ("FIFRA") as statutory support for the Proposed Rule. Upon closer examination, these provisions do not provide the necessary authority for this Rule.

First, EPA points to Section 20(a), 7 U.S.C. § 136r(a), which provides:

> (a) Research
>
> The Administrator shall undertake research including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this subchapter, and the Administrator shall conduct research into integrated pest management in coordination with the Secretary of Agriculture. The Administrator shall also take care to ensure that such research does not duplicate research being undertaken by any other Federal agency.

By its plain language, this provision authorizes research, not the use of scientific studies in regulating pesticides. Thus, EPA's reliance on this provision as support for this rule is misplaced.

Second, the Proposed Rule cites Section 25(a)(1), 7 U.S.C. § 136w, which authorizes the EPA Administrator "to prescribe regulations to carry out the provisions of this subchapter." However, this broad authority is expressly limited to regulating "in accordance with the procedure[]" prescribed in FIFRA itself. *Id*. Yet, as discussed more fully in Section V, EPA failed to comply with these requisite procedures. Accordingly, this provision provides no authority for EPA's issuance of this rule.

vii. Toxic Substances Control Act ("TSCA")

EPA's reliance on the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2609, as authority for the Proposed Rule, fares no better. Indeed, much like many of the other statutory provisions upon which EPA relies, this provision governs EPA's authority to conduct and support research, and does not address EPA's authority to use scientific data or research in support of regulatory decisions.

Specifically, section 2609 grants EPA authority to "conduct such research, development, and monitoring as is necessary to carry out the purposes of this chapter. [EPA] may enter into contracts and may make grants for research, development, and monitoring under this subsection." 15 U.S.C. § 2609(a). Section 2609 grants EPA additional related authorities, including authority to:

- Create and operate information systems to store data relevant to chemical substances, *id*. § 2609(b);

- Develop "screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical[s]," *id*. § 2609(c);

- Establish a research program to develop chemical "monitoring techniques and instruments," *id*. § 2609(d);

- Conduct "basic research" on chemical screening and monitoring, *id*. § 2609(e), and train federal scientists on chemical screening and monitoring, *id*. § 2609(f); and

- Develop systems for information sharing among "Federal, state, and local authorities," *id*. § 2609(g).

Notably absent from the list of authorities under section 2609 is EPA's authority to determine what science it can consider when making regulatory decisions. Instead, the provision solely focuses on EPA's ability to conduct research or to fund research, independent of whether that research will or may be used by EPA to make regulatory decisions. Thus, section 2609 does not provide any basis for the authority claimed in the Proposed Rule.

Moreover, § 2625 of TSCA governs how EPA uses science when exercising its main regulatory powers under the statute, and establishes detailed criteria that EPA must use when "the Administrator makes a decision based on science" when carrying out its regulatory powers. 15 U.S.C. § 2625(h). Thus, this provision, and not those cited by EPA, would theoretically govern a rule related to the use of science. *See Bennett v. Islamic Republic of Iran*, 618 F.3d 19, 25 (D.C. Cir. 2010) ("'where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion.'" (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983))). However, and as discussed more fully *infra*, Section IV.A, the Proposed Rule contravenes the requirements of § 2625 that EPA consider all "reasonably available information" when making regulatory decisions, and thus is not authorized by this provision either.

viii. Resource Conservation and Recovery Act ("RCRA")

The Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. § 6901 *et seq*., gives EPA the authority and responsibility to manage and control solid and hazardous waste, including the generation, transportation, treatment, storage, and disposal of the waste. EPA points to two provisions in RCRA for support of this Proposed Rule, neither of which authorizes this action.

The first provision of RCRA cited as authority for this rule, § 6912(a)(1), provides the Administrator with the general authority to "prescribe, in consultation with Federal, State, and regional authorities, such regulations as are necessary to carry out his functions under this chapter." 42 U.S.C. § 6912(a)(1). RCRA defines the functions of EPA in the area covered by RCRA, and therefore, EPA cannot rely upon the general authority to make rules provided by the statute. *Am. Petroleum Inst.*, 52 F.3d at 1119 ("EPA cannot rely on its general authority to make rules necessary to carry out its functions when a specific statutory directive defines the relevant

functions of EPA in a particular area."). Moreover, limiting the consideration of reliable health science when promulgating regulations that have significant health and environmental impacts is in no way "necessary" for the Administrator to carry out his functions under RCRA, and thus, for this reason too, the general rulemaking provision does not authorize this rule. *See Mourning*, 411 U.S. at 369.

The second provision of RCRA upon which EPA relies, § 6979, is inapposite. This provision pertains to labor standards related to wages for laborers and mechanics. 42 U.S.C. § 6979. This provision has no relevance to the Proposed Rule whatsoever and certainly does not provide the authority for it. Thus, nothing that EPA cites to in RCRA provides the requisite authority for this Proposed Rule.

ix. 5 U.S.C. § 301

In its notice extending the comment period and adding a public hearing, as an implicit admission that it has not cited sufficient authority for the Proposed Rule, EPA adds a new source of alleged authority, stating that "EPA is proposing this rule under authority of 5 U.S.C. 301, in addition to the authorities listed in the April 30th document." *See* 83 Fed. Reg. 24,255, 24,256 (May 25, 2018). Just like with the other statutory provisions upon which it relies, EPA is trying to fit a square peg in a round hole.

Section 301 of Title 5 provides "[t]he head of an Executive department or military department" authority to "prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." This provision governs internal organizational and bureaucratic steps required for operations. It allows all agencies to issue regulations to preserve and use their own papers and property. This section is plainly focused on allowing executive agencies to issue rules necessary to carry out the performance of their agencies' internal workings, not to allow EPA to regulate scientific material in rulemakings.

Indeed, the "purpose" of this section, "which originated in 1789 as a law 'to enable General Washington to get his administration underway by spelling out the authority of Government officers to set up offices and to file Government documents'. . . is to set up merely internal guidelines for a given governmental agency" to perform its job. *United States v. Lewis*, No. C-CR-89-114-01, 1990 WL 11111, *5 (W.D. N.C. Feb. 5, 1990) (citation omitted). That is why it is known as the "Housekeeping Statute," to literally allow the federal government to set up and keep house. *U.S. ex. Rel. O'Keefe v. McDonnell Douglas Corp.*, 132 F.3d 1252, 1254 (8th Cir. 1998) (citing H.R. Rep. No. 85-1461 (1958), *reprinted in* 1958 U.S.C.C.A.N. 3352). The Act was amended in 1966 as "codifying the general and permanent laws relating to the organization of the Government of the United States and to its civilian officers and employees." Pub. L. No. 89-554, 80 Stat. 378 (Sept. 6, 1966).

In *Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979), the Supreme Court evaluated the Housekeeping Statute and held that it does not provide statutory authority for substantive regulations. After a brief historical analysis of the provision, the Court wrote:

> Given this long and relatively uncontroversial history, and the terms of the statute itself, it seems to be simply a grant of authority to the agency to regulate its own affairs. . . It is indeed a "housekeeping statute," authorizing what the APA terms "rules of agency organization procedure or practice" as opposed to "substantive rules."

Id. at 309–10. Multiple courts have agreed and limited rulemaking under this provision to non-substantive rules. *See, e.g.*, *McDonnell Douglas Corp.*, 132 F.3d at 1256 (citing examples).[46]

Based on this long line of authority, EPA's reliance on this authority is sorely misplaced. EPA's attempt to "construe [this provision] as something more" is a "misuse" that "twist[s]" the statute beyond its intended purpose; EPA may not "twist this simple administrative statute into an authorization for the promulgation of substantive rules." *Id.* at 1255 (citing and quoting *Chrysler Corp.*, 441 U.S. at 310 n.41 (quoting H.R. Rep. No. 85–1461 at 7 (1958))).

The Proposed Rule does not relate to the organization of EPA or how it preserves its papers or keeps house. EPA's exclusion of critical health studies is such a far cry from being necessary to "set up offices" and to "file Government documents," that reliance on this provision hardly passes the laugh test. As discussed extensively in these Comments, the Proposed Rule is by no means necessary for EPA to perform its job but rather is antithetical to the very statutes it is responsible for effectuating. Accordingly, for the same reasons the general rulemaking authority provisions under all of the environmental statutes EPA cites do not authorize this rule, § 301 likewise does not permit EPA to issue a rule that undermines scientific integrity as well as all of the public health and environmental protections EPA is charged with enforcing.

B. EPA Has No Inherent Authority to Issue This Proposed Rule.

EPA's lack of statutory authority to propose this rule is fatal, as it has no inherent power to act. Indeed, it is well settled that a federal agency "literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); *see also Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."); *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) ("[I]t is 'axiomatic' that 'administrative agencies may act only pursuant to authority delegated to them by Congress'" (citation omitted)); *Ohio Dep't of Medicaid v. Price*, 864 F.3d 469, 476 (6th

[46] *See, e.g.*, *In re Bankers Tr. Co.*, 61 F.3d 465, 470 (6th Cir. 1995) (Federal Reserve Board regulation requiring subpoenaed party to refuse production of confidential Federal Reserve Board information, contrary to Federal Rule of Civil Procedure 34, was not authorized by the Housekeeping Statute and "exceed[ed] the congressional delegation of authority"); *Exxon Shipping Co. v. U.S. Dep't of Interior*, 34 F.3d 774, 776–78 (9th Cir. 1994) (Housekeeping Statute did not authorize regulations allowing agency to withhold deposition testimony of federal employees); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 826–27 (S.D. Ohio 1995) (Housekeeping Statute did not authorize 1953 Defense Department directive on the use of human volunteers in experimental research); *McElya v. Sterling Med., Inc.*, 129 F.R.D. 510, 514 (W.D. Tenn. 1990) (Housekeeping Statute did not give Department of Navy authority to create general discovery privilege for persons under its jurisdiction).

Cir. 2017) ("Agencies, after all, are creatures of statutory authority." (citation and internal quotations omitted)). This is because, under the Constitution, Congress is the branch of government with lawmaking power. *City of Arlington, Tex. v. FCC*, 569 U.S. 290, 317 (2013) (noting that an agency has no lawmaking power unless Congress delegates that power to it). "The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes." *Chrysler Corp.*, 441 U.S. at 302. Thus, EPA only has rulemaking power to the extent that Congress delegated it such power. *Lyng v. Payne*, 476 U.S. 926, 937 (1986) ("an agency's power is no greater than that delegated to it by Congress.").

Moreover, the fact that Congress has given EPA the authority to regulate in a certain area does not mean that it has general authority to make any rule within that area. This argument has been squarely rejected:

> The [agency's] position in this case amounts to the bare suggestion that it possesses *plenary* authority to act within a given area simply because Congress has endowed it with *some* authority to act in that area. We categorically reject that suggestion. Agencies owe their capacity to act to the delegation of authority from Congress.

Am. Library Ass'n. v. FCC, 406 F.3d 689, 708 (D.C. Cir. 2005) (quoting *Ry. Labor Executives' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 670 (D.C. Cir. 1994)) (internal quotations omitted; emphasis in original); *see also Liberty Mut. Ins. Co. v. Friedman*, 639 F.2d 164, 169 (4th Cir. 1981) ("a court must reasonably be able to conclude that the grant of authority contemplates the regulations issued." (citation and internal quotation marks omitted)). "[T]he power to issue regulations is not the power to issue any regulations." *Nat'l Mining Ass'n v. U.S. Dep't of the Interior*, 105 F.3d 691, 694 (D.C. Cir. 1997). In light of the statutory limitation on EPA's authority to restrict science in the way it proposes to do, *see infra*, Section IV, any general rulemaking authority on which it might otherwise try to rely does not authorize the Proposed Rule. *See, e.g., Nat. Res. Def. Council, Inc. v. Reilly*, 976 F.2d 36, 40-41 (D.C. Cir. 1992) (refusing to allow EPA to rely on general rulemaking authority to trump specific limitations on its authority because a vague "open-ended power" does not "trump the specific provisions of the [Clean Air] Act"; and "EPA's construction of the statute is condemned by the general rule that when a statute lists several specific exceptions to the general purpose, others should not be implied." (citation and internal quotation marks omitted)).

Accordingly, EPA has no general or inherent authority permitting it to lawfully adopt the Proposed Rule or otherwise limit what science may be considered in the rulemaking process. It, therefore, must be acting pursuant to some grant of authority by Congress for the Proposed Rule to be lawful. Yet none of the stated authorities upon which EPA relies provides the necessary

authority to promulgate this rule.[47] Given that EPA has no statutory authority to issue the Proposed Rule, its action is *ultra vires*. *See, e.g.*, *McDonnell Douglas Corp.*, 132 F.3d at 1257 ("An agency's promulgation of rules without valid statutory authority implicates core notions of the separation of powers, and we are required by Congress to set these regulations aside." (citing cases finding *ultra vires* agency action)). The Proposed Rule is therefore unlawful.

IV. THE PROPOSED RULE VIOLATES PROVISIONS OF THE LISTED AUTHORIZING STATUTES, AS WELL AS NUMEROUS OTHER STATUTES, POLICIES, AND EXECUTIVE ORDERS, AND IS THEREFORE UNLAWFUL.

A. The Proposed Rule Violates the Purported Authorizing Statutes.

Agency "regulations, in order to be valid, must be consistent with the statute under which they are promulgated." *Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 609 (2013) (quoting *United States v. Larionoff*, 431 U.S. 864, 873 (1977)). As discussed below, the Proposed Rule violates a number of provisions in the statutes upon which EPA relies as statutory authority. For this reason, too, the Proposed Rule is invalid.

i. CAA

The Clean Air Act's specific rulemaking provisions do not allow EPA to create the restrictions on the consideration or use of health science that EPA proposes. Rather, these provisions govern each type of CAA rulemaking, and to the extent science can and must be considered under these provisions, EPA may not lawfully restrict the use of such science.[48] The Proposed Rule contravenes a number of CAA provisions and is thus unlawful.

First, sections 108 and 109 of the Clean Air Act do not allow EPA to restrict science as proposed and demonstrate that the Proposed Rule cannot lawfully be applied to any NAAQS rulemakings. These provisions specify that EPA's air quality criteria (on which the NAAQS are based) must "accurately reflect the latest scientific knowledge." 42 U.S.C. § 7408(a)(2); *id.* § 7409(b) (requiring those "criteria" be used to set NAAQS). This language unambiguously requires EPA to consider "all identifiable effects on public health," not just some. *Id.* § 7408(a)(2). The criteria "shall include information" on defined factors, "to the extent practicable." *Id.* This provision leaves no room for EPA to ignore or exclude studies because underlying data is not disclosed.

EPA cannot possibly ensure its air quality criteria "accurately reflect the latest scientific knowledge" if it refuses to even read certain studies based on an arbitrary public disclosure test. EPA's past practice illustrates this: for decades, the Agency's practice has been to review ***all*** available scientific studies, including those relying on non-public data. *See, e.g.*, *Battery Recyclers*, 604 F.3d at 616; *see also* EPA, *Integrated Science Assessment (ISA) for Particulate*

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[47] EPA may not now add any new authority (if any exists) to try to save this action, as doing so would violate public notice-and-comment requirements under the statutes cited herein, as well as under the Administrative Procedure Act.

[48] Commenters do not concede that the Proposed Rule would necessarily apply to every action under these provisions.

Matter (Final Report, Dec 2009) (2009), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=216546; EPA, *Air Quality Criteria for Particulate Matter*, Vols. II-III (1996), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2832. The legislative history of § 108 confirms that Congress's intent was for EPA to "establish such national goals on the basis of ***the best information available***," not to sit idly by until industry representatives no longer dispute questions regarding health effects. S. Rep. No. 91-1196 (Sept. 17, 1970), CAA70 Leg. Hist. 19, 110 (emphasis added).

In addition, the Proposed Rule would direct EPA to violate the statutory procedures that must be followed when the Agency sets NAAQS. This includes EPA's appointment of an independent scientific review committee, including certain defined members, *see* 42 U.S.C. § 7409(d)(2)(A), and consideration of the recommendations of that committee when setting the NAAQS, *id*. § 7409(d)(2)(B)-(C); *see also, e.g.*, *Mississippi v. EPA*, 744 F.3d 1334, 1346 (D.C. Cir. 2013) (explaining NAAQS development process). That committee shall advise EPA regarding whether there are "areas in which additional knowledge is required." 42 U.S.C. § 7409(d)(2)(C). In promulgating NAAQS in the past, EPA has recognized that the CAA requires it to consider scientific advice and recommendations from such experts, including those that rely on health studies where underlying data is not disclosed.[49] Directing the Agency to ignore scientific studies presented by CASAC, just because the underlying data is not public, contravenes these statutory requirements.

Second, section 7409 of the Act requires EPA to adopt NAAQS based on the criteria, at levels requisite to protect public health with an adequate margin of safety. "[T]he Act requires [a] . . . preventative and precautionary" approach to setting NAAQS, whereby EPA must protect public health from "not just known adverse effects, but those of scientific uncertainty or that research has not yet uncovered." *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (citation and quotation marks omitted). Congress "specifically directed" EPA "to protect against . . . effects whose medical significance is a matter of disagreement." *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980); *accord Nat. Res. Def. Council, Inc. v. EPA*, 824 F.2d 1146, 1152 (D.C. Cir. 1987) (en banc) (discussing legislative history). EPA's proposal would

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[49] *See, e.g.*, EPA, *Integrated Science Assessment (ISA) of Ozone and Related Photochemical Oxidants (Final Report, Feb 2013)*, EPA/600/R-10/076F (2013), http://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=247492; EPA, *Integrated Science Assessment (ISA) for Particulate Matter (Final Report, Dec 2009)*, EPA/600/R-08/139F (2009), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=216546; *see also* EPA, *Integrated Science Assessment (ISA) for Lead (Final Report, Jul 2013)* (July 2013), https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=255721; EPA, CASAC Review of the EPA's *Integrated Science Assessment for Lead (Third External Review Draft – November 2012)* (June 4, 2013), https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/39A3C8177D869EA085257B80006C7684/$File/EPA-CASAC-13-004+unsigned.pdf; *see also* EPA, EPA Clean Air Scientific Advisory Committee (CASAC) (last updated Aug. 3, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/WebProjectsbyTopicCASAC!OpenView (NAAQS assessments and criteria document).

flout these precedents by refusing to consider scientific studies – even those published in peer-reviewed journals by reputable scientists – based on an arbitrary data transparency policy.

To the extent the CAA allows EPA to weigh particular studies based on its expert judgment, this does not authorize EPA to categorically exclude an entire class of studies from being considered when performing a rulemaking to fulfill the Agency's statutory directive to protect public health and welfare. 42 U.S.C. § 7409(b)(1) (requiring primary NAAQS to be standards "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health"). EPA cannot rationally engage in its task of determining an appropriate level for the NAAQS if it entirely excludes relevant health studies from its consideration simply because underlying data has not been publicly released. Under the Proposed Rule, EPA would refuse to consider studies indicating that adverse health effects occur at a specific pollutant level—even where multiple studies reach the same results—where the studies fail to meet the agency's arbitrary disclosure tests. This would contradict the statutory requirement to assure public health protection by ignoring some of the most important health science relevant to that question and is the epitome of irrational agency action.

Third, the Proposed Rule violates section 7412 of the CAA, which includes myriad provisions that require EPA to evaluate health risks and effects of hazardous air pollutants ("HAPs" or "air toxics") and to set emission standards to reduce these risks and effects, based on certain science-based legal tests applicable to particular § 7412 rulemakings. *See, e.g.*, 42 U.S.C. § 7412(a), (b)(1)-(4), (f)(1)-(2). In no place does the statute limit EPA's consideration of scientific studies on health effects or risks to those studies where underlying data is publicly disclosed, nor does it authorize EPA to so limit its consideration of such scientific information. Instead, § 7412 includes language repeatedly indicating the requirement, embodying Congressional intent, for EPA to consider ***all*** relevant scientific information regarding health risks and effects, actual or potential, of hazardous air pollutants.

For example, § 7412(f) requires EPA to investigate and report, among other things, on "the actual health effects with respect to persons living in the vicinity of sources," and "***any available epidemiological or other health studies***" regarding the effects of HAPs, as part of the residual risk requirements. *Id.* § 7412(f)(1)(C) (emphasis added); *id.* § 7412(f)(1) (also providing other requirements for EPA's investigation and report to Congress). EPA submitted that report to Congress in 1999.[50] Section 7412(f) further provides that, in the absence of Congressional action on recommendations provided in EPA's Residual Risk Report to Congress, EPA "shall . . . promulgate standards for [each air toxics] category or subcategory if promulgation of such standards is required in order to provide an ample margin of safety to protect public health in accordance with this section (as in effect before November 15, 1990)." *Id.* § 7412(f)(2)(A). This provision also directs that:

> Emission standards promulgated under this subsection shall provide an ample margin of safety to protect public health in accordance with this section (as in effect before November 15,

[50] EPA, *Residual Risk Report to Congress*, EPA-453/R-99-001 (Mar. 1999), https://www.epa.gov/fera/residual-risk-report-congress-1999.

> 1990), unless the Administrator determines that a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. If standards promulgated pursuant to subsection (d) and applicable to a category or subcategory of sources emitting a pollutant (or pollutants) classified as a known, probable or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million, the Administrator shall promulgate standards under this subsection for such source category.

Id. § 7412(f)(2)(A). It would not be possible for EPA to fulfill its statutory directives under § 7412(f) to ensure that air toxics emissions standards "provide an ample margin of safety to protect public health," and to assess and remove any unacceptable health risks, unless EPA considered all relevant scientific studies in assessing such health risks. *Id.* § 7412(f)(2).

Further, § 7412(f)(2) also explicitly refers to EPA's Benzene Rule, which interpreted the prior version of this provision and which itself relied on certain studies and guidelines for which underlying data was not disclosed. *Id.* § 7412(f)(2)(B) (citing 54 Fed. Reg. 38,044 (Sept. 14, 1989)).[51] As EPA determined, and Congress, the D.C. Circuit, and EPA have affirmed through citation and reliance on that rule, § 7412(f) standards must be "based on the most current scientific knowledge," and on risk assessment guidelines and methods developed by EPA scientists and expert independent scientists. 54 Fed. Reg. at 38,062-63.[52] EPA has repeatedly recognized this reliance on an expansive array of scientific support that includes information that relies on epidemiological and other health studies for which the underlying data is not published in later § 7412(f) rulemakings as well.

Indeed, EPA itself has interpreted its legal responsibility pursuant to this provision as "incorporating into our assessments the best available science with respect to dose-response information."[53] To achieve that, EPA has followed scientific recommendations by the Office of

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[51] In that rule, among other studies, "the Agency compiled and presented a 'Survey of Societal Risk' in its July 1988 proposal (53 FR 28512-28513)." 54 Fed. Reg. at 38,046. The underlying data for that survey was not disclosed, yet the Agency both considered and relied on it. *Id.*

[52] In that rule, EPA explained that risk assessments and § 7412(f) rules must be based on "the most current scientific knowledge and on sound scientific judgment"; EPA stated that it had based that rule on "an evaluation of the currently available information and on the regulatory mission of EPA to protect public health"; EPA also relied on the then-applicable Cancer Guidelines, and Guidelines for Exposure Assessment, explaining that "these guidelines were developed by scientists in EPA, and were extensively reviewed by the public and by expert scientists in industry, academia, environmental groups, and other governmental agencies." 54 Fed. Reg. at 38,062-63.

[53] *See, e.g.*, EPA, *Residual Risk Assessment for the Portland Cement Manufacturing Source Category in Support of the Sept. 2017 Risk and Technology Review Proposed Rule* at 23 (July 2017), https://www.regulations.gov/document?D=EPA-HQ-OAR-2016-0442-0153 (describing the Agency's current policy and scientific methodology for this type of health risk assessment); *see also e.g.*, EPA, *Residual Risk Assessment for Pulp Mill Combustion Sources in Support of the October, 2017 Risk and*

Air Quality Planning and Standards, and has prioritized certain sources of such dose-response information according, in part, to "level of peer review received."[54] These guidelines direct EPA to consult dose-response assessments such as a reference concentration (RfC, for inhalation), reference dose (RfD, for ingestion), and a unit risk estimate (URE, for cancer risk) and/or slope factor (SF, for cancer risk).[55] EPA's scientific method is to consult and rely on IRIS (an EPA database containing peer-reviewed scientific health assessment information) as a top priority source of such information, due in part to the high level of peer review. As EPA's guidelines explain: "IRIS is a critical resource for risk assessors because the database contains toxicity information that reflects a consensus among EPA program offices."[56] EPA also prioritizes dose-response information from the U.S. Agency for Toxic Substances and Disease Registry ("ATSDR"), and the California EPA Office of Environmental Health Hazard Assessment.[57]

Technology Review Final Rule at 6, 18-19 (July 2017), https://www.regulations.gov/document?D=EPA-HQ-OAR-2014-0741-0266 (same). In citing these examples, Commenters do not contend that EPA's approach is the most health-protective or that it fully incorporates the extent of current scientific knowledge, as they have repeatedly urged EPA to follow the more conservative and more scientifically up-to-date approach of the NAS Silver Book, as the Agency is well aware from submitted comments and from reviewing that report. *See, e.g.*, NAS, *Science & Decisions: Advancing Risk Assessment* (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment; Nat. Res. Def. Council, *Strengthening Toxic Chemical Risk Assessments to Protect Human Health* (Feb. 2012), https://www.nrdc.org/sites/default/files/strengthening-toxic-chemical-risk-assessments-report.pdf (describing ways EPA needs to strengthen, not weaken, risk assessments based on NAS recommendations). However, refusing to look at IRIS or other health reference values that rely in any way on non-public data as EPA proposes would represent a significant backward step by EPA, away from current science, as well as an about-face from its well-developed scientific policy and current methods which are based on years of evaluation and have gone through extensive peer review by the Science Advisory Board. *See, e.g.*, SAB, *Risk and Technology Review (RTR) Risk Assessment Methodologies* (May 2010) (supporting EPA's approach and urging EPA to take a more protective scientific approach on certain issues).

[54] EPA, *Cement Kilns Risk Assessment*, *supra* n.53, at 23 (citing EPA, 2014a. Table 1); EPA, Table 1: Prioritized Chronic Dose-Response Values for Screening Risk Assessments (June 18, 2018), https://www.epa.gov/sites/production/files/2014-05/documents/table1.pdf.

[55] EPA, *Cement Kilns Risk Assessment*, *supra* n.53, at 23 (The RfC is defined as an "estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." The RfD is "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." The URE is defined as "the upper-bound excess cancer risk estimated to result from continuous lifetime exposure to an agent at a concentration of 1 µg/m3 in air." The SF is "an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime exposure to an agent. This estimate, [is] usually expressed in units of proportion (of a population) affected per mg/kgday . . .").

[56] EPA, *Air Toxics Risk Assessment Reference Library*, Vol. 1 Tech. Res. Manual, EPA-453-K-04-001A at 3-9 (April 2004), https://www.epa.gov/sites/production/files/2013-08/documents/volume_1_reflibrary.pdf; *id.* at 12-25 ("Dose-response assessments that have achieved full intra-agency consensus are incorporated in the Integrated Risk Information System (IRIS), which is regularly updated and available on-line (www.epa.gov/iris).").

[57] EPA, *Cement Kilns Risk Assessment*, *supra* n.53, at 24.

Each of these recognizes the value of relevant scientific information without regard to whether full underlying data can be or has been publicly disclosed.[58]

Section 7412(a)(11) likewise illustrates the constraints the CAA imposes on limiting consideration of science when establishing cancer risk. This provision defines "carcinogenic effect" as having "the meaning provided by the Administrator under Guidelines for Carcinogenic Risk Assessment as of the date of enactment." 42 U.S.C. § 7412(a)(11). These Guidelines for Carcinogenic Risk Assessment ("Cancer Guidelines"), in turn, direct that EPA shall rely on "established scientific peer review processes," and state that "[t]he cancer guidelines incorporate basic principles and science policies based on evaluation of the currently available information."[59] The Cancer Guidelines also provide that EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens ("Supplemental Guidance") should be considered along with the Guidelines.[60] Both the Cancer Guidelines and Supplemental Guidance cite as relevant and in some instances important some of the very types of scientific studies that EPA's Proposed Rule would categorically exclude: epidemiological studies which rely on private or confidential medical information, or assessments such as IRIS, California Environmental Protection Agency's ("Cal. EPA") assessments, and other health reference concentration information that rely on such studies.[61] The Cancer Guidelines do not preclude the

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[58] As IRIS values show, IRIS considers relevant and often essential epidemiological evidence for which underlying private confidential or medical information is not released. *See, e.g.*, EPA, *EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments, Vol. 1*, CAS No. 1746-01-06, EPA/600/R-10/038F, at 1-7 (Feb. 2012), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/supdocs/dioxinv1sup.pdf (discussing the use of two human epidemiological studies "as co-critical studies" to derive the reference dose in the IRIS assessment, and the SAB's agreement with EPA that these represent best available science); EPA, *Toxicological Review of Hexavalent Chromium* (Aug. 1998), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0144tr.pdf (relying on human epidemiologic studies); EPA, *Toxicological Review of Formaldehyde-Inhalation Assessment* (June 2010), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=497038 (relying on epidemiologic studies).

[59] EPA, *Guidelines for Carcinogen Risk Assessment* (*hereinafter* "Cancer Guidelines") at 1-2 (Mar. 2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[60] EPA, *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*, EPA/630/R-03/003F (Mar. 2005), https://www3.epa.gov/airtoxics/childrens_supplement_final.pdf.

[61] For example, the Supplemental Guidance states: "[The] critical data are either human epidemiological data on childhood exposures resulting in adult cancer or research studies with rodents involving early postnatal exposures. The major human data available are from radiation exposures . . . with very limited data available for humans exposed during childhood to chemicals." Suppl. Guidance at 13. The Cancer Guidelines and later EPA policy state that "***[a]ll studies that are considered to be of acceptable quality***, whether yielding positive or null results, or even suggesting protective carcinogenic effects, ***should be considered in assessing the totality of the human evidence***. Conclusions about the overall evidence for carcinogenicity ***from available studies in humans*** should be summarized along with a discussion of uncertainties and gaps in knowledge." Cancer Guidelines, *supra* n.59, at 2-4 (emphasis added). They further provide that "[h]uman data may come from epidemiologic studies or case reports . . . The most common sources of human data for cancer risk assessment are epidemiologic investigations . . .

consideration of any "one kind of data" as relevant, but instead "cover the assessment of available data," explaining that "[i]t is very important that all analyses consider the basic standards of quality, including objectivity, utility, and integrity."[62]

Thus, EPA's Proposal to ignore studies because underlying data is not disclosed is antithetical to the Guidelines upon which EPA relies when determining carcinogenic effects in § 7412(a)(11). The statute's text and incorporation of EPA's science guidelines on cancer risk are unambiguous and leave no gap to fill regarding what "carcinogenic" means. Thus, in regulating carcinogens EPA may not apply the Proposed Rule's exclusion of any relevant health science regarding carcinogens and carcinogenic risk from air pollutants in rulemakings.

Consistent with the reliance on all relevant health science to determine carcinogenic effects, for cancer and other health risks under § 7412(f), EPA has an existing policy of what it describes as using the "the best available science with respect to dose-response information. The recommendations are based on the following sources, in order of priority": (1) EPA IRIS values which have all gone through independent, external peer-review; (2) ATSDR values, which follow an approach similar to EPA's IRIS program; and (3) Cal. EPA values for which "[t]he process for developing these assessments is similar to that used by EPA to develop IRIS values and incorporates significant external scientific peer review."[63] Likewise, for non-cancer health risks from air pollution, EPA's guidelines do not exclude science that is relevant, even if underlying data is not disclosed.[64] Notably, the vast majority of health reference values that EPA uses in § 7412(f) come from EPA's IRIS program, which includes a scientific literature review of all available relevant studies, without excluding any due to a lack of disclosure of underlying data.[65]

Epidemiologic data are extremely valuable in risk assessment because they provide direct evidence on whether a substance is likely to produce cancer in humans, thereby avoiding issues such as: species-to-species inference, extrapolation to exposures relevant to people, effects of concomitant exposures due to lifestyles. Thus, epidemiologic studies typically evaluate agents under more relevant conditions. When human data of high quality and adequate statistical power are available, they are generally preferable over animal data and should be given greater weight in hazard characterization and dose-response assessment, although both can be used." *Id*. at 2-3.

[62] *Id.* at 1-5.

[63] *See, e.g.*, EPA, *Final Residual Risk Assessment for the Petroleum Refining Source Sector* at 15-16 (Sept., 2015), https://www.regulations.gov/document?D=EPA-HQ-OAR-2010-0682-0800.

[64] EPA, *Risk Assessment for Other Effects* (last updated Jan. 31, 2017), https://www.epa.gov/fera/risk-assessment-other-effects. *See also*, EPA, *Guidelines for Mutagenicity Risk Assessment* (1986), http://www2.epa.gov/risk/guidelines-mutagenicity-risk-assessment; EPA. *Guidelines for Developmental Toxicity Risk Assessment* (1991), http://www2.epa.gov/risk/guidelines-developmental-toxicity-risk-assessment; EPA, *Guidelines for Neurotoxicity Risk Assessment* (1998), http://www2.epa.gov/risk/guidelines-neurotoxicity-risk-assessment; EPA, *Guidelines for Reproductive Toxicity Risk Assessment* (1996), http://www2.epa.gov/risk/guidelines-reproductive-toxicity-risk-assessment; EPA et al., *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (1994), http://www2.epa.gov/risk/methods-derivation-inhalation-reference-concentrations-and-application-inhalation-dosimetry.

[65] EPA, IRIS Process for Developing Human Health Assessments (last updated March 7, 2018), https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process.

Fourth, the Proposed Rule is unlawful because EPA is considering costs and is relying on implementation costs as a basis for the Rule, in direct violation of § 7409, § 7412(f)(2), and other provisions of the Clean Air Act where cost is not a relevant or permissible factor in determining health and environmental impacts. *See, e.g.*, 83 Fed. Reg. at 18,768 (indicating that Proposed Rule would apply to "regulations for which the public is likely to bear the cost of compliance"); *see also id*. at 18,774 (proposed § 30.8) (requiring agency to implement the Proposed Rule "in a manner that minimizes costs"). Section 7412(f)(2) prohibits consideration of economic costs in assessing and determining whether the health risks that a major air toxics source causes are "unacceptable," as it requires a determination of what is required to provide an "ample margin of safety to protect the public health." *Nat. Res. Def. Council, Inc.*, 824 F.2d at 1164-65 (quotation marks omitted); Benzene Rule, 54 Fed. Reg. at 38,048-49 (citing Vinyl Chloride decision as prohibiting consideration of costs when determining a "safe" or "acceptable" emission level).[66] Similarly, as EPA explained in the Cancer Guidelines: "Risk assessments may be used to support decisions, but in order to maintain their integrity as decision-making tools, they are not influenced by consideration of the social or economic consequences of regulatory action." Cancer Guidelines, *supra* n.59, at 1-5 to 1-6. It is therefore both unlawful and arbitrary to use cost as a justification to ignore and exclude health science from residual risk air toxics assessments, and thus as part of the determination of whether risk is acceptable or unacceptable, pursuant to § 7412(f)(2).

Fifth, section 7412(n) directs EPA to "perform a study of the hazards to public health reasonably anticipated to occur as a result of emissions by electric utility steam generating units of pollutants listed under subsection (b) after imposition of the requirements of this chapter," and to list such sources "after considering the results of [this] study." 42 U.S.C. § 7412(n)(1). This provision includes no limitation on the data EPA can or must consider for this question, based on EPA's own interpretation. Thus, previously, in fulfilling its duty pursuant to this provision, EPA considered a wide array of scientific studies as relevant, regardless whether underlying data was disclosed.[67] Excluding consideration of relevant scientific material addressing such hazards

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[66] *See also, e.g.*, NESHAP Proposed Rule, Pulp Mills, 81 Fed. Reg. 97,046, 97,064 (Dec. 30, 2016) (citing Benzene Rule and vinyl chloride decision) ("If risks are unacceptable, the EPA must determine the emissions standards necessary to bring risks to an acceptable level without considering costs."); NESHAP Proposed Rule, Friction Materials Mfg., 83 Fed. Reg. 19,499, 19,502 (May 3, 2018) (same); *see also Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468-71 (2001) (EPA is prohibited from considering costs in adopting national ambient air quality standards under the Clean Air Act rules).

[67] *See, e.g.*, EPA, Supplemental Finding That It Is Appropriate and Necessary To Regulate Hazardous Air Pollutants From Coal- and Oil-Fired Electric Utility Steam Generating Units; Final Rule, 81 Fed. Reg. 24,420, 24,421-23, 24,438, nn.1, 10, 11 (Apr. 25, 2016) (citing peer-reviewed risk assessments on human health effects and additional peer review of the Mercury Risk Assessment as well as evaluation of the non-mercury HAP risk assessment and co-benefits from reductions in PM2.5 and SO2 emissions in the MATS Regulatory Impact Analysis) (U.S. EPA. 2011. *Revised Technical Support Document: National-Scale Assessment of Mercury Risk to Populations with High Consumption of Self-caught Freshwater Fish In Support of the Appropriate and Necessary Finding for Coal- and Oil-Fired Electric Generating Units*. Office of Air Quality Planning and Standards. November. EPA– 452/R–11–009. Docket ID No. EPA-HQ–OAR–2009–0234–19913; U.S. EPA. 2011. *Supplement to Non-mercury Case Study Chronic Inhalation Risk Assessment for the Utility MACT Appropriate and Necessary Analysis*. Office of Air Quality Planning and Standards. November. Docket ID No. EPA–HQ–OAR–2009–0234–19912; U.S.

solely because underlying data is not available would arbitrarily lead to an incomplete assessment of relevant information and flout the statute's preventative and health-protective intent. EPA may not apply the Proposed Rule under this provision, as EPA has already recognized – for example, in acting pursuant to § 7412(n)(1) to reach the determination that it is "appropriate and necessary" to regulate power plants due to their health hazards[68] – but rather must consider the types of studies the Proposed Rule would ignore. EPA cannot depart from its decision to consider such studies relevant without meeting the *State Farm* and *Fox* tests, *see supra* at 23, which it unquestionably has not done here.

In addition, the listing and delisting provisions for HAPs and source categories, and the requirements for the urban air toxics program, require EPA to assess particular and potential health effects and risks from HAPs. *See, e.g.*, 42 U.S.C. § 7412(b)(2)-(3), (c)(9), (k). EPA's Proposal to ignore relevant scientific information due to the lack of public disclosure violates these requirements.

Sixth, CAA § 7429 requires EPA to evaluate health risks and does not allow the exclusion of relevant scientific information. For example:

- § 7429(a)(3) – standards must include new unit siting requirements that, on a site specific basis, minimize potential risks to public health or the environment;
- § 7429(e) requires permits to include site-specific provisions "if the Administrator or the State determines that emissions in the absence of such limitations or measures may reasonably be anticipated to endanger public health or the environment";
- § 7429 (h)(3) requires residual risk review under § 112(f), and § 129(b)(1) requires the inclusion of any residual risk standards in the guidelines for existing units.

Seventh, the Proposed Rule is antithetical to the very purpose of the Clean Air Act, which is "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population." 42 U.S.C. § 7401(b)(1). A "primary goal" is "pollution prevention." *Id.* § 7401(c). Each of the above provisions must be read in a way that advances that goal; the Proposed Rule would do the contrary and is thus inconsistent with the statute and unlawful. EPA's Proposal runs directly counter to these goals and objectives by arbitrarily excluding consideration of science that discloses health impacts of air pollution. The Proposal is not neutral. It only excludes health-based science (dose-response studies, epidemiological studies) where underlying data is not disclosed, generally because it cannot or should not be disclosed to protect individual participants' privacy and confidentiality. EPA cannot exclude whole categories of scientific data untethered from a specific context or study, but rather must assess each health study on a case-by-case basis to determine whether or not it should be considered in a particular rulemaking, under EPA's long-standing scientific guidelines and policies and its regular approach in CAA rulemakings. Instead, this Proposed Rule excludes health studies from consideration as a class, up front, before EPA is even in the rulemaking stage

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EPA. 2011. *Regulatory Impact Analysis for the Final Mercury and Air Toxics Standards*. EPA–452/R–11–011. Docket ID No. EPA–HQ–OAR–2009–0234–20131.).

[68] 81 Fed. Reg. at 24,422-23.

under its authority. And it does so not for scientific reasons, but simply due to industry preferences – most notably because industry cannot pick them apart by replicating decades of air pollution health effects, or by contacting individuals who shared private medical information to replicate the collection of data.

While the CAA provides for protection of "public health and welfare," the Proposed Rule favors excluding science even if it is the most relevant and important evidence regarding how to protect public health. While the CAA aims for "pollution prevention" to protect public health, the Proposed Rule would prevent consideration of science relevant to these very goals. Therefore, EPA's Proposed Rule is unlawful and arbitrary. Thus, EPA cannot lawfully satisfy § 7429 for similar reasons as described above, unless it evaluates relevant information on risks.

Eighth, a number of **i**mportant CAA provisions require EPA to act based on a finding that air pollution is reasonably anticipated to endanger health or the environment. *See, e.g.*, 42 U.S.C. §§ 7415, 7422, 7521. The D.C. Circuit has ruled that such language "requires a precautionary, forward-looking scientific judgment about the risks of a particular air pollutant, consistent with the CAA's 'precautionary and preventative orientation.'" *Coal. for Responsible Regulation v. EPA*, 684 F.3d 102, 122 (D.C. Cir. 2012) (citation omitted). Such a precautionary approach does not require scientific certainty. "If a statute is 'precautionary in nature' and 'designed to protect public health,' and the relevant evidence is 'difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge,' EPA need not provide 'rigorous step-by-step proof of cause and effect' to support an endangerment finding." *Id*. at 121 (citation omitted). Thus, the court expressly rejected the notion that EPA can or should disregard uncertain or "difficult to come by" evidence under "endangerment" statutes. Indeed, the court rejected the notion that EPA could not rely on studies that synthesized the research of others:

> It makes no difference that much of the scientific evidence in large part consisted of "syntheses" of individual studies and research. Even individual studies and research papers often synthesize past work in an area and then build upon it. This is how science works. EPA is not required to re-prove the existence of the atom every time it approaches a scientific question.

Id. at 120. Thus, in making endangerment determinations, there is no lawful or rational basis for EPA to automatically exclude reliance on any studies that synthesize and evaluate research by others.

The Courts have also rejected EPA's attempts to avoid endangerment determinations based on considerations other than the specific endangerment criteria. In *Massachusetts v. EPA*, the Court held that the endangerment language in section 7521(a)(1) required EPA to assess whether motor vehicle emissions cause or contribute to air pollution which may reasonably be anticipated to endanger public health and welfare due to climate change, and to so determine exclusive of any other policy considerations. *Massachusetts v. EPA*, 549 U.S. 497, 532-34 (2007). Likewise, here, EPA cannot avoid its duty to make endangerment findings by arbitrarily rejecting scientific studies to serve vague and disingenuous policy interests such as allegedly fostering greater public trust and greater transparency in agency decisions.

The Proposed Rule also conflicts with specific language in § 7415 requiring an endangerment finding notification,

> [w]henever the Administrator, upon receipt of reports, surveys or studies from any duly constituted international agency has reason to believe that any air pollutant or pollutants emitted in the United States cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare in a foreign country or whenever the Secretary of State requests him to do so with respect to such pollution which the Secretary of State alleges is of such a nature, the Administrator shall give formal notification thereof to the Governor of the State in which such emissions originate.

42 U.S.C. § 7415(a). This provision does not allow EPA to ignore any such "reports, surveys or studies," if they show "reason to believe" that an air pollutant endangers public health. *Id.*

Similarly, § 7422 directs that EPA "shall review ***all available relevant information***," to determine whether to make an endangerment finding for certain radioactive pollutants (including source material, special nuclear material, and byproduct material), cadmium, arsenic and polycyclic organic matter. 42 U.S.C. § 7422(a) (emphasis added). This language expressly forecloses EPA's refusal to consider available studies based on an arbitrary transparency screen. *See also* 42 U.S.C.§ 7521(a)(1)-(a)(3)(B) (providing for EPA to promulgate revised standards for heavy duty trucks "[o]n the basis of information available to the Administrator concerning the effects of air pollutants emitted from heavy-duty vehicles or engines and from other sources of mobile source related pollutants on the public health and welfare, and taking costs into account").

Finally, the CAA's rulemaking provision for air standards and limitations does not allow EPA to ignore relevant scientific information, including information provided by Commenters, and likewise may not direct a court to ignore this data. Section 7607 of the CAA – which provides for judicial review of air rulemakings – prescribes more detailed rulemaking procedures than those provided by the Administrative Procedure Act for a designated list of air emission standards and rules. 42 U.S.C. § 7607(d)(1). These procedures protect the public's right to notice and comment, in part, by requiring EPA to place into the docket and to consider and respond to all such comments. *Id.* § 7607(d)(4)(B)(i) ("Promptly upon receipt by the agency, all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period shall be placed in the docket."); *id.* § 7607(d)(5) ("In promulgating a rule to which this subsection applies (i) the Administrator shall allow any person to submit written comments, data, or documentary information; (ii) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions . . ."); *id.* § 7607(d)(6)(B) ("The promulgated rule shall also be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period.").

EPA's Proposed Rule contravenes these requirements and is therefore unlawful because it allows EPA to decide, before even receiving comments, that it will not consider or respond through regulatory action to any comments that submit scientific material for which underlying information is not disclosed. Under § 7607(d), EPA may not lawfully decide to ignore an entire class of science; if submitted by commenters as relevant, EPA must consider and respond in the context of the statutory test that applies to its rulemaking. Failure to do so is unlawful and arbitrary. *Id.* § 7607(d)(9).[69]

Relatedly, for certain rules where recommendations are provided from scientific experts, § 7607 requires additional material to be placed into the docket, without EPA discretion. *Id.* § 7607(d)(3) (requiring a "statement" that "shall also set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee established under section 7409(d) of this title and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences."). EPA's Proposed Rule unlawfully violates this provision because it would direct EPA to refuse to consider or discuss such information if based on studies for which underlying data were not disclosed.

More generally, EPA may not attempt to restrict, before a rulemaking has even begun, the type of information it will consider in that rulemaking. Doing so impinges on the federal courts' authority to determine what scientific evidence is relevant to application of CAA requirements in rulemakings. Pursuant to § 7607, the relevant court of appeals, and most frequently the D.C. Circuit, has jurisdiction to consider a petition for review of an EPA air rule. 42 U.S.C. § 7607(b). This grant of jurisdiction includes a grant allowing the court to decide what record material is relevant. *Id.*; *see also id.* § 7607(c). Notably, the court rules provide that the record on review of an agency order or regulation must include, *inter alia*, "the pleadings, evidence, and other parts of the proceedings before the agency." D.C. Cir. R. 16 ("If necessary, the court may direct that a supplemental record be prepared and filed."); *see also* Fed. R. App. P. 16. Similarly, the Federal Rules of Evidence require courts, not EPA or any other federal agency, to determine what evidence is "relevant" and "admissible." *See, e.g.*, Fed. R. Evid. 401-402 (allowing courts, and Congress by statute, but not federal agencies, to prescribe rules of evidence and determine admissibility of evidence and expert testimony).[70] Scientific information

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[69] Ignoring an entire class of science is also unlawful under the APA – which applies to all EPA rulemaking – as the APA likewise requires notice and comment and requires EPA to respond to all submitted comments. *See* 5 U.S.C. § 553. EPA has also promulgated rules specific to certain statutes that likewise require notice and comment as well as consideration of and responses to those comments by EPA. *See, e.g.*, 40 C.F.R. § 25.3 (rulemaking under the CWA, SDWA, and RCRA require "public participation," including "providing access to the decision-making process, seeking input from and conducting dialogue with the public, assimilating public viewpoints and preferences, and demonstrating that those viewpoints and preferences have been considered by the decision-making official"). Thus, for the same reason the Proposed Rule violates the CAA's rulemaking provision, so too does it violate the APA and a number of other statutes that EPA is responsible for implementing.

[70] "Relevant evidence is admissible unless any of the following provides otherwise: the United States Constitution; a federal statute; these rules; or other rules prescribed by the Supreme Court." Fed. R. Evid. 402. "A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized

submitted by commenters undoubtedly qualifies as "evidence" that the court must consider, even if EPA refuses to do so.[71] EPA may not lawfully prevent submission of such evidence, or attempt to exclude it from a rulemaking record. *Id.*[72]

Where EPA previously attempted to restrict or change the statutory test and authority granted to courts to evaluate CAA cases, the D.C. Circuit rejected that as unlawful and outside of the bounds of EPA's authority. *Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1062 (D.C. Cir. 2014) (vacating affirmative defense to civil penalties because it changed the standard set by statute for court's discretion in enforcement cases, and thus violated § 7604 and § 7413). For this reason, too, the Proposed Rule is invalid.

ii. CWA

The Proposed Rule violates the Clean Water Act in two ways: *first*, it runs afoul of its requirement to use all relevant science and the best technology available; and *second*, it undermines its mandate to protect public health. For each of these reasons, the rule cannot stand.

First, pursuant to Section 1251 of the Clean Water Act, the primary objective of the CWA is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a). Toward that end, a fundamental policy underlying the CWA is "to support and aid research relating to the prevention, reduction, and elimination of pollution." *Id*. § 1251(b). The CWA thus promotes the use of good science. The Proposed Rule handicaps EPA from accomplishing these broad goals and objectives by limiting the available science and research.

For example, section 1313(c) of the CWA governs the establishment and modification of water quality standards. Pursuant to this provision, these standards "shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of" the CWA. *Id*. § 1313(c)(2)(A). In setting these standards, EPA must "tak[e] into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation." *Id.* If EPA limits the type of science acceptable for these purposes, it is not fulfilling this obligation of the CWA as it is not using all means to accomplish this requirement.

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knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702; *See also, Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

[71] Courts have repeatedly allowed the use of certain health studies as proof of harm from air pollution even though their underlying data are not publicly disclosed. *See, e.g.*, *Battery Recyclers*, 604 F.3d at 623.

[72] Not only does this apply to appeals of decisions under the Clean Air Act, but it also applies more generally to any agency rulemaking decision arising out of any statute under EPA's authority that is appealed to an appellate court where the Federal Rules of Appellate Procedure and Federal Rules of Evidence apply.

Similarly, section 1313(d) requires states to establish "the total maximum daily load" for certain identified pollutants, and it must do so "at a level necessary to implement the applicable water quality standards with seasonal variations and a margin of safety which takes into account any lack of knowledge concerning the relationship between effluent limitations and water quality." *Id.* § 1313(d)(1)(C). As with Section 1313(c), if EPA is required to do this without all available science, it is not fulfilling its obligations under this provision.

Not only do the limitations on science undermine the Agency's ability to most effectively fulfill the obligations of the Clean Water Act, but they likewise contradict provisions in the Act that require use of the best technology available. For example, section 1311(p)(1) requires that any modified requirements of effluent limitations in certain permits apply "the best available technology economically achievable." Failure to do so will render the effluent limitations invalid. *See, e.g.*, *Nat. Res. Def. Council v. EPA*, 808 F.3d 556, 564 (2d Cir. 2015). Several other provisions likewise require the use of the best technology to carry out the purpose of the Act. *See, e.g.*, 33 U.S.C. § 1314(b)(1) (regulations establishing or revising effluent limitations must apply "the best practicable control technology currently available" to identify "the degree of effluent reduction attainable"); *id.* § 1314(b)(2)(A) (regulations establishing or revising effluent limitations must apply "the best control measures and practices achievable" to identify "the degree of effluent reduction attainable . . . including treatment techniques, process and procedure innovations, operating methods, and other alternatives for classes and categories of point sources")); *id.* § 1314(b)(4)(A) (regulations establishing or revising effluent limitations must apply "the best conventional pollutant control technology" to identify "the degree of effluent reduction attainable . . . for classes and categories of point sources").

Second, the CWA also contains several additional provisions that demonstrate its overarching goal of protecting the public health. For example, one of the provisions in section 1254 – one of the two sections cited by EPA as authorizing this Proposed Rule – addresses the "collection and dissemination of scientific knowledge on the effects and control of pesticides in water." 33 U.S.C. § 1254(l). Pursuant to this provision, the Administrator is charged with developing and issuing to the States for the purpose of carrying out the CWA "the latest scientific knowledge available in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water in varying quantities," and updating that information "whenever necessary to reflect developing scientific knowledge." *Id.* There are no qualifications or other limiting factors in the type of scientific knowledge that must be considered. Rather, the provision contemplates inclusiveness to most effectively accomplish the CWA's objectives.

Several other provisions likewise address science and research as they relate to the public health goals of the CWA. For example, section 1254a requires the Administrator to "conduct research on the harmful effects on the health and welfare of persons caused by pollutants in water." A provision addressing protection of the Great Lakes states, in part, that "[t]he Administrator may not carry out a project under this paragraph for remediation of contaminated sediments located in an area of concern— (i) if an evaluation of remedial alternatives for the area of concern has not been conducted, including a review of the short-term and long-term effects of

the alternatives on human health and the environment." *See* 33 U.S.C. § 1268(c)(11)(D). Section 1311(g)(2), which addresses requirements for modifications to effluent limitations, requires that such modifications not result in "the discharge of pollutants in quantities which may reasonably be anticipated to pose an unacceptable risk to human health or the environment." And section 1314(a)(9) provides that the Administrator "shall publish new or revised water quality criteria for pathogens and pathogen indicators (including a revised list of testing methods, as appropriate), based on the results of the studies conducted under section 1254(v)," for the purpose of protecting human health in coastal recreation waters, and that at least once every five years, the Administrator must review and if necessary revise the water quality criteria. And EPA has long recognized that the NPDES (§ 402 permit) and fill discharges (§ 404 permit) programs require protection of public health. *See, e.g.*, 33 U.S.C. §§ 1342, 1344 (authorizing EPA to prohibit, withdraw, or veto a discharge that "will have an unacceptable adverse effect on municipal water supplies, shellfish beds and fishery areas . . . wildlife, or recreational areas") and implementing regulations, including Section 404(b)(1) Guidelines (40 C.F.R. Part 230).[73]

Taken together, these provisions demonstrate that the overall focus of the CWA is to promote and protect the public health and water quality in the most comprehensive way possible. Thus, any measure that could limit science or research supporting these objectives is antithetical to the Act. For these reasons, EPA's reliance on the CWA to support its restrictions on science is entirely misplaced.

iii. SDWA

EPA's proposal to exclude reliable, accessible, and relevant science is antithetical to the requirements of the SDWA and thus is unlawful. The SDWA was established to protect the quality of the drinking water in the United States. To accomplish this, the SDWA requires EPA to limit contaminants in public water systems. As discussed *supra*, it does this by establishing a "maximum contaminant level goal" for each contaminant "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." 42 U.S.C. § 300g-1(b)(4)(A). And in deciding whether to regulate any particular contaminant to protect public health, EPA must rely on "the ***best available public health information***." *Id*. § 300g-1(b)(1)(B)(ii)(II) (emphasis added). And to the extent EPA relies on science, it must use "***the best available, peer-reviewed science and supporting studies***" available. *Id*. § 300g-1(b)(3)(A) (emphasis added). Thus, any decision to categorically ignore or otherwise fail to consider relevant scientific information when regulating drinking water would be unlawful under the SWDA.

[73] *See, e.g.*, 40 C.F.R. Part 122 (requiring permits to implement water quality standards and protect public health); 40 C.F.R. § 230.10(c)(1), § 230.11 (prohibiting discharge of dredged or fill material which will cause or contribute to significant degradation of the waters of the United States, which includes: "[s]ignificantly adverse effects of the discharge of pollutants on human health or welfare, including but not limited to effects on municipal water supplies, plankton, fish, shellfish, wildlife, and special aquatic sites."); *see also* § 230.50 (municipal and private water supplies).

iv. CERCLA

Under CERCLA, Congress created a hazardous substance research and classification regime based largely on studies that "determine relationships between exposure to toxic substances and illness"—the very dose response studies that the Proposed Rule would stifle. 42 U.S.C. § 9604(i)(1). The statute requires EPA and ATSDR to annually update a list of hazardous substances commonly found at facilities on the National Priorities List that the agencies determine "pos[e] the most significant potential threat to human health due to their known or suspected toxicity to humans and the potential for human exposure to such substances . . ." *Id.* § 9604(i)(2)(A), (B). EPA must also develop guidelines for ATSDR's toxicological profiles of each listed substance, which must include "available toxicological information and epidemiologic evaluations . . . to ascertain the levels of significant human exposure for the substance and the associated acute, subacute, and chronic health effects." *Id.* § 9604(i)(3)(A). For any substance for which adequate information is unavailable, EPA and ATSDR must create a program of toxicological and epidemiological research to develop that information. *Id.* § 9604(i)(5).

Congress specified that CERCLA health assessments include:

> preliminary assessments of the potential risk to human health posed by individual sites and facilities, based on such factors as the nature and extent of contamination, the existence of potential pathways of human exposure (including ground or surface water contamination, air emissions, and food chain contamination), the size and potential susceptibility of the community within the likely pathways of exposure, the comparison of expected human exposure levels to the short-term and long-term health effects associated with identified hazardous substances and any available recommended exposure or tolerance limits for such hazardous substances, and the comparison of existing morbidity and mortality data on diseases that may be associated with the observed levels of exposure.

42 U.S.C. § 9604(i)(6)(F). And when assessing alternate remedial actions under CERCLA, EPA must "at a minimum, take into account . . . the persistence, toxicity, mobility, and propensity to bioaccumulate of such hazardous substances and their constituents [and] short- and long-term potential for adverse health effects from human exposure." *Id.* § 9621(b)(1).

EPA's Proposed Rule would prevent the Agency from using the very types of health assessments that Congress mandates. It undermines both the letter and spirit of the statute, and is therefore unlawful.

v. EPCRA

The Proposed Rule also violates EPCRA. EPCRA requires EPA to make determinations about whether to list new chemicals in the statute's Toxic Release Inventory program "based on

generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, available to [EPA]." 42 U.S.C. § 11023(d)(2). Specifically, Congress instructs EPA to add a chemical to the Toxic Release Inventory list when:

> (A) The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.
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> (B) The chemical is known to cause or can reasonably be anticipated to cause in humans—
>
> > (i) cancer or teratogenic effects, or
> >
> > (ii) serious or irreversible—
> >
> > > (I) reproductive dysfunctions,
> > >
> > > (II) neurological disorders,
> > >
> > > (III) heritable genetic mutations, or
> > >
> > > (IV) other chronic health effects.
>
> (C) The chemical is known to cause or can reasonably be anticipated to cause, because of—
>
> > (i) its toxicity,
> >
> > (ii) its toxicity and persistence in the environment, or
> >
> > (iii) its toxicity and tendency to bioaccumulate in the environment,
> >
> > a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

Id. EPA thus has a mandate from Congress to consider the types of toxicological studies that EPA's Proposed Rule would prevent the Agency from considering. For this reason, the Proposed Rule cannot withstand scrutiny.

vi. FIFRA

Not only does FIFRA not provide authority for the Proposed Rule, but it likewise contains provisions directly at odds with the purpose and effect of the Rule.

Under FIFRA, EPA must register a pesticide (with rare exceptions) before it may be sold or used in the United States. 7 U.S.C. § 136a(a). To register or re-register a pesticide, EPA must

determine that its use "will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(D); *see id.* § 136(bb) (definition of "unreasonable adverse effects"). FIFRA defines "unreasonable adverse effects" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id*. § 136(bb).

EPA requires a company seeking establishment or retention of a pesticide registration to submit data and information to enable EPA to make its unreasonable adverse effects determination. In addition to a standard set of data, EPA can issue data call-in notices requiring additional testing and information. Often, EPA requires the registrant to conduct particular laboratory tests to assess the pesticide's toxicity. As Nancy Beck noted during the drafting of the rule, pesticide regulations require manufacturers to submit to EPA "a huge amount of data," and that the studies come to EPA as Confidential Business Information ("CBI"). *See* Maria Hegstad, "Absent ORD Chief, Trump's Toxics Pick Expands Reach Across EPA Science," *Inside EPA* (May 10, 2018), https://insideepa.com/weekly-focus/absent-ord-chief-trumps-toxics-pick-expands-reach-across-epa-science. The raw data underlying the industry laboratory studies is rarely made available to the public, and the registrants would almost certainly oppose such disclosure on CBI grounds. Nor are such studies typically peer reviewed.

In addition, after a pesticide has been registered, the registrant must provide EPA all factual information regarding the pesticide's unreasonable adverse effects. 7 U.S.C. § 136d(a)(2). Such information comes in a variety of forms – from academic studies, poisoning incident reports, or studies conducted for other regulatory authorities at the state, federal, or international level. Often, the raw data are unavailable.

The Proposed Rule thus conflicts with FIFRA's pesticide registration requirements as it eliminates from consideration important studies used to show the unreasonable adverse effects of the pesticide toxins. As Beck herself acknowledged of an early version of the rule, the directive would "'jeopardize our entire pesticide registration/re-registration process.'" Maria Hegstad, "Absent ORD Chief, Trump's Toxics Pick Expands Reach Across EPA Science," *Inside EPA* (May 10, 2018). Accordingly, the Proposed Rule cannot stand.

vii. TSCA

EPA's proposed refusal to consider or use science relevant to decisions that will affect public health directly contravenes the newly enacted revisions to TSCA. Numerous provisions of TSCA make clear that EPA may not prohibit the consideration of non-public data in regulatory decision-making under TSCA. Indeed, when viewed as a whole, TSCA establishes a comprehensive scheme for how EPA is to evaluate and use science in making regulatory decisions that forecloses the Proposed Rule.

First, TSCA requires EPA to consider all "***reasonably available information***" when making any regulatory decisions under sections 2603, 2604, and 2605. 15 U.S.C. § 2625(k) (emphasis added) (EPA "shall take into consideration information relating to a chemical . . . that

is reasonably available to [the Agency]"); *also id.* § 2605(c)(2)(A).[74] Thus, the statute mandates that if a study is reasonably available to EPA, EPA must consider it when making a significant regulatory decision under these provisions of the statute. Whether the data underlying a scientific study is publicly available has no bearing on whether the study itself is reasonably available to EPA. Because the Proposed Rule purports to apply to all significant regulatory decisions made by EPA under TSCA – including those made under these provisions – it is unlawful.

Second, when making any regulatory decision under sections 2603, 2604, and 2605, TSCA requires EPA to make an individualized evaluation of any information reasonably available to the Agency, and thus, prohibits the blanket ban erected in the Proposed Rule. Section 2625(h) establishes five statutory factors that EPA must consider when "mak[ing] a decision based on science." 15 U.S.C. § 2625(h)(1)-(5). One of these statutory factors expressly addresses situations in which non-public scientific data is before the Agency, and requires the Agency to "consider . . . the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models." *Id.* § 2625(h)(5). In addition, EPA must consider whether the methodologies used to collect the data are "reasonable," *id.* § 2625(h)(1), and the "degree of clarity and completeness" with which the methods used were documented, *id.* § 2625(h)(3). In sum, Section 2625(h) requires EPA to review each scientific study on a case-by-case basis to determine whether and how to use it. This case-by-case evaluation requires EPA to consider the public or non-public nature of the underlying data as one of many factors and prohibits EPA from implementing a blanket ban on the use of non-public data in significant regulatory decisions under TSCA.

Third, the Proposed Rule is at odds with the requirement that EPA act "***consistent with the best available science***." *Id.* § 2625(h) (emphasis added). Although Congress did not define the term in TSCA, it is clear from other statutes that an agency cannot lawfully act consistent with the best available science when it categorically bars consideration of any science based on non-public data. For example, the Endangered Species Act requires federal agencies to consider the "best scientific and commercial data available," *see* 16 U.S.C. § 1536(a)(2), and courts have held that this provision requires an agency to consider "***all*** relevant data . . . even when it is imperfect, weak, and not necessarily dispositive." *League of Wilderness Defenders/Blue Mountains Biodiversity Project v. Connaughton*, 752 F.3d 755, 763-64 (9th Cir. 2014) (emphasis added); *see also Bldg. Indus. Ass'n of Superior Cal. v. Norton*, 247 F.3d 1241, 1246 (D.C. Cir. 2001) (an agency "must utilize the 'best scientific . . . data ***available***,' not the best scientific data ***possible***") (emphasis in original). EPA itself acknowledged that this sort of restriction on

[74] "In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on ***reasonably available information*** with respect to—(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture; (ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture; (iii) the benefits of the chemical substance or mixture for various uses; and (iv) the reasonably ascertainable economic consequences of the rule . . ." 15 U.S.C. § 2605(c)(2)(A) (emphasis added).

science is contrary to the requirements of TSCA; when analyzing the same restrictions proposed in the HONEST Act, EPA recognized:

> Provisions under the newly amended Toxic Substance Control Act (TSCA) . . . would be significantly impacted by the HONEST Act. First, a number of provisions in section 26 could not be upheld under the HONEST Act. Section 26(h) requires the Agency to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with best available science." . . . ***[T]he HONEST Act would not allow EPA to use the best available science***. ***Section 26(i) requires the Agency to use the "weight of scientific evidence" in making decisions under TSCA, and EPA believes this would not be possible given that the provisions of the HONEST Act would prohibit the use of some data***. Finally, section 26(k) requires the Agency to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonable available." EPA would be in violation of the HONEST Act when upholding these provisions under TSCA, namely ***instead of using the best available science and all reasonable available data for chemical regulations, EPA would be restricted to selecting information based on availability***. This approach would introduce research bias that would compromise the quality of the Agency's work.

EPA, EPA Analysis of HONEST Act to CBO at 3-4 (2016), https://www.scribd.com/document/344731162/EPA-analysis-of-Honest-Act-to-CBO (emphasis added).

Indeed, where Congress has sought to qualify a best available science requirement by implementing a total bar on particular types of science, it has done so expressly. For example, in the Consumer Productive Safety Improvement Act of 2008, Congress directed a panel studying phthalates to use "the most recent, best-available, ***peer-reviewed***, scientific studies." 15 U.S.C. § 2057c(b)(2)(B) (emphasis added). The absence of any such prohibition in TSCA is further proof that the Proposed Rule is prohibited by the statute's best-available-science requirement.

Fourth, the Proposed Rule is inconsistent with the TSCA requirement that EPA make regulatory decisions using a "weight of the scientific evidence" approach. *Id.* § 2625(i). As EPA has itself recognized, this approach requires the Agency to individually evaluate the strengths and weakness of any study reasonably available to the Agency. 40 C.F.R. § 702.33 (defining "weight of scientific evidence" as "comprehensively, objectively, transparently, and consistently, identify[ing] and evaluat[ing] ***each stream of evidence***, including strengths, limitations, and relevance of ***each study*** and [] integrat[ing] evidence as necessary and appropriate based upon strengths, limitations, and relevance" for purposes of risk evaluations under 15 U.S.C. § 2605 (emphasis added)). Thus, the Proposed Rule's outright ban on

consideration of scientific studies that rely on non-public data is prohibited by the weight of the scientific evidence approach required under TSCA.

In sum, these provisions – considered together and in light of other provisions of the statute – establish a comprehensive scheme for how EPA is to consider scientific data, and this scheme prohibits the Proposed Rule's ban on the consideration of non-public data. Together, they require EPA to: consider ***all*** reasonably available scientific information; evaluate each piece of information, including the methods by which it was acquired and analyzed; use each piece of information in a manner consistent with the best available science; and give each piece of information its due weight.

In addition, in deciding whether or not "there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings," EPA must consider "any . . . information available to the Administrator." 15 U.S.C. § 2603(f). And other provisions of TSCA expressly address certain types of non-public data and authorize EPA to consider it in making regulatory decisions. *See* 15 U.S.C. §§ 2604(b), 2613.

In light of the numerous provisions of TSCA addressing the consideration of scientific data, it is evident that if Congress had intended to allow EPA to bar the consideration of non-public data, it surely would have said so expressly. Given the comprehensiveness of these provisions providing otherwise, there is simply no room for a blanket ban on science that relies on non-public data. The Proposed Rule is therefore unlawful.

viii. RCRA

Not only do the provisions of RCRA upon which EPA relies not provide the requisite statutory authority, but other provisions of RCRA render the Proposed Rule unlawful. Specifically, section 8001 of RCRA provides that the Administrator shall conduct or otherwise assist in research, investigations, experiments, and other studies without limitation on what studies or data can be considered. 42 U.S.C. § 6981. The law mandates a broad and inclusionary role for science, requiring EPA to consider studies without limitation. The Proposed Rule's elimination from consideration of entire categories of scientific data conflicts with the requirements of this section of RCRA, and thus cannot stand. *See Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597 (2013).

B. The Limitations on Science Also Contradict Other Environmental Statutes.

Not only does the Proposed Rule contravene the statutes upon which EPA relies as statutory authority, but its limitations on science likewise conflict with core provisions of other environmental statutes. For example, the Food Quality Protection Act ("FQPA"), which regulates pesticide residue in conjunction with FIFRA, sets safety standards based on the consideration of ***all available data***. Limiting the data available to conduct studies necessary to evaluate the harmful effects of pesticides runs counter to this mandate.

Specifically, Congress overhauled our food safety laws when it unanimously passed the FQPA, amending both the Federal Food, Drug, and Cosmetics Act ("FFDCA")[75] and FIFRA. The overhaul responded to a seminal 1993 National Academy of Sciences ("NAS") report criticizing EPA for treating children like "little adults" by failing to address the unique susceptibility of children to pesticide exposures based on the foods they eat, their play, metabolism, and sensitive stages of their development. NAS, *Pesticides in the Diets of Infants and Children* (1993). The NAS recommended that EPA revamp and strengthen its pesticide regulations to account for children's vulnerabilities, consumption patterns, and exposures. Because it would take time to fill gaps in knowledge, safeguards and methodologies, the NAS recommended that additional protection be afforded in the form of "uncertainty" or "safety factors." The NAS first described how EPA has regularly used uncertainty factors and then proposed an additional uncertainty factor for fetal developmental toxicity and where data are incomplete: "In the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children. To validate this presumption, the sensitivity of mature and immature individuals should be studied systematically to expand the current limited data base on relative sensitivity." *Id*.

The FQPA strengthened the food safety standard in several ways. ***First***, under the FQPA, the EPA Administrator "may establish or leave in effect a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe." 21 U.S.C. § 346a(b)(2)(A)(i). In other words, the absence of sufficient information to find a pesticide safe means it cannot be allowed in or on our food.

Second, safe "means the Administrator has determined there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id*. § 346a(b)(2)(A)(ii). The FQPA, therefore, requires that EPA conduct an assessment based on aggregation of all exposures to a pesticide whether from eating foods, drinking water with residues of the pesticide, or uses of the pesticide in and around the home or other places where people can be exposed. 21 U.S.C. § 346a(b)(2)(A)(ii), (C)(i)(I) & (ii). The FQPA also requires EPA to assess and protect against unsafe risks posed by cumulative exposures to pesticides that share a "common mechanism of toxicity," as is the case with pesticides in the organophosphate, carbamate, and pyrethroid families. *See* 21 U.S.C. § 346a(b)(2)(C)-(D).

Third, EPA must make specific safety determinations for infants and children. *Id*. § 346a(b)(2)(C)(ii)(I) & (II). It must consider available information concerning "the special susceptibility of infants and children," including "neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." *Id*.

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[75] Under the FFDCA, EPA must establish the maximum residue of a pesticide allowed on food, called a "tolerance," in order for a pesticide to be permitted on food that is imported or sold in interstate commerce. 21 U.S.C. § 346a(b) & (c). EPA may "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe." *Id*. § 346a(b)(2)(A)(i). If it finds a pesticide residue would not be safe, EPA must revoke a tolerance. *Id*.

§ 346a(b)(2)(C)(i)(II). EPA must also base its tolerance decisions on available information about food "consumption patterns among infants and children." *Id*. § 346a(b)(2)(C)(i)(I) & (III).

Fourth, EPA must account for children's sensitivities, scientific uncertainty, and gaps in available data. The statute requires that "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre -and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." *Id*. § 346a(b)(2)(C). EPA can depart from this requirement and use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id*.; *see Nw. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1046 (9th Cir. 2008) (reversing EPA's shrinkage of the safety factor in the absence of supporting data).

As an over-arching mandate, the FQPA directs EPA to make its tolerance determinations based on its assessment of the pesticide's risk. 21 U.S.C. § 346a(b)(2)(C)(i). And throughout its mandates to assess the full effects of a pesticide, the FQPA directs EPA to base its risk assessment on "available information" about consumption patterns, special susceptibility of infants and children, and cumulative effects. *Id*. The FQPA also expressly directs EPA to consider the validity, completeness, and reliability of the available data from studies, the nature of the toxic effect, available information about the relationship between study results and human risk, and available information about aggregate and cumulative effects. *Id*. § 346a(b)(2)(C)(ii).

The Proposed Rule upends these mandates by requiring EPA to put on blinders and ignore a huge and important subset of the available data. It collides squarely with the congressional direction to consider all available data and information in order to protect our food and children in particular. It also conflicts with the congressional mandate to afford greater protection to children and our food when gaps in data prevent a full quantitative assessment and establishment of a dose-response. It thus undermines EPA's ability to carry out its obligations under the FQPA.[76]

C. Administrative Statutes Prohibit the Proposed Prohibitions.

EPA's Proposed Rule likewise ignores requirements set forth in two administrative statutes that govern its rulemaking: the Regulatory Flexibility Act and the Data Quality Act. Under the Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq*., federal agencies must consider the impacts their regulations will have on small entities and must consider less burdensome alternatives. In developing a new regulation, an agency must take one of two actions: certify that a proposed rule will not have a significant economic impact on a substantial number of small

[76] The FQPA also amended FIFRA's "unreasonable adverse effects" definition to include "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FQPA] standard." 7 U.S.C. § 136(bb)(2). Accordingly, EPA can register or re-register a pesticide only if there is a reasonable certainty of no harm from aggregate and cumulative exposures to the pesticide under the FQPA standard. The FQPA's science standards therefore extend to EPA's FIFRA determinations. Accordingly, just as the Proposed Rule runs afoul of the FQPA's standards, so too does it violate FIFRA's mandates, as amended by the FQPA.

entities, or prepare an initial regulatory flexibility analysis. EPA must publish its initial regulatory flexibility analysis or a summary of it in the Federal Register along with the proposed rule. Here, EPA includes a certification with the Proposed Rule stating that it will not have a significant economic impact on a substantial number of small entities. However, it provides no support for this certification.

Pursuant to the Data Quality Act, also known as the Information Quality Act, Treasury and General Government Appropriation Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515 Appendix C, 114 Stat. 2763A-153 (2000), the Office of Management and Budget ("OMB") issued government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies. . . ." The OMB guidelines directed each federal agency to issue its own information quality guidelines to "ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency." 67 Fed. Reg. 8451, 8459 (Feb. 22, 2002). Following OMB's instructions, EPA issued its own guidelines that apply to information it disseminates to the public. EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, or Information Disseminated by the Environmental Protection Agency* (Oct. 2002), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf. According to these guidelines, EPA uses a "weight-of-evidence" approach that "considers ***all relevant information*** and its quality, consistent with the level of effort and complexity of detail appropriate to a particular risk assessment." EPA Guidelines 6.4 (emphasis added). The Proposed Rule contravenes these requirements, as it will prevent EPA from considering all relevant information by precluding consideration of certain data.

Moreover, pursuant to EPA's guidelines, EPA must ensure that the information it disseminates "is accurate, reliable and unbiased." EPA Guidelines 6.4(A). To do so, it uses:

> ***the best available science and supporting studies*** conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).

Id. (emphasis added). Given that the Proposed Rule eliminates from consideration any scientific study where the underlying data cannot be made publicly available, it undoubtedly precludes the use of the best available science in certain situations. Thus, the Proposed Rule is inconsistent with EPA's implementation of the Data Quality Act.

D. The Proposed Rule is Entirely Inconsistent with the Executive Orders Upon Which EPA Relies for Support.

EPA also cites to a number of Executive Orders as support for the Proposed Rule. However, upon examination, it is eminently clear that these orders are wholly inconsistent with the intent and effect of the Proposed Rule. Regardless, Executive Orders cannot lawfully or

constitutionally substitute for statutorily granted authority or contradict statutory requirements; thus, the Executive Orders provide no support or authority for the Proposed Rule.

i. Exec. Order No. 13,777, 82 Fed. Reg. 12,285

EPA asserts that the Proposed Rule is consistent with Executive Order 13,777, 82 Fed. Reg. 12,285 (Mar. 1, 2017), titled "Enforcing the Regulatory Reform Agenda." It is not. This Executive Order establishes a task force to "evaluate existing regulations . . . and make recommendations to the agency head regarding their repeal, replacement, or modification." It thus seeks to ***reduce*** regulation, and in no way authorizes EPA to promulgate new rules.[77]

Additionally, the Proposed Rule is contrary to the stated purpose and policy of Executive Order 13,777, which is to "lower regulatory burdens on the American people by implementing and enforcing regulatory reform." The Proposed Rule will do just the opposite. It will preclude EPA from considering certain data regarding health and environmental impacts of pollutants, contaminants, and other substances in its rulemaking process. The overall impact of such limitations on rulemaking aimed at protecting public health and the environment will be increased burdens on the American people.

ii. Exec. Order No. 13,783, 82 Fed. Reg. 16,093

EPA also asserts that the Proposed Rule is consistent with Executive Order 13,783, 82 Fed. Reg. 16,093 (Mar. 31, 2017), titled "Promoting Energy Independence and Economic Growth." Yet again, EPA is wrong.

In an effort to show the Proposed Rule's consistency with this Executive Order, EPA quotes the following part of the Order: "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics." 83 Fed. Reg. at 18,769, n.5. However, as these Comments reveal, the Proposed Rule contravenes this policy in a number of ways: it fails to comply with a number of statutes and executive orders; the costs of the rule far outweigh the benefits; it will cause substantial and far-reaching harm to public health and the environment; and it has been developed through a process that lacks transparency. *See* Sections II, III, IV, V. Moreover, if implemented, the Proposed Rule will lead to future rulemakings that likewise will be inconsistent with this Executive Order, as it will preclude EPA from considering the best available peer-reviewed science and economics, which in turn will impact the cost-benefit analysis, and may violate notice-and-comment and judicial review procedures. *See* Section V.A. Thus, the Proposed Rule is entirely ***inconsistent*** with Executive Order 13,783.

[77] That EPA would say that the Proposed Rule is consistent with an Executive Order focused on deregulation is tantamount to an admission that the Rule's purpose and effect is to limit the development of rules that are critical to the protection of public health and the environment.

Executive Order 13,783 also provides that greenhouse gas impact estimates should be consistent with guidance in OMB Circular A-4 (Sept. 17, 2003), which specifically requires that this analysis be based on "the best reasonably obtainable scientific, technical, and economic information available." Though the Circular states that, where available, peer-reviewed, transparent, and reproducible studies should be used, it neither requires nor authorizes the preclusion of consideration of scientific studies based on data that cannot be made publically available. Instead, it recognizes that there will be circumstances "[w]here other compelling interests (such as privacy, intellectual property, trade secrets, etc.) prevent the public release of data or key elements of the analysis," and provides in those cases that, rather than precluding the data, the use of "especially rigorous robustness checks to analytic results" should be applied and documented. Accordingly, for this reason too, the Proposed Rule is inconsistent with Executive Order 13,783.

iii. Exec. Order No. 13,563, 76 Fed. Reg. 3821

Executive Order 13,563 states that "[o]ur regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. ***It must be based on the best available science***. . .." 76 Fed. Reg. 3821, 3821 (Jan. 18, 2011) (emphasis added). EPA's reliance on this Executive Order cannot be taken seriously.

While EPA states in the preamble that "[t]he best available science must serve as the foundation of EPA's regulatory actions," 83 Fed. Reg. at 18,769 & n.1, the Proposed Rule undermines this foundational requirement. It has the purpose and effect of precluding the use of some of the best available science, that is, all science based on non-public data, simply because the underlying data is not publicly available. Best available science means "all existing scientific evidence relevant to the decision," and agencies simply "cannot ignore existing data." *Ecology Ctr., Inc. v. U.S. Forest Serv.*, 451 F.3d 1183, 1194 n.4 (10th Cir. 2006) (quoting *Heartwood Inc. v. U.S. Forest Serv.*, 380 F.3d 428, 436 (8th Cir. 2004)). Yet the Proposed Rule requires EPA to ignore existing data if it is not available for public release. Therefore, the Proposed Rule is inconsistent with Executive Order 13,563, as well as those statutes or principles that requires EPA to consider the best available science. *See* Section IV.

iv. No Executive Order Can Authorize or Contradict Enacted Statutory Restrictions on EPA's Authority.

EPA cannot lawfully or rationally rely on an executive order to authorize the Proposed Rule, and cannot allow any cited order to influence development of the final rule. As detailed in other parts of these comments, the Clean Air Act and other statutes provide specific requirements for rulemakings with which EPA's Proposal conflicts, and which do not authorize this Proposal.

An executive order cannot override a statute, limit the delegated authority and the legal responsibilities provided to the EPA Administrator by federal law, add factors that are impermissible under the statute, or delay statutorily required agency action. *See, e.g., In re: United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 551 (D.C. Cir. 1999). In addition,

weakening or delaying public health protections based on an executive order would be unconstitutional, violating separation of powers and the requirement to follow duly enacted laws passed by Congress and signed by the President. It would likewise be unlawful, contrary to the public health obligations and rulemaking requirements of EPA's governing statutes. And EPA cannot consider or apply any other executive order in any way in this rulemaking without providing the requisite public notice and opportunity for comment that the Clean Air Act and APA require, as further discussed elsewhere in these comments.[78]

E. The Proposed Rule Violates Public Law 95-622 and the Common Rule for Research Involving Human Subjects.

EPA's Proposed Rule also conflicts with Public Law 95-622 and the interagency regulations on testing of human subjects required by that law. In 1978, Congress created a President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (the "Commission") and directed the Commission to study the "protection of human subjects," defined to include the "health, safety, and ***privacy*** of individuals." 42 U.S.C. § 300v–1(b)(2), (f)(2) (emphasis added). This included a study of and issuance of recommendations concerning, among other subjects, procedures and mechanisms "to safeguard the ***privacy*** of human subjects of behavioral and biomedical research, [and] to ensure the ***confidentiality*** of individually identifiable patient records." *Id*. § 300v–1(a)(1)(E), (a)(4) (emphasis added).

In response to this charge, in 1981, the Commission recommended that all federal agencies adopt uniform regulations concerning the protection of human research subjects. *See* 47 Fed. Reg. 13,272 (March 29, 1982). Accordingly, in 1991, EPA and 13 other federal departments and agencies adopted uniform regulations on this issue (the "Common Rule"), *see* 56 Fed. Reg. 28,003 (June 18, 1991), requiring that all research involving human subjects that is "conducted, supported or otherwise subject to regulation by any Federal department or agency" be reviewed and approved by an institutional review board ("IRB"). 40 C.F.R. § 26.101(a). In order to approve research involving human subjects, an IRB must ensure that "there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." *Id*. § 26.111(a)(7).

In particular, the Common Rule prohibits EPA from relying on research that is "deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm . . . or impaired their informed consent." *Id*. §§ 26.1704(b)(2), 26.1705(b). It recognizes that the protection of private information of the subject is central to a subject's ability to provide informed consent. *See generally id*. § 26.116. And the protection of private information is central to the Common Rule more broadly – one of only two situations under which IRBs may waive the requirement to obtain written consent is if the release of the consent form risks linking the subject to the research. *Id*. § 26.117(c)(1).

EPA's Proposed Rule is thus antithetical to the confidentiality requirements of the Common Rule. It would ignore relevant health science absent publication of personal data that is

[78] *See, e.g.*, 42 U.S.C. § 7607(d)(3)-(7), (h).

required to be kept confidential under the Common Rule. To enable EPA to consider their studies in a relevant rulemaking, IRBs would have to make the underlying data publicly available, which would place them at risk of termination of federal funding, termination of ongoing studies, denial of approval for new studies, or disqualification of the IRB or its parent institution. 40 C.F.R. Part 26 subpart O & §§ 26.103, 26.123, 26.1123.

V. EPA FAILED TO FOLLOW PROPER PROCEDURES

A. EPA Failed to Follow the Administrative Procedure Act as Required for Meaningful Public Participation and Judicial Review.

The Administrative Procedure Act ("APA") establishes rulemaking procedures and judicial review requirements for agency rules that EPA has failed to follow here. 5 U.S.C. §§ 553, 706. These requirements – which EPA entirely and unlawfully ignores – are central both to ensure an opportunity for the affected public to comment, and to ensure an adequate record for judicial review. This includes:

- Providing a meaningful opportunity for notice-and-comment;
- Ensuring that the docket contains all documents on which EPA relies;
- Providing additional information regarding what the public is being asked to comment on, and adding details that are missing from the proposal, before taking further comment.

EPA has failed to comply with these mandates, rendering this rulemaking unlawful under the APA, for several reasons.

First, in issuing this Proposed Rule, EPA violated the APA by failing to place in the administrative record all of the documents on which it purports to rely. The preamble to the Proposed Rule cites more than thirty specific documents on which EPA purportedly relies. *See, e.g.*, 83 Fed. Reg. at 18,769-72 & nn.1-2, 4-24. Of the specifically cited and relied upon documents, only about 12 are included in the docket, available at www.regulations.gov, Docket ID: EPA-HQ-OA-2018-0259, as of the date of publication of the Proposed Rule. In addition, EPA provides no support for its proposed conclusion that "EPA believes the benefits of this proposed rule justify the costs." 83 Fed. Reg. at 18,772. Nothing in the record demonstrates what costs or benefits EPA considered to reach this determination, or whether it evaluated at all the harm to public health and to privacy that this Proposed Rule would cause.

Absent the ability to review such documents, the public is deprived of adequate notice or an ability to provide informed comments regarding the Proposal and EPA's rationale for issuing the Proposed Rule. EPA's failure to put the documents on which it relies into the record violates notice-and-comment under the APA and other statutes that supplement such notice requirements. *See, e.g.*, *Am. Radio Relay League v. FCC*, 524 F.3d 227 (D.C. Cir. 2008) (agency may not cherry-pick documents on which it relies for public review; it is a violation of public notice and comment to refuse to put the documents in full on which the agency relied into the record).

Second, failing to place all of the documents on which EPA relies into the record also violates the judicial review provision of the APA by making it impossible for commenters to provide adequate comments or a complete record for judicial review of any final action EPA takes. 5 U.S.C. § 706 ("In making the foregoing determinations, the court shall ***review the whole record*** or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error." (emphasis added)); *Am. Radio Relay League*, 524 F.3d at 242-43 (Tatel, J., concurring) (reiterating importance of the requirement for agency to place unredacted studies into the docket because not doing so "undermines this court's ability to perform the review function APA section 706 demands"); *see also Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971)) ("[R]eview is to be based on the ***full*** administrative record that was before the Secretary ***at the time*** he made his decision." (emphasis in original)).

Not only is EPA's failure to include in the regulatory docket all of the documents upon which it relies a violation of the APA, but it likewise contravenes procedural requirements in Title 28 of the U.S. Code that govern judicial review of agency action. *See, e.g.*, 28 U.S.C. § 2112(b) ("The record to be filed in the court of appeals . . . shall consist of the order sought to be reviewed or enforced, ***the findings or report upon which it is based***, and the pleadings***, evidence***, and proceedings before the agency . . . concerned." (emphasis added)); Fed. R. App. P. 16 ("The record on review or enforcement of an agency order consists of . . . ***any*** findings or report on which it is based." (emphasis added)); *see also* 28 U.S.C. §§ 2071-77 (providing federal courts with authority to establish binding rules of procedure and evidence). Thus, EPA's slipshod creation of the regulatory docket for the Proposed Rule cannot withstand scrutiny under either the APA or the judicial review provisions for Title 28.

Third, EPA has violated the APA (and all statutes that track its notice-and-comment requirements) by failing to provide sufficient specificity regarding the Proposed Rule. Under the APA, notice is only sufficient "'if it affords interested parties a reasonable opportunity to participate in the rulemaking process,' and if the parties have not been 'deprived of the opportunity to present relevant information by lack of notice that the issue was there.'" *WJG Tel. Co., Inc. v. FCC*, 675 F.2d 386, 389 (D.C. Cir. 1982) (citations omitted); *see Fla. Power & Light Co. v. Nuclear Regulatory Comm'n*, 846 F.2d 765, 771 (D.C. Cir. 1988). The Proposed Rule is plagued by a lack of detail as to how EPA will interpret the broad and vague terms it creates, how it will use the Rule in connection with particular rulemakings, and how it will implement the new "independent peer review" and "exemption" provisions, and these shortcomings undermine the sufficiency of the notice provided by the Proposal. For example:

- The new definitions of "dose response data and models," "pivotal regulatory science," "regulatory decisions," "regulatory science," and "research data," in § 30.2 are extremely broad and impermissibly vague. EPA provides no specific examples of what these terms mean or how they will actually be implemented under the long list of statutes implicated by this rule.

- Sections 30.1, 30.2, 30.3 – discussing the purpose of the Proposed Rule, the applicable definitions, and how the Proposed Rule will apply – provide broad requirements for EPA without giving any information regarding how or when EPA will implement them in connection with any given proposed or final rule.

- EPA states in § 30.5 that the Proposal will require EPA to "ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation . . ." Yet EPA provides no indication of what this means, how it will so "ensure," or what it will do if it is not possible to ensure this, among other shortcomings.

- Section 30.6 addresses the "additional requirements" related to the use of dose response data and models underlying "pivotal regulatory science," but it is devoid of details necessary to assure meaningful public review and comment on how, when, or in what way EPA will implement this. It also cites no specific science and gives no indication of how or why EPA is attempting to redefine scientific information on dose response differently than it has done in the past to allow for informed consideration of why EPA is even attempting to address this issue.

- Sections 30.7 and 30.9 describe the "role" of "independent peer review" in the Proposal and permissible "exemptions" under the Rule, yet these descriptions fail to provide the process that will be used to inform the public of when a given document or study impacted by this rule does or does not qualify for an exemption. There is no indication of whether EPA will provide notice or comment, or any steps allowing for public participation, when deciding whether or not to exclude a given study from consideration.

- The preamble to the Proposed Rule is replete with broad (and unsubstantiated) statements regarding limits on EPA's ability to consider and use science in rulemakings, as well as environmental issues EPA envisions being impacted by the Proposed Rule – for example, the NAAQs – but EPA fails to provide any specific information to inform public notice and comment on the purported impact of Proposed Rule. Commenters have done their best in view of this to provide comment on all of the likely harm that EPA's vague and general statements would cause if fully implemented in regulatory language, but they are severely prejudiced due to EPA's refusal to provide specific notice as required by the APA.

In sum, EPA has failed to satisfy the requirements for specific public notice that can assure meaningful comment, falling far short of the fundamental threshold requirements for notice and comment. This shortcoming is fatal to its ability to finalize this Proposed Rule.

In addition, it is especially problematic that EPA's Proposal states that EPA will apply the Proposed Rule to "regulatory decisions" which it defines as "final regulations determined to be 'significant regulatory actions' by [OMB]." 83 Fed. Reg. at 18,773 (proposed § 30.2). Under

this definition, EPA can exclude and ignore science in future rulemakings without specifying where or how it will do so and without providing any public notice or comment in a future rulemaking that would be impacted by this Rule. EPA's attempt to limit the rulemaking process for undefined other rules in this manner is a violation of the APA for all of the reasons described above.

Finally, EPA's APA violations would cause significant harm to Commenters and the public if the Rule were finalized without correcting these problems. The inability to review and attempt to understand the documents on which EPA relies and thus to comment meaningfully and receive effective judicial review cause severe prejudice to the affected public. *See* 5 U.S.C. § 706(2). Even if EPA were to add documents to the docket at a later date, that would not cure this fatal flaw. Given the sweeping scope of this Proposed Rule – which would restrict the consideration and use of important health science in rulemakings which, in turn, would likely lead to a weakening of air, water, waste, chemical, pesticide and other protections – the failure to publish the documents for review for an adequate time period has undermined the public's ability to comment meaningfully, and impermissibly prevented the affected public from being able to seek and receive effective judicial review based on the record.

B. EPA Failed to Follow Procedural Requirements Under FIFRA.

EPA likewise failed to follow the specific procedures required by the Federal Insecticide, Fungicide, and Insecticide Act ("FIFRA") when issuing the Proposed Rule. Specifically, section 25w of FIFRA requires, among other things, that EPA provide a copy of any proposed rule or regulation to the Secretary of Agriculture for review and comment 60 days before a proposed rule is published in the Federal Register. 7 U.S.C. § 136w(a)(2)(A). EPA must then provide the Secretary a copy of the rule EPA intends to publish as a final rule no later than 30 days before publication. *Id*. § 136w(a)(2)(B). EPA must also consult with its own Scientific Advisory Panel in an effort to receive comments from it regarding the impact the proposed rule will have on health and the environment. *Id*. § 136w(d).[79] Such consultation must occur under the same timelines sets forth for consulting with the Secretary of Agriculture. *Id*. § 136w(d)(1). Lastly, before a final rule can take effect, EPA is required to submit the rule to Congress and "the rule or

[79] Indeed, FIFRA sets forth a specific role for its Scientific Advisory Panel, yet EPA entirely ignored them in this process:

> [t]he Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this subchapter. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections.

7 U.S.C. § 136w(d)(1).

regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted." *Id*. § 136w(a)(4).

Thus, FIFRA sets forth a clear process in which EPA must consult with a number of entities, including both the U.S. Department of Agriculture and a Scientific Advisory Panel when issuing rules impacting pesticides. *See, e.g.*, *Nat'l Coal. Against the Misuse of Pesticides v. EPA*, 867 F.2d 636 (D.C. Cir. 1989) (noting that "FIFRA generally requires the Administrator [of EPA] to consult with the Secretary of Agriculture . . . and a seven member Scientific Advisory Panel (on environmental health questions) prior to making public any notice of intent to cancel," in context of pesticide registration cancellation). Yet it is indisputable that EPA utterly failed to take these necessary steps. For this reason, too, EPA's Proposal cannot stand.

C. EPA Failed to Follow the Procedural Requirements Under TSCA.

Pursuant to section 2609 of TSCA, prior to promulgating any rules, EPA must "consult[] and cooperate[] with the Secretary of Health and Human Services and with other heads of appropriate departments and agencies." 15 U.S.C. § 2609(a); *see also id*. § 2609(b)(2)(A), (c), (d), (e), (g). Therefore, to the extent EPA relies on TSCA as authority for the Proposed Rule, it must consult and cooperate with the Secretary of Health and Human Services. Yet nowhere in the Proposed Rule does EPA indicate that it has done so. Failure to comply with this requirement would render any final rule unlawful. *See* 5 U.S.C. § 706(2)(D) (a reviewing court "shall . . . hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law").

D. EPA Failed to Follow the Procedural Requirements Under the CAA.

EPA's Proposal is also deficient because it fails to follow particular procedural requirements under the CAA that are legally required for EPA to issue certain types of rules. Specifically, the CAA requires that the Clean Air Scientific Advisory Committee ("CASAC") complete a review of air quality criteria and the NAAQS every five years. 42 U.S.C. § 7409(d)(2)(B). Because the Proposed Rule aims to "preclude [the Agency] from using [non-public] data in future regulatory actions," it would impact the CASAC's review of air quality criteria. 83 Fed. Reg. at 18,769, n.3. Accordingly, EPA was required to follow the path prescribed by the CAA – including submission of the proposed rule to CASAC for review, allowing CASAC to provide recommendations to the Administrator, and then requiring the Administrator to include a statement regarding the recommendations made by CASAC in the Proposed Rule. 42 U.S.C. §§ 7409(d)(2)(B), 7607(d)(3); *see also* 42 U.S.C. § 7607(b), (d). Yet, there can be no dispute that none of these steps were taken before issuance of the Proposed Rule.

E. EPA Failed to Perform the Analysis Required by EO 12,898.

EPA's Proposed Rule also violates the environmental justice requirements of Executive Order 12,898, 59 Fed. Reg. 7629 (Feb. 16, 1994). By its own admission, EPA entirely ignored its obligation to assess the environmental justice impact of this rule prior to issuing the Proposal, dismissively stating – without any justification – that "this action is not subject to Executive Order 12,898 (59 Fed. Reg. 7629, February 16, 1994) because it does not establish an

environmental health or safety standard." 83 Fed. Reg. at 18,773. EPA's rationale is inconsistent with the Order, contrary to EPA's own environmental justice plan, inconsistent with EPA's prior positions and practices, and results in the very harms the Order is designed to protect against.

First, by its own terms, and despite EPA's mischaracterization, Executive Order 12,898 applies to more than just "standards." Indeed, the Order applies to all agency "programs, policies, and activities." *See, e.g.*, 59 Fed. Reg. at 7629 (agencies must make "achieving environmental justice part of its mission by identifying and addressing as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations"). Toward that end, when promulgating rules "that substantially affect human health or the environment" – which this Proposed Rule indisputably does – EPA must ensure that the rule does not have a disproportionate impact on minorities, and it must "provide minority populations and low-income populations the opportunity to comment on the development and design of research strategies undertaken pursuant to this order." *Id*. at 7631. EPA's novel and unsupported interpretation is wholly untethered from both the spirit and the text of the Order.

Second, EPA's limiting interpretation ignores EPA's own environmental justice plan – promulgated pursuant to Executive Order 12,898 – the ultimate vision of which is for EPA to "integrate[] environmental justice into everything" it does. EJ2020 Action Agenda at iii. To accomplish this vision, EPA sets forth eight different priority areas, the first of which is "rulemaking." *Id*. Specifically, EPA aims to "institutionalize environmental justice in rulemaking," including performance of "rigorous assessments of environmental justice analyses in rules," in order to "deepen environmental justice practice within EPA programs to improve the health and environment of overburdened communities." *Id*. Recognizing that "[r]ulemaking is an important function used by the EPA to protect human health and the environment for all communities," EPA devotes the second chapter of the plan to "Rulemaking," and through this chapter, aims to "ensure environmental justice is appropriately analyzed, considered, and addressed in EPA rules with potential environmental justice concerns, to the extent practicable and supported by relevant information and law." *Id*. at 13. Consistent with its environmental justice plan and with Executive Order 12,898, EPA issued its own *Guidance on Considering Environmental Justice During the Development of Regulatory Actions*, recognizing how "vital" it is "that Agency rule-writers identify and address potentially disproportionate environmental and public health impacts experienced by minority populations, low-income populations, and/or indigenous peoples," *Guidance* at 1 (May 2015), https://www.epa.gov/sites/production/files/2015-06/documents/considering-ej-in-rulemaking-guide-final.pdf, as well as a *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis*. *Technical Guidance* (June 2016), https://www.epa.gov/sites/production/files/2016-06/documents/ejtg_5_6_16_v5.1.pdf. Thus, EPA has regularly and purposefully focused on the need for environmental justice assessments of its rulemakings. EPA's blithe claim that this Proposed Rule does not require an environmental justice assessment is clearly at odds with what the Agency itself recognizes it must do to comply both with Executive Order 12,898, as well as its own policies.

Third, EPA's failure to perform an environmental justice impact analysis is entirely inconsistent with EPA's regular practice. Indeed, EPA consistently performs this sort of assessment when acting under the CAA, CWA, and other statutes.[80] This information unquestionably has been relevant to public health rulemakings in the past. EPA's refusal to consider the environmental justice consequences of the Proposed Rule – consequences that are certainly "relevant" under *State Farm* – and its departure from its long-standing pattern and practice of considering such data without a reasoned explanation for changing course are therefore arbitrary and capricious.

Fourth, and as discussed more fully below, *see infra* Section VIII, EPA's Proposed Rule will result in the very kind of disproportionate impact on low-income and minority communities that the Executive Order was designed to protect against. As EPA itself recognizes, minority, low-income, and tribal communities "may face greater risks" to public health and the environment "because of proximity to a contaminated sites or because fewer resources are available to avoid exposure to pollution." *Envtl. Justice FY2017 Progress Report* at 8, https://www.epa.gov/sites/production/files/2018-04/documents/usepa_fy17_environmental_justice_progress_report.pdf. Examples include disproportionate exposure to lead, particulate matter, and other hazardous air pollutants. *See, e.g.*, *id.* at 8 ("reduction in lead exposure has not been realized equally across the United States and it remains a top childhood environmental health problem, disproportionately impacting minority and/or low-income populations"); *id.* at 9 ("[l]ow-income populations are among the populations that are most at-risk for adverse health effects from exposure to [particulate matter]"). Indeed, study after study has confirmed that communities of color and economically disadvantaged communities are disproportionately located near toxic waste and other sources of pollution, and that these communities disproportionately suffer adverse public health and environmental impacts.[81] It is also the case that these discrete communities are frequently the

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[80] *See, e.g.*, 78 Fed. Reg. 3086, 3267 (2013) (describing the goal of Executive Order 12,898 and EPA's actions to comply with these goals, noting that it "conducted an outreach and information call with environmental justice organizations" and "identified potential disproportionately high and adverse effects on minority and/or low-income populations related to PM2.5 exposures," and "identified persons from lower socioeconomic strata as an at-risk population for PM-related health effects," and noting that "the EPA has carefully evaluated the potential impacts on low-income and minority populations. . . ."); *see also* EC/R Inc., *Risk and Technology Review - Final Analysis of Socio-Economic Factors for Populations Living Near Secondary Lead Smelting Facilities*, prepared by EC/R Inc. for EPA (Dec. 2011), http://earthjustice.org/sites/default/files/Leadsmeltersocioeconomicanalysis.pdf; EC/R Inc., *Risk and Technology Review - Analysis of Socio-Economic Factors for Populations Living Near Petroleum Refineries*, prepared by EC/R Inc. for EPA (Jan. 2014).

[81] These studies include, but are not limited to: Mohai, P. et al., *Racial and Socioeconomic Disparities in Residential Proximity to Polluting Industrial;* Zwickl, K. et al., *Regional Variation in Environmental Inequality: Industrial air toxics exposure in U.S. Cities*, Political Economy Research Institute Working Paper Series No. 342 at 20 (Feb. 2014); Cal. EPA, OEHHA, *Cumulative Impacts: Building a Scientific Foundation* at 5-17 (Dec. 2010), http://oehha.ca.gov/media/downloads/calenviroscreen/report/cireport123110.pdf (citing numerous research studies showing that exposure to pollution-emitting facilities, hazardous waste facilities and disposal, toxic releases, non-attainment air areas, high motor vehicle air pollution areas, and other types

subjects of epidemiological studies that measure the health impacts of environmental and public health programs. Indeed, EPA previously recognized the importance of "strengthen[ing] the foundational link between EPA science and the needs of underserved and overburdened communities, in areas of air, water, land, health disparities, and in tribal science grants." *2017 Progress Report* at 6. Yet now, with no explanation or need, EPA does an about-face and attempts to destroy this link. EPA's Proposal to eliminate reliance on epidemiological health studies will thus have the effect of excluding critical and available evidence of adverse harms particular to these discrete groups, thereby removing from consideration the very science that has historically led to much-needed protections for the most vulnerable communities.

In sum, EPA was required under Executive Order 12,898 – as well as its own environmental justice plan and guidance – to conduct an assessment of the environmental justice impact of the Proposed Rule, but admittedly failed to so do. Its blatant (and acknowledged) failure to comply with its obligations is yet another reason why the Proposed Rule cannot stand.

VI. THE PROPOSED RULE IS ARBITRARY

Not only is EPA's Proposed Rule unlawful both substantively and procedurally, but it is also impermissibly arbitrary. Indeed, the Proposed Rule is the epitome of arbitrary rulemaking: in crafting the rule, EPA

> relie[s] on factors which Congress has not intended it to consider, entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

State Farm, 463 U.S. at 43 (defining "arbitrary and capricious" agency action). EPA wholly fails to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). To the contrary, as described below, EPA has mischaracterized its prior policy, relied on authorities that undermine its reasoning and conclusions, failed to adequately account for the Proposed Rule's costs and benefits, granted itself unfettered discretion to decide whether and how the Rule will apply, and created an unjustified inequity between what science can be used to support a decision *not* to

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of pollution is more likely to be concentrated in communities with higher minority and lower income populations); Boyce, J.K. et al., *Measuring environmental inequality*, Political Economy Research Institute Working Paper Series No. 409 at 14-16 (Dec. 2015); Hicken, M.T. et al., *A novel look at racial health disparities: the interaction between social disadvantage and environmental health*, 102:12 Am. J. of Pub. Health 2344, 2346-47 (Dec. 2012); Vipputuri, S. et al., *Blood lead level is associated with elevated blood pressure in blacks*, 41:3 Hypertension 463, 464-65 (Mar. 2003); deFur, P.L. et al., *Vulnerability as a Function of Individual and Group Resources in Cumulative Risk Assessment*, 115:5 Envtl. Health Persp. 817, 820-21 (2007).

regulate dangerous chemicals as compared to what can be used to support a decision to regulate. For all of these reasons, the Proposed Rule cannot stand.

A. The Proposed Rule Conflicts with Existing Government Policies and EPA's Prior Positions, and EPA Has Not Adequately Explained this Inconsistency.

Although each new administration has some authority to change course, changes "cannot be solely a matter of political winds and currents." *N.C. Growers Ass'n v. United Farm Workers*, 702 F.3d 755, 772 (4th Cir. 2012) (Wilkinson, J. concurring). Instead, an agency must at least "display awareness that it ***is*** changing position" and "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. at 515. If the new policy "rests upon factual findings that contradict those which underlay its prior policy[] or when [the] prior policy has engendered serious reliance interests that must be taken into account," the agency must provide "a reasoned explanation . . . for disregarding those facts and circumstances." *Id.* at 516; *see also Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) ("An unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." (internal quotation marks omitted) (quoting *Nat'l Cable & Tele. Commc'ns Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005))). Without "some fidelity to law and legal process, . . . government becomes a matter of the whim and caprice of the bureaucracy." *N.C. Growers Ass'n*, 702 F.3d at 772.

In stark contrast to these principles, EPA has done an about-face here, proposing a rule contrary to prior policy and based entirely on partisan politics and bureaucratic impulse. Though EPA asserts that the Rule "builds upon prior EPA actions in response to government wide data access and sharing policies," and corrects the Agency's failure to "consistently follow[] previous EPA policy (*e.g.*, EPA's Scientific Integrity Guidance . . .) that encouraged the use of non-proprietary data and models," 83 Fed. Reg. at 18,770, n.13, this is entirely untrue. Rather, as the prior policies and actions identified in the Proposed Rule demonstrate – and as summarized above (*see, e.g.*, Section IV.A (CAA)) – EPA has long been committed to sound science, including reliance on the best available science regardless of the nonpublic nature of the underlying data. For example, EPA's Scientific Integrity Policy states that the dissemination of scientific information should be "uncompromised by political and other interference" and expressly "[p]rohibits all EPA employees, including scientists, managers, and other Agency leadership, from suppressing, altering, or otherwise impeding the timely release of scientific findings or conclusions." EPA, *U.S. Environmental Protection Agency Scientific Integrity Policy* at 4–5 (Feb. 2012), https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf. The Proposed Rule clearly contravenes this policy.

The Proposed Rule is also inconsistent with EPA's Plan to Increase Access to Results of EPA-Funded Scientific Research. This Plan acknowledges that "[f]ederal agencies have a responsibility to protect confidentiality and personal privacy" and cautions that "some research data cannot be made fully available to the public but instead may need to be made available in more limited ways, e.g., establishing data use agreements with researchers that respect necessary

protections." EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* at 4 (Nov. 29, 2016), https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research. The Plan expressly concludes that "***[w]hether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications.***" *Id.* at 4–5 (emphasis added); *see also* OMB, 67 Fed. Reg., 8452, 8456 (Feb. 22, 2002) (explaining that "the reproducibility standard does not apply to all original and supporting data disseminated by agencies" and, in any case, "[e]ven in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard"). EPA's Proposal to exclude reliable science based solely on consideration of whether the underlying data is fully available to the public is a complete reversal in position from its own prior Plan, with no legitimate explanation for the change.

Equally problematic, the Proposed Rule is entirely inconsistent with prior positions EPA has taken on this very issue. Most notably, in March 2017 – just one year before issuance of this Proposed Rule – EPA responded to questions from Congress on the proposed HONEST Act of 2017, and took a position that is squarely at odds with the Proposed Rule. *See* EPA, *CBO Questions for EPA Regarding H.R. xxxx, The HONEST Act of 2017* at 1 (2017), https://www.scribd.com/document/344731162/EPA-analysis-of-Honest-Act-to-CBO ("HONEST Act Q&A"). For example, in noting its opposition to the HONEST Act, EPA stated:

> EPA supports access to data and is already on a path to make data public and transparent. EPA will do this at no additional cost to the taxpayer. EPA will do this while protecting [Personally Identifiable Information] and CBI. EPA will do this while preserving its ability to use the best available science. And EPA will do this while retaining its ability to respond quickly to emergency events. EPA strongly opposes the HONEST Act because it does none of these things and ***will significantly impede EPA's ability to protect the health and the environment of Americans***.

Id. at 4 (emphasis added). The Agency further explained that:

> The HONEST Act would not protect [Personally Identifiable Information] and CBI, and this would strongly discourage industry and academia from working with EPA. Many scientists, including those from the private sector, would not be willing to provide their data because EPA could not guarantee to protect their information, such as their trade secrets, intellectual property, or their study participants' medical records. Scientific research is a competitive field, and it is likely that not all investigators from the private sector, or academia, will be willing to make their underlying data available – at least not immediately. ***In some instances, EPA might be***

> ***precluded from using the best available science if the underlying data is not made available or is embargoed for a period of time***. Therefore, in accordance with the HONEST Act, EPA could not use these studies to help protect health and the environment. ***This would impede EPA's ability to use the best available science, because it is presumptively not the best available science if you cannot access all the science.***

Id. at 2-3 (emphasis added). It further explained that limiting science in the way proposed by the HONEST Act – and thus as proposed in the Proposed Rule –

> would mean that ***EPA would be unable to develop policies, guidance or regulations using the best available science***. Instead of using the best-available research for their assessments, EPA would be restricted to selecting studies based on their data availability. This approach would introduce potential research bias that could compromise the quality of the agency's work.

Id. at 4-5 (emphasis added). EPA recognized that the HONEST Act would restrict the use of reliable science, noting that the proposed legislation

> ***would certainly limit access to the majority of studies currently in the peer reviewed literature***. It's not just the number of studies but the type of studies and the integration of the results of these different types of studies with that inform the underlying scientific basis of EPA's decisions. The most informative studies include large comprehensive datasets, such as epidemiology studies, and animal toxicology studies from the open scientific literature, generally do not have all necessary information available on publication. With no new resources, the number of studies that EPA would be able to draw from would be greatly reduced ***– EPA roughly estimates it could be reduced by approximately 95% given the stated data-availability requirements and processes in this bill.*** And for industry-sponsored data submitted for pesticide registration, little to no data may be publicly available prior to a new registration . . ..
>
> Few peer-reviewed studies published in scientific journals meet the requirements described in this bill. Therefore, EPA roughly estimates that less than perhaps 5% would have all of the information publicly available to independently confirm the study details as required under this bill.

Id. at 6 (emphasis added).

EPA's current stance on the category of health studies it now seeks to ban is likewise an about-face from the position it took in 2011 in response to a request by CropLife America for

EPA to establish "firm criteria for quality assessment of epidemiological studies to be used in risk assessment." In response to CropLife America's effort – which, like EPA's Proposed Rule, was allegedly aimed at increasing transparency in the rulemaking process – EPA emphasized its view that mandating requirements around science would stifle scientific development and would be antithetical to the need to weigh various considerations when resolving science questions.[82] Specifically, EPA stated:

> EPA's general practice is to address issues through non-binding guidance documents rather than by mandatory regulations. There are several reasons for this approach. First, and probably most important, ***science questions usually cannot be reduced to a rigid decisional framework; rather science questions invariably involve the weighing of multiple considerations and the use of scientific judgment.*** As the SAP report on EPA's Draft Framework noted in its recommendations on criteria to be used in EPA decision-making: "Inevitably, it will be necessary to exercise some degree of scientific judgment in this assessment." Second, encasing science decision-making in a rigid rule structure is inconsistent with the fluid and developing nature of science. Thus, ***EPA is concerned that writing science decision-making rules will stultify or freeze the science underlying the rule making scientific advances less likely***. Finally, the nature of science issues is not easily compatible with the timeframes associated with formal rulemaking. Given the extended time often required to promulgate or amend a rule, the science underlying science-based criteria may well have significantly advanced between the time of the proposal and the time of the final rule. EPA may then be forced into restarting the rulemaking process or may end up being locked into outdated science decision-making until a rule can be amended. There are numerous examples of EPA appropriately addressing important science questions through guidance, not rules, at both the Agency and the program-specific (pesticide) level.
>
> [CropLife America] has offered no compelling reason to follow a different course with regard to epidemiological data. Epidemiological data are no more "important" to pesticide risk assessments than many other data or inputs or science-related issues. . . . [T]here are many ways to insure a transparent process for science decision-making guidelines other than through rulemaking. Finally, ***there is nothing unique about***

[82] Letter from Steven P. Bradbury, Director, Office of Pesticide Programs, EPA, to Dr. Wendelyn Jones, CropLife America, *re: Petition for Rulemaking To Establish Criteria For Acceptance Of Epidemiological Evidence Into the Pesticide Risk Assessment Process for Human Health Effects* at 2 (April 15, 2011) (attached).

> ***epidemiological data that would indicate that EPA could not craft non-binding guidelines for incorporating epidemiological data in risk assessments***, including non-binding guidance on specific criteria to be considered in weighing the value of particular epidemiological data.
>
> EPA agrees that transparency is a critical part of its science decision making. Our decisions on important policies and guidance documents always follow a transparent process with numerous opportunities for public comment.[83]

And as discussed *supra*, Section IV.A, EPA's position contradicts the stance it took when setting the Particulate Matter NAAQS in 1997, where it noted that "[i]t would be impractical and unnecessary for EPA to review underlying data for every study upon which it relies as support for every proposed rule or standard." 62 Fed. Reg. 38,652, 38,689 (July 18, 1997). EPA now ignores what it acknowledged before, namely that "[i]f EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, ***then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment***." *Id*. (emphasis added).

In the current rulemaking, EPA seems to have conveniently forgotten these prior inconsistent positions. Instead, EPA implausibly characterizes the Proposed Rule as a mere extension of existing policies, ignores its prior positions on landmark scientific studies, and contradicts its approach to considering science in the rulemaking process. EPA fails to demonstrate any awareness that it is dramatically changing course with respect to the use and consideration of scientific information, and fails to provide an adequate reason for the change. The Proposed Rule is arbitrary and capricious as a result.

B. The Proposed Rule is Based on Irrational, Unsupported Conclusions.

Not only is the Proposed Rule a drastic departure from EPA's prior policies, positions, and procedures, but it likewise is predicated on irrational and unsupported conclusions. Indeed, a close examination of generally applicable data access policies and guidelines – including policies and recommendations of third party organizations and major scientific journals upon which EPA allegedly relies – reveals that EPA's Proposed Rule is not based on a reasoned explanation and has no rational connection to facts in the record, but rather is entirely baseless.

1. <u>EPA's Proposal is inconsistent with generally applicable data access policies and guidelines.</u>

According to EPA, "[t]he proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science" and "the policies recently adopted by some major scientific journals, spurred in some part by the 'replication crisis.'" 83 Fed. Reg. at 18,770. However, a review of the websites of these organizations and

[83] *Id*. at 2-3 (emphasis added).

journals, and statements made by journal editors regarding the Proposed Rule, indicate that the policies and guidelines on which EPA allegedly relies do not provide any support. Instead, they are wholly inconsistent with what EPA is attempting to do with this Rule.

i. *EPA's Proposal is inconsistent with policies and recommendations of third party organizations upon which it relies.*

Though EPA cites "the policies or recommendations of third party organizations who advocated for open science" as support for the Proposed Rule, 83 Fed. Reg. at 18,770, many of the policies and recommendations do nothing of the sort. Instead, they acknowledge that: there are numerous barriers to the disclosure of data, such as requirements to protect personal privacy; disclosure of data necessarily varies among scientific fields based on these barriers; flexibility in data access policies and guidelines is essential; and the best available science is inclusive and not exclusive in nature. EPA's Proposal to exclude studies solely because the studies include nonpublic data contradicts these principles.

For example, the Administrative Conference of the United States ("ACUS") Science in the Administrative Process Project, which EPA listed, recommends that agencies take a flexible approach to data disclosure: "To the extent practicable and in compliance with applicable legal restrictions, privileges, protections, and authorities, agencies should seek to provide disclosure of data underlying scientific research[.]" 78 Fed. Reg. 41,352, 41,358 (July 10, 2013). This recommendation thus states only that agencies should "seek to provide disclosure" of data "to the extent practicable" and acknowledges that many legitimate barriers to disclosure of data may exist. *Id*. Furthermore, ACUS contemplates scenarios where "data are not subject to legal or other protections" but where "the data's owners nonetheless will not provide such access." *Id*. In these cases, ACUS does not recommend that agencies deprive themselves of data. Rather, ACUS writes, "agencies should note [that the data's owner did not provide access] and explain why they used the results if they chose to do so." *Id*. Thus, the ACUS's policy in no way supports exclusion of studies simply because the underlying data is not publicly available.

The Bipartisan Policy Center's ("BPC") Science for Policy Project, another organization upon which EPA relies, emphasizes similar flexibility. Rather than rejecting science when the underlying data have not been made public, the BPC encourages online publication of methods and data but notes that "[t]he extent to which data and methods should be made public will vary by field[.]"[84] In fact, in its comments requesting an extension of the deadline for filing comments in this rulemaking, BPC expressly states that it

> never suggested excluding studies from consideration in developing regulation if data from those studies were not publicly available. Indeed, the panel's overarching recommendation for assembling the "best available science" reads: "Agencies and their scientific advisory committees should ***cast a wide net*** (emphasis added) in reviewing studies relevant to regulatory policy, and

[84] BPC, *Improving the Use of Science in Regulatory Policy* at 46 (2009), http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf.

> should make their methods for filtering and evaluating those studies more transparent."[85]

Its policies in no way support the exclusion of relevant science.

The Center for Open Science likewise does not advocate for excluding science merely because the underlying data is not public, but rather counsels flexibility in determining what level of transparency is appropriate for a given study. Its Transparency and Openness Promotion ("TOP") Guidelines for journals[86] "recognize[] that not all of the standards are applicable to all journals or all disciplines. Therefore, rather than advocating for a single set of guidelines, the TOP Committee defined three levels for each standard."[87] These levels "provide flexibility for adoption depending on disciplinary variation."[88] The Center for Open Science has invited journals to "suggest revisions that improve the guidelines or make them more flexible or adaptable for the needs of particular subdisciplines."[89] Like the other organizations upon which EPA relies, it too has adopted a flexible approach to transparency and thus provides no support for EPA's rigid exclusion.

EPA also cites "policies and recommendations from . . . members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology[.]" 83 Fed. Reg. at 18,770, n.10. In reality, these "policies and recommendations" are merely responses to an online questionnaire by a limited number of members of the three societies.[90] A report on the questionnaire's methodology and results acknowledged extremely low response rates ranging from 23 to 27 percent across the three groups surveyed.[91] Furthermore, the report stated that nearly two-thirds of people who responded to the survey worked in industry or were consultants who may perform work for industry clients.[92] No more than 13 percent of respondents were based in academia.[93] If the survey attempted to ascertain any potential conflicts of interest among industry and consultant respondents, such results were not included in the report. EPA should not rely on a limited set of responses to an online poll, especially when the Agency does not possess information about conflicts of interest among respondents.

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[85] BPC, *Bipartisan Policy Center comments on "Strengthening Transparency in Regulatory Science"*, Docket ID No. EPA-HQ-OA-2018-0259-0670 (May 22, 2018), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0670.
[86] Center for Open Science, TOP Guidelines, https://cos.io/our-services/top-guidelines (accessed July 2, 2018).
[87] Nosek B.A. et al., *Promoting an open research culture*, Science, 348, 1422-1425, 1423-1424 (2015).
[88] Center for Open Science, TOP Guidelines, https://cos.io/our-services/top-guidelines (accessed July 2, 2018).
[89] Nosek B.A. et al., *Promoting an open research culture*, Science, 348, 1422-1425, 1423-1424 (2015).
[90] *See* Center for Media and Public Affairs and Center for Health and Risk Communication at George Mason University, *Expert Opinion on Regulatory Risk Assessment* (Dec. 6, 2013), http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf.
[91] *Id*. at 5.
[92] *Id*. at 6.
[93] The report states that "13 percent [were] based in academia or non-profit organizations." *Id*.

ii. *EPA's Proposal is inconsistent with policies adopted by major scientific journals.*

As additional support for its ill-advised rule, EPA claims that "policies recently adopted by some major academic journals" informed the data access guidelines and policies that EPA allegedly considered as it developed the Proposed Rule. 83 Fed. Reg. at 18,770. In particular, it cites "related policies from the *Proceedings of the National Academy of Sciences*, *PLOS ONE*, *Science*, and *Nature*." *Id.* But EPA provides no information as to how these journals' policies supposedly informed the data access guidelines and policies. Despite this lack of transparency by EPA, one thing is clear: the Proposed Rule is decidedly inconsistent with the policies these journals have adopted, as stated by the journals themselves.

Indeed, a joint statement by the editors of *Proceedings of the National Academy of Sciences* (*PNAS*), *PLOS*, *Science*, *Nature*, and *Cell* indicates that their journals follow the TOP Guidelines and provide necessary flexibility in how data are shared. The editors write that the TOP Guidelines "recognize the array of workflows across scientific fields and make the case for data sharing at different levels of stringency; ***in not every case can all data be fully shared***."[94] The editors cite "data sets featuring personal identifiers" as an important example of "data that cannot be shared openly with all."[95] Ultimately, the editors conclude that the Proposed Rule would jeopardize the development of science-based policies:

> It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. ***Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes***.[96]

EPA's reliance on these journals' policies is thus sorely misplaced.

iii. *EPA has not shown the existence of a replication crisis or its potential relevance to dose-response data and models.*

EPA also premises the Proposed Rule on a so-called "replication crisis." It claims – with no support – that the policies of major scientific journals that purportedly informed the development of the Proposed Rule were "spurred in some part by the 'replication crisis.'" 83 Fed. Reg. at 18,770. This alleged crisis is a complete fabrication. The term "replication crisis" does not occur in any of the sources cited by EPA in support of this clause. *Id*. at 18,770, n.12.

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[94] Jeremy Berg et al., "Joint statement on EPA proposed rule and public availability of data," *Science* (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116 (emphasis added).
[95] *Id*.
[96] *Id.* (emphasis added).

Indeed, the word "crisis" only appears in one of the sources, which refers to a "reproducibility crisis" and then notes that it is "debatable" whether this term is appropriate.[97]

Nonetheless, EPA asserts without support that such a crisis exists and implies that its existence supports imposing the rigid requirements of the Proposed Rule. This is untrue. While there are discussions within certain scientific fields, such as clinical psychology, about inconsistent results that have been obtained when experiments conducted in those fields are repeated,[98] EPA has not explained why these discussions should cast doubt on the dose-response data or models used by the Agency. In support of the "replication crisis" clause, EPA provides web addresses to three commentaries authored by Dr. John Ioannidis of Stanford University,[99] an editorial in the journal *Science*,[100] and an editorial by *The Economist* newspaper.[101] 83 Fed. Reg. at 18,770, n.12. EPA does not explain why any of the observations made in these commentaries or editorials are relevant to dose-response data and models. Perhaps that is because they are not.

In fact, the authors cited by EPA have sharply criticized the Proposed Rule. Dr. Ioannidis wrote, "If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim."[102] *Science* editorialized, "Here, a push for transparency appears actually to be a mechanism for suppressing important scientific evidence in policy-making, thereby threatening the public's well-being."[103] *The Economist* has described the proposal as part of "a campaign to stifle science at the EPA."[104] As they put it, "[a]ir-quality rules and pesticide limits rely on analyses of confidential medical records—which Mr Pruitt may now label suspect and try to undo."[105] Once again, EPA's cited support undermine, rather than support, the Proposed Rule.

2. <u>There is no evidence that the benefits justify the costs much less a rational finding of that; instead, available evidence shows the opposite.</u>

In the preamble to the Proposed Rule, EPA states – with no evidence or justification – that "the benefits of this proposed rule justify the costs." 83 Fed. Reg. at 18,772. This conclusory statement is the very definition of arbitrary and capricious. *State Farm*, 463 U.S. at 42-43. EPA provides no evidence of what it considered to reach this statement, much less why

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[97] Munafò M.R. et al., *A manifesto for reproducible science*, Nature Human Behavior 1, 1 (2017).
[98] *See, e.g.*, Open Science Collaboration, *Estimating the reproducibility of psychological science*, Science, 349, aac4716 (2015).
[99] Munafò M.R. et al., *A manifesto for reproducible science*, Nature Human Behavior 1, 1 (2017); Goodman S.N. et al., *What does research reproducibility mean?*, Science Translational Medicine 8, 1-6 (2016); Ioannidis J.P.A., *Why Most Published Research Findings Are False*, PLoS Medicine 2, e124 (2005).
[100] McNutt M., *Reproducibility*, Science 490, 229 (2012).
[101] "How science goes wrong," *The Economist* (2013).
[102] Ioannidis J.P.A., *All science should inform policy and regulation*, PLOS Medicine 15 at 2 (2018).
[103] Berg J., *Obfuscating with transparency*, Science 360, 133 (2018).
[104] "Scott Pruitt embarks on a campaign to stifle science at the EPA," *The Economist* (Apr. 26 2018), https://www.economist.com/united-states/2018/04/26/scott-pruitt-embarks-on-a-campaign-to-stifle-science-at-the-epa.
[105] *Id*.

its conclusion is rational. Indeed, EPA provides no information at all about what the "benefits" or "costs" of the Proposed Rule are, or what it evaluated to reach its conclusion. There is simply nothing in the record to support EPA's conclusory statement.

Despite the lack of evidence in the regulatory docket, as these and other comments make clear, the costs of this Proposed Rule are far-reaching and substantial, while EPA has failed to identify any alleged benefits at all, other than vague and unsupported references to improved transparency. EPA's Proposal to undermine, exclude, and ignore important and relevant health science in rulemaking proceedings will have serious implications on public health, privacy, the environment, and the judicial review process, and thus the costs will be significant. EPA cannot ignore these harms in its cost-benefit analysis,[106] even if the costs are not readily quantifiable. *See, e.g.*, *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (costs include "harms that regulation might do to human health or the environment"); Executive Order 12,866, 58 Fed. Reg. 51,735, 51,735 (Oct. 4, 1993) (it is "essential to consider" the "qualitative measures of costs and benefits that are difficult to quantify"); *see also* Food Labeling: Nutrition Labeling of Standard Menu Items in restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. 20,825, 20,828 (May 4, 2017) (acknowledging that delaying a nutrition labeling requirement would lead to millions of dollars in lost health benefits). Yet there is no evidence that EPA evaluated any of these adverse impacts, quantitatively or qualitatively.[107] Moreover, EPA itself estimated that the economic cost of this type of restriction on science would cost "considerably more" than $250 million.[108]

In addition, in performing certain CAA and other rulemakings, EPA may not consider the economic implications of considering or excluding certain science ***at all***. *See* Section IV.A. Yet

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[106] Not only does EPA provide no support for its claim that the benefits justify the costs for this Proposed Rule, but it likewise failed to follow the procedures ordinarily used to obtain confirmation of its cost-benefit analysis. In fact, EPA entirely sidestepped the procedures set forth in Executive Order 12,866 pursuant to which the Office of Information and Regulatory Affairs reviews regulatory actions to ensure the Agency's analysis of costs and benefits is accurate, to provide time for interagency review and stakeholder meetings, and to provide the agency with any necessary changes to the proposed rule. For this Proposed Rule, OIRA completed its review ***only four days after receiving it***. And these four days fell over the weekend, meaning that OIRA spent roughly two working days reviewing a rule that will have significant and far-reaching consequences across multiple statutes.

[107] Indeed, in a recent report on rulemakings related to health – the very type of rulemakings most impacted by the Proposed Rule – EPA and OMB quantified some of the benefits of various regulations that would be dramatically weakened under the new rule. *See, e.g.*, OMB, *2017 Draft Report to Congress on the Benefits and Costs of Federal Regulations*, https://www.whitehouse.gov/wp-content/uploads/2017/12/draft_2017_cost_benefit_report.pdf; EPA, *Benefits & Costs of the Clean Air Act from 1990 to 2020, the Second Prospective Study* (Apr. 2011), https://www.epa.gov/clean-air-act-overview/benefits-and-costs-clean-air-act-1990-2020-second-prospective-study, https://www.epa.gov/sites/production/files/2015-07/documents/fullreport_rev_a.pdf. These recent studies show health rulemakings, particularly air rulemakings, create significant benefits (including health and protection of life, reductions in the need for health care and health care costs, as well as job creation, and other economic values in avoiding days lost at work and school) that are quantitatively larger and more qualitatively valuable than the costs of pollution controls or other economic costs of the regulations.

[108] EPA, *CBO Questions for EPA Regarding H.R. xxxx, the HONEST Act of 2017* at 1, 2, 8, 10 (2017), https://www.scribd.com/document/344731162/EPA-analysis-of-Honest-Act-to-CBO.

EPA's failure to provide any lawful or rational justification for its costs/benefits statement for the Proposed Rule suggests that economic cost may have impermissibly played a role in its analysis. Had EPA focused on health rather than cost, EPA could not possibly find that the benefits of ignoring health science outweigh the costs for public health rulemakings.

C. Section 30.9 Allows Standardless and Arbitrary Application of the Rule.

The Proposed Rule is arbitrary and capricious because its standardless provisions give EPA unfettered discretion in deciding whether and how the Rule applies. It has long been held that regulations must contain "narrow, objective, and definite standards to guide the [decisionmaking] authority,' . . . thereby to guard against the danger of arbitrary action." *United States v. Abney*, 534 F.2d 984, 986 (D.C. Cir. 1976) (quoting *Shuttlesworth v. City of Birmingham, Ala.*, 394 U.S. 147, 149 (1969)). "When administrators provide a framework for principled decision-making" by "articulat[ing] the standards and principles that govern their discretionary decisions in as much detail as possible," "the result will be to . . . enhanc[e] the integrity of the administrative process." *Envtl. Def. Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 598 (D.C. Cir. 1971). But where a regulation is "wholly silent as to what factors the agency is to consider in granting exceptions . . . [a]gency discretion is unfettered," and the regulation is "arbitrary, capricious and contrary to law." *Nat. Res. Def. Council, Inc. v. EPA*, 863 F.2d 1420, 1432 (9th Cir. 1988).

EPA's Proposed Rule lacks the requisite standards and principles that are the hallmark of lawful agency decision-making. The vague definitions proposed in 40 C.F.R. § 30.2 invite limitless agency discretion to decide when the Rule's requirements apply. For example, the Proposed Rule defines "regulatory science" as "scientific information . . . that provide the basis for EPA final significant regulatory decisions." 83 Fed. Reg. at 18,773. But this definition lacks any discernible meaning. There is no standard or definition for determining when scientific information does or does not "provide the basis" for a regulatory decision, nor are there any standards or definitions for what subset of "regulatory decisions" should be deemed "significant." Likewise, the Proposed Rule defines "pivotal regulatory science" as studies that "drive the requirements and/or quantitative analysis" of EPA's action, *id.*, but this too lacks any understandable meaning. There is no standard governing what science does or does not "drive" the regulatory action. The lack of regulatory standards here means that EPA staff will impermissibly determine applicability of the rule "based upon their own unwritten personal standards." *White v. Roughton*, 530 F.2d 750, 754 (7th Cir. 1976).

In contrast to the definitions of proposed section 30.2 – which lack any meaning or standards at all – proposed section 30.9 provides a veritable grab bag of reasons the Administrator may use in his discretion to decide when not to apply the Rule. It allows the Administrator to grant a case-by-case exemption to the Rule's requirements if the Administrator determines it is not "feasible" to ensure that data may be made publicly available "in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." 83 Fed. Reg. at 18,774. It also authorizes the Administrator to exempt application of the Rule if it is not "feasible" to conduct peer review for the multiple reasons outlined in OMB

guidance. *Id*. Here, the many vague and discretionary "exception[s] . . . threaten[] to swallow the rule," *Nat. Res. Def. Council, Inc.*, 863 F.2d at 1432, empowering the Administrator to pick and choose the preferred scientific studies he wants considered or excluded from consideration in any given rulemaking procedure with no clear standards or principles to keep this discretion in check.

Proposed sections 30.2 and 30.9 thus give EPA unfettered discretion to be a case-by-case arbiter of scientific information, without notice-and-comment, any oversight, or any stated standards or principles limiting this discretion. These provisions allow for arbitrary application of the Rule, rendering the Proposed Rule arbitrary and thus unlawful.

D. The Proposed Rule Impermissibly Favors So-Called "Secret Science" That Supports a Decision *Not* to Regulate a Chemical While Disfavoring Public Health Research that Supports a Decision to Regulate a Chemical.

Under the terms of the Proposed Rule, EPA must ensure that underlying data is publicly available only "[w]hen promulgating significant regulatory actions." 83 Fed. Reg. at 18,773 (proposed to be codified as 40 C.F.R. § 30.5). But as defined in the Proposed Rule, a significant regulatory action refers only to the ***promulgatio****n* of a new rule or regulation.[109] Accordingly, as written, the Proposed Rule arguably allows EPA to utilize non-public studies or studies that rely on non-public data to justify a decision not to regulate at all. This creates a lopsided and inequitable playing field whereby EPA can rely upon studies that it prohibits others to use when it decides not to issue a new regulation.

An example highlights the dangerousness of this inequity. Under TSCA, many provisions involve go/no-go decisions about whether to promulgate regulations at all. Thus, upon consideration of whether to regulate a chemical, EPA could arguably utilize non-public studies or studies that rely on non-public data to justify a decision not to regulate. For example, EPA could use non-public data to justify a finding that a chemical does not pose an unreasonable risk to health or the environment under Section 2605 and thus does not require regulation. Pursuant to the definitions in the Proposed Rule, such a decision does not qualify as a significant regulatory action, because a finding of no unreasonable risk does not trigger any new rule or regulation. By contrast, EPA would not be able to rely on non-public studies or studies that rely on non-public data to justify a decision to regulate a chemical.

The Proposed Rule thus creates a regulatory regime in which EPA ***can*** consider science based on non-public data if it shows that a chemical is not harmful (or minimizes the harmful

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[109] In the Proposed Rule, a significant regulatory action means "final regulations determined to be 'significant regulatory actions' by the Office of Management and Budget pursuant to Executive Order 12866." 83 Fed. Reg. at 18,773 (proposed to be codified as 40 C.F.R. § 30.2). In turn, Executive Order 12,866 defines a significant regulatory action, in relevant part, as "any regulatory action that is ***likely to result in a rule*** that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency . . ." Exec. Order 12,866, 58 Fed. Reg. 51,735 (emphasis added).

effects of a chemical) and supports not regulating the chemical, but ***cannot*** consider science that shows that a chemical has harmful effects if it is similarly based on non-public data but supports a decision to regulate the chemical. EPA has not, and indeed cannot, provide any explanation or basis for this differential treatment. For this reason, too, the Proposed Rule is arbitrary and capricious and cannot stand.

Equally problematic, the Proposed Rule could lead to absurd results. For example, when determining whether a chemical poses an unreasonable risk of harm under TSCA, EPA has to consider all relevant scientific studies. If EPA finds that a chemical poses an unreasonable risk and that it must issue a regulation on that basis, the Proposed Rule mandates exclusion of studies based on non-public data from consideration, even if those same studies provide the basis for the unreasonable risk finding. Absent these particular studies, the remaining research may show no unreasonable risk of harm, obviating the need for regulation, and in turn, eliminating the Proposed Rule's requirement that EPA not consider the excluded studies. Instead, when determining no unreasonable risk of harm, EPA ***must*** consider the excluded studies because such a finding does not result in a significant regulatory action and thus the Proposed Rule's ban on non-public data would not apply. But because the excluded study demonstrates that the chemical ***is*** unreasonably risky, EPA could not go forward with an unreasonable-risk determination. This could create an endless cycle of review and re-review with certain studies included, then excluded, and then included again, ***ad infinitum***. In such situations, application of the Proposed Rule creates a catch-22 in which EPA cannot make ***any*** determination that complies with both the APA's requirement of reasoned decision-making and the requirements of the Proposed Rule.

These flaws would plague any decision made under any provision of the statute in which EPA is required to choose between issuing or not issuing a regulation and, therefore, renders the Proposed Rule arbitrary and capricious. *See e.g.* 15 U.S.C. § 2603(a) (EPA must require testing if it finds that a chemical "may present an unreasonable risk").

E. EPA Has Failed to Show Any Need or Reasoned Basis for the Proposed Rule.

EPA's stated justifications for the Proposed Rule consist of vague platitudes such as a purported desire to strengthen the transparency and integrity of EPA regulatory science and to enhance the public's ability to understand and meaningfully participate in the regulatory process. 83 Fed. Reg. at 18,769. Yet the Proposal does not show how or why EPA's existing practices fail to adequately achieve these purposes, or how the proposed new procedures would do a better job. In reality, EPA's historic practices in adopting health and welfare standards are extraordinarily transparent, public, and accessible to interested persons.

By way of example, EPA's NAAQS process begins with preparation of an Integrated Science Assessment ("ISA"), an extensive review of available science relevant to the development of NAAQS. *See* EPA, *Integrated Science Assessment for Ozone and Related Photochemical Oxidants*, EPA 600/R-10/076F, at 1i-1ii (Feb. 2013). Preparation of the ISA is preceded by a public workshop and call for information. *Id*. EPA collects and screens studies (with a heavy focus on studies that have been peer reviewed), prepares an initial characterization of evidence, and then provides a peer review process of the initial draft materials for scientific

quality of "building blocks" from scientists from both outside and within EPA. *Id*. at 1vii. There is then preparation of draft syntheses of the studies and draft conclusions and causal determinations, followed by CASAC input and an opportunity for public comment before preparation of the final ISA. After that, EPA staff prepares a Policy Assessment ("PA") based on integration and interpretation of the findings of the ISA and a separate risk and exposure assessment ("REA"). Both the PA and REA are themselves subject to separate rounds of public comment. And there is yet another round of public comment after EPA proposes its action on the NAAQS. *Id*.

All of the foregoing comprises one of the most open, publicly accessible processes ever devised for the development of health standards. There are multiple layers of peer review and more than ample opportunity for the public to raise questions about the adequacy and accuracy of the studies and models presented. EPA does not and cannot rationally explain why this system requires yet another layer of complexity to provide adequate transparency, integrity, and public understanding of the process.

EPA's process for revising ambient water criteria for the protection of human health provides another example of the transparency afforded to its rulemaking, as it provides open access to information for interested persons. In 1998, EPA "improved" this process "to provide expanded opportunities for public input, and to make the process more efficient." 63 Fed. Reg. 68,354, 68,355 (Dec. 10, 1998). To revise its ambient water criteria, EPA must follow a multi-step process. *First*, EPA must "undertake a comprehensive review of available data and information" before developing draft criteria. *Id*. *Second*, EPA must "publish a notice in the Federal Register and on the Internet announcing its assessment . . . of the pollutant" which "describe[s] the data available to the Agency," and solicits "scientific views as to the application of the relevant Agency methodology." *Id*. *Third*, EPA must "utilize information obtained from both the Agency's literature review and [from] the public [comments] to develop draft recommended water quality criteria." *Id*. *Fourth*, and concurrent with the development of the draft criteria, EPA must publish in the Federal Register a notice soliciting the public's "scientific views on the draft criteria," and must "initiate . . . a documented critical review by qualified independent experts." *Id*. *Fifth*, EPA must then evaluate and respond on the record to all "[m]ajor scientific issues" (if any) raised during the peer review or public comment period. *Id.* *Finally*, EPA must "revise the draft criteria as necessary, and announce the availability of the final water quality criteria in the Federal Register and on the Internet." *Id*. Like the NAAQS process, this process too is fully open and transparent.

Moreover, it would be irrational and impracticable to require EPA to seek out the underlying data for, and demand separate peer review of, all data and models the Agency uses for purposes of characterizing the quantitative relationship between dose or exposure and magnitude of a predicted health or environmental impact. For instance, in the last ozone NAAQS review, EPA reviewed more than 4,000 studies and references for the ISA, and cited more than 2,200 in the final ISA. *See* EPA, Health and Environmental Research Online, ISA-Ozone (2013) (last updated July 2, 2018), https://hero.epa.gov/hero/index.cfm/project/page/project_id/1628. It is neither practicable nor

necessary for EPA to demand production of underlying data from thousands or even hundreds of studies, and to require new peer reviews of each. EPA cannot construe the statute in a way that would render it impossible to complete the review and revision of the NAAQS that Congress mandated.

EPA further tries to justify the Proposed Rule as a way to ensure the Agency is not arbitrary and capricious in its conclusions. But as previously noted, the D.C. Circuit has twice rejected the notion that EPA must obtain and disclose data underlying the studies it relies on in NAAQS development.

VII. OTHER PROVISIONS OF THE RULE ARE UNLAWFUL

A. EPA's Requirement in Proposed 30.6 to Give Explicit Consideration to Studies that Explore Threshold Models Is Arbitrary.

EPA's Proposed Rule requires the Agency to "give explicit consideration to high quality studies that explore . . . various threshold models across the dose or exposure range[.]" 83 Fed. Reg. at 18,774 (proposed 40 CFR § 30.6). A "threshold" is a dose or exposure "below which effects do not occur or are extremely unlikely."[110] A "threshold model" – a type of "non-linear" model[111] – is a dose-response model in which there is no response below the threshold dose or exposure.[112] EPA's proposed prioritization of threshold models is arbitrary, for at least three reasons.

First, EPA provides no evidence to justify the proposed requirement that it consider threshold models in dose-response assessments. EPA baldly asserts that "there is growing empirical evidence of non-linearity [*i.e.*, a threshold[113]] in the concentration-response function for specific pollutants and health effects[,]" but provides not a single example or citation for this unsubstantiated claim.[114] *Id*. at 18,770. By contrast, EPA has found strong empirical evidence of no-threshold concentration-response functions for lead and reduced IQ, and particulate matter and increased mortality, following extensive reviews of the relevant literature to inform the

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[110] National Research Council, *Science and Decisions: Advancing Risk Assessment* at 128 (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.

[111] EPA uses the terms "threshold" and "nonlinear" repeatedly but does not define them in the Proposed Rule. According to EPA Risk Assessment Guidelines, "the term 'nonlinear' refers to threshold models (which show no response over a range of low doses that include zero) and some nonthreshold models[.]" EPA, *Guidelines for Carcinogen Risk Assessment* at 1-11, n.3 (2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[112] A threshold model "show[s] no response over a range of low doses that include zero[.]" *Id*.

[113] EPA appears to use the terms "non-linearity" and "threshold" interchangeably. If so, then EPA has asserted that there is growing evidence of thresholds in unspecified concentration-response functions but has failed to provide a supporting example or citation. If not, then EPA has not even asserted that there is growing evidence of such thresholds and has failed to state, let alone support, any scientific rationale for the proposed requirement to give explicit consideration to studies that explore threshold models.

[114] A "concentration-response function" is a dose-response model in which the "dose" is the concentration of an air pollutant.

Agency's national ambient air quality standards.[115] EPA's failure to provide any support for its claim is telling.

Second, the proposed requirement to consider threshold models ignores essential science, namely the approach to dose-response assessment recommended by the NAS in *Science and Decisions: Advancing Risk Assessment*. Historically, researchers applied no-threshold dose-response models to carcinogens and threshold models to non-carcinogens.[116] But in *Science and Decisions*, NAS determined that, due to the variability in susceptibility and exposures to other chemicals (background exposures) within populations, the effects of non-carcinogens may lack thresholds in ***populations*** even when these effects have thresholds in certain ***individuals*** who are less susceptible and/or have lower background exposures.[117] In other words, thresholds vary by individual; for some, effects have high thresholds, while for others, effects have practically no threshold due to increased susceptibility or background exposures,[118] and this latter group may develop disease when a population is exposed, even at very low levels.[119] Based on these findings, NAS concluded that no-threshold models should be applied to ***both*** carcinogens and non-carcinogens unless reliable data affirmatively support a threshold model based on detailed assessments of mode of action (how a chemical causes disease), susceptibility, and background exposures.[120] EPA's Proposed Rule entirely ignores *Science and Decisions*, its recommended approach to dose-response assessment, and the need for a detailed assessment before concluding that a threshold model is appropriate.

The "explicit consideration" of "studies that explore . . . various threshold models" required under the Proposed Rule does not qualify as a "detailed assessment" of the type recommended by NAS. While NAS recommends consideration of the available data on mode of action, susceptibility, and background exposure ***before*** deciding whether dose-response models are appropriate,[121] the Proposed Rule requires consideration of threshold models regardless of this data. EPA provides no justification for ignoring NAS' researched approach to dose-response data.

Third, EPA's proposed requirement also disregards the Agency's own Guidelines for Carcinogen Risk Assessment, which expressly state that, in cancer risk assessments, no threshold should be assumed unless the mode of action is known and the chemical does not cause cancer

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[115] EPA, *Integrated Science Assessment for Lead* at lxxxviii (2013), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=518908 ("[T]here is no evidence of a threshold below which there are no harmful effects on cognition from [lead] exposure."). EPA, *Integrated Science Assessment for Particulate Matter* at 2-25 (Dec. 2009), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=494959 ("Overall, the studies evaluated further support the use of a no-threshold log-linear model[.]").
[116] NAS, *Science and Decisions*, *supra* n.110, at 127-128.
[117] *Id*. at 131.
[118] *See id*.
[119] *See id*.
[120] *See id*. at 148.
[121] *Id*. The sequence of steps recommended by NAS, including the assessment of mode of action, susceptibility of vulnerable populations, and background exposure *before* model selection is depicted by Figure 5-8. *Id*. at 144.

by inducing DNA mutations that initiate tumor development.[122] Like *Science and Decisions*, the Cancer Guidelines state that it is necessary to assess mode of action to determine whether a threshold or no-threshold model is appropriate.[123] EPA has historically followed this approach to ensure that its cancer risk assessments are adequately health-protective.[124] The Proposed Rule breaks from this prior practice and instead disregards science that the Cancer Guidelines say should be considered. EPA's reversal of longstanding policy is unjustified and arbitrary, and should not be permitted.

B. The Requirement in Proposed 30.7 that EPA Independently Peer-Review All Pivotal Regulatory Science Used to Make Regulatory Decisions is Arbitrary.

As part of the Proposed Rule, EPA injects a new requirement – without justification – that EPA "conduct independent peer review on all ***pivotal regulatory science*** used to justify ***regulatory decisions*** consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions described therein." 83 Fed. Reg. at 18,774. Once again, a review of the support upon which EPA relies demonstrates that this peer review obligation is contrary to current policy. It is also unnecessary, costly, and unrealistic. It seems the only things this new peer review process would accomplish is the exclusion of reliable science, increased cost and time for effective reviews, and delay of regulatory decisions that impact public health.

1. Independent Peer Review by EPA Is Unnecessary.

There is no dispute that independent peer review plays a pivotal role in the regulatory development process, subjecting original research methods and outcomes to a panel of experts in the same field.[125] Independent peer review "is a process for enhancing a scientific or technical work product so that the decision or position taken by the Agency, based on that product, has a sound, credible basis".[126] Peer reviewers are individuals with technical expertise in the area of the work or product under review. Independent peer review processes eliminate issues arising due to conflicts of interest between the reviewer and the developers of the product/scientific work.[127] When conducted properly, independent peer review provides validation for original research and ensures that basic scientific integrity practices are employed to aid decision makers

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[122] Specifically, the Guidelines say that a linear model is used as a default approach unless these conditions apply. *See* EPA, *Guidelines for Carcinogen Risk Assessment*, *supra* n.111, at 3-21. A linear model, known more fully as a low-dose-linear model, is a model "whose slope is greater than zero at a dose of zero[,]" which implies no threshold. *Id*. at 1-11, n.3.
[123] *Id* at 3-21.
[124] *Id*.
[125] *See, e.g.*, Bruce P. Dancik, *Importance of Peer Review*, The Serials Librarian 19:3-4, 91-94 (1991), https://www.tandfonline.com/doi/pdf/10.1300/J123v19n03_11; Frank Gannon, *The essential role of peer review*, EMBO Rep. 2(9): 743 (Sept. 2001), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1084042/; *see also* NAS, *Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices* (2000), http://www.nap.edu/catalog/9882.html.
[126] *Id.*
[127] EPA, *EPA Science Policy Council HANDBOOK – Peer Review – 2nd Edition*.

in making sound policy decisions. OMB's Final Information Quality Bulletin for Peer Review ("OMB Bulletin") confirms these principles: "Peer review can increase the quality and credibility of the scientific information generated across the federal government."[128] Overall, it is well understood that peer review is an essential element of the regulatory process.

While it is certainly a best practice to consider only science that has been independently peer reviewed when making regulatory decisions, that does not necessitate independent peer review ***by EPA***. Rather, most scientific bodies – including *Nature, Science*, the Bipartisan Policy Center, and *Proceedings of the National Academies of Sciences* – employ some of the most robust peer review practices that they already apply to the types of studies for which the Proposed Rule will require EPA review. Thus, as the OMB Bulletin recognizes, "[p]ublication in a refereed scientific journal may mean that adequate peer review has been performed."[129] Thus, additional review by EPA is duplicative and wholly unnecessary.

More importantly, EPA's Proposal is antithetical to the science communities' policies. Rather than strengthening science, the independent peer review process would serve to exclude reliable and tested science that has been foundational to protecting public health and the environment. Indeed, despite EPA's reliance on the policies of several major scientific journals, the Editors-in-Chief of *Science*, *Nature*, *Proceedings of the National Academy of Sciences*, and several other highly revered scientific journals and members of the scientific community released a joint statement in response to the Proposed Rule, making clear that the Rule itself "does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which concludes ever more rigorous features, inform the landscape of decision making."[130] The joint statement concludes: "[e]xcluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."[131]

2. <u>EPA's Independent Peer Review Requirement Will Lead to Unnecessary Delay and Increased Costs.</u>

Not only is independent peer review by EPA unnecessary, but it is also impractical and irrational for EPA to conduct its own independent peer review of the underlying data for studies that already have undergone a rigorous scientific review process, which is the case for those studies published in scientific journals or independently evaluated by a scientific body. It would also lead to undue delay. The standard time taken to review scientific manuscripts in the fields of medicine, public health, and natural sciences is, on average, 12-14 weeks.[132] If EPA were to follow a comparably rigorous independent peer review on all pivotal science utilized in the regulatory decision making process, such an action would result in untimely delays in

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[128] OMB, *Final Information Quality Bulletin for Peer Review* at 1 (Dec. 16, 2004), http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf.
[129] *Id* at 22.
[130] Jeremy Berg et al., "Joint statement on EPA proposed rule and public availability of data," *Science* (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.
[131] *Id.*
[132] Janine Huisman & Jeroen Smits, *Duration and quality of the peer review process: the author's perspective*, Scientometrics 113:633 (2017), https://doi.org/10.1007/s11192-017-2310-5.

implementation of public health protections. For example, the NAAQS Integrated Science Assessment and Risk and Exposure Assessments regularly include the review of thousands of scientific studies. It would be enormously inefficient and costly (if even possible) for EPA to re-review all of these studies.

Moreover, as clearly outlined in the OMB Bulletin, the independent peer review guidelines "do[] not cover time-sensitive health and safety disseminations, for example, a dissemination based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began. For this purpose, 'health' includes public health, or plant or animal infectious diseases".[133] This encompasses most of the studies that EPA intends to review, including but not limited to, the Integrated Risk Information System ("IRIS") assessments, TSCA risk evaluations, and National Emissions Standards for Hazardous Air Pollutants risk assessments.[134] In each case, EPA utilizes scientific data to make safety determinations for chemical pollutants and impacts on human health and the environment, and thus, timely review is tantamount to protecting public health. The Proposal to add another layer of review – one that is wholly unnecessary and duplicative – is antithetical to the time sensitive nature of these reviews.

Furthermore, the Bulletin makes clear that agencies should "ensure peer review does not unduly delay the release of urgent findings."[135] Thus, if EPA wants to independently peer review all pivotal science, then it must clearly outline how it will ensure the process will not lead to undue delay. It has failed to do so. For example, there is nothing in the Proposed Rule outlining how EPA will conduct an independent review of the studies underlying the NAAQS standard, which will require review of hundreds if not thousands of science documents, within the NAAQS review cycle. The standard review period in the independent peer review process (*i.e.*, from submission of a manuscript to final review) is time intensive. If it can take months to review one manuscript,[136] it is difficult to envisage how EPA could subject every piece of pivotal regulatory science to the same standard of review and still complete scientific assessments in a timely manner.

Equally problematic, the proposed independent EPA review will lead to undue costs in terms of the time and resources required to review the relevant data. In *Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer Review Practice* ("NAS Review"), the National Academy of Sciences states that "[t]he cost of a peer review

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[133] *Id.*

[134] EPA, Basic Information about the Integrated Risk Information System (last updated March 7, 2018), https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system; EPA, Risk Evaluations for Existing Chemicals under TSCA (last updated June 11, 2018), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca; EPA, Risk and Technology Review (last updated June 22, 2018), https://www3.epa.gov/airtoxics/rrisk/rtrpg.html.

[135] OMB, *Final Information Quality Bulletin for Peer Review* at 1 (Dec. 16, 2004), http://www.cio.noaa.gov/services_programs/pdfs/OMB_Peer_Review_Bulletin_m05-03.pdf.

[136] Janine Huisman & Jeroen Smits, *Duration and quality of the peer review process: the author's perspective*, Scientometrics 113:633 (2017), https://doi.org/10.1007/s11192-017-2310-5.

effort should be carefully considered in terms of in-house staff time and resources, as well as the limited time and energy of busy experts who must take time from other worthwhile endeavors."[137] EPA ignores this aspect in its cost-benefit analysis of the Proposed Rule, rendering the resulting rule arbitrary.

C. Section 30.8's Requirement to Consider and Minimize Costs is Unlawful.

Proposed Section 30.8, which would require EPA to implement the provisions of the Rule "in a manner that minimizes cost," is unlawful and arbitrary, for several reasons.

First, because EPA has only the authority conferred to it by statute, the Agency must identify the statutory authority upon which it bases its regulatory decisions about what data and models to consider on the minimization of cost. *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) (quoting *Verizon v. FCC*, 740 F.3d 623, 632 (D.C. Cir. 2014) ("It is 'axiomatic' that 'administrative agencies may act only pursuant to authority delegated to them by Congress.'") (alteration and citations omitted)). The Agency has failed to do so here.

Second, EPA's proposal to base these decisions on cost is inconsistent with statutory mandates requiring the Agency to base regulatory decisions on the best available science. *See, e.g.*, 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II) (directing EPA to base its determination about whether to regulate any particular contaminant "on the best available public health information"); 15 U.S.C. § 2625(h) (requiring EPA to act "consistent with the best available science"). Plain meaning and common usage confirm that "best available science" does not refer to whatever science is least costly. *See also supra*, Section IV.A.

Third, EPA's proposal to base its data quality decisions on cost is inconsistent with applicable statutory mandates requiring EPA to make regulatory decisions based on considerations of public health. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 469 (2001) (cost "is ***both*** so indirectly related to public health ***and*** so full of potential for canceling the conclusions drawn from direct health effects that it would surely have been expressly mentioned . . . had Congress meant it to be considered." (emphasis in original)).[138]

Fourth, section 30.8 is also unlawfully vague. As the Supreme Court has explained, "'cost' includes more than the expense of complying with regulations; any disadvantage could be termed a cost." *Michigan v. EPA*, 135 S. Ct. at 2707. Yet the provision does not specify to what types of costs it refers. And despite the fact that various types of costs would necessarily need to be weighed against one another when applying this provision, the Proposed Rule is notably silent as to how that will be done. As proposed, it appears to confer nearly limitless discretion on EPA

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[137] NAS, *Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices* (2000), http://www.nap.edu/catalog/9882.html.

[138] If anything, EPA's proposal to base decisions on consideration of cost here is even more irrational than it was in *Whitman*, because in this case, decision-making about the science used to inform EPA's regulatory decisions will result in a proliferation of costs and benefits that resist quantification, monetization, and comparison. These include substantial and important non-market values, including privacy, transparency, health and environmental considerations, and even the value of scientific knowledge itself.

to decline to collect and utilize relevant science on grounds of cost, in contravention of applicable statutory mandates and reasoned decision-making. *See U.S. Sugar v. EPA*, 830 F.3d 579, 644 (D.C. Cir. 2016) ("in light of the unambiguous statutory command [to regulate toxic pollution sources] . . . [t]he Agency was obligated to collect the data it needed").

Finally, even if EPA had authority to base its data quality decisions on cost, it would be irrational and arbitrary for EPA to ignore all the costs and benefits to the public – including public health and environmental costs and benefits and privacy-related costs and benefits –that may flow from its decisions. EPA must treat costs and benefits alike, and may not "put a thumb on the scale by undervaluing the benefits and overvaluing the costs of more stringent standards." *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008). And it may not ignore the public health, environmental, and privacy-related costs of its action or inaction of its decision just because they are not quantified. *See, e.g.*, Exec. Order No. 13,563 § 1, 76 Fed. Reg. at 3821; Exec. Order No. 12,866 § 1, 58 Fed. Reg. at 51,735 (it is "essential to consider" the "qualitative measures of costs and benefits that are difficult to quantify"). OMB Circular A-4 cautions agencies against ignoring the potential magnitude of unquantified benefits, because the approach with the "largest quantified and monetized . . . estimate" is not necessarily the most cost-justified. Under all of these authorities, a "full accounting" of the costs and benefits of a rule requires that indirect benefits be counted "equivalently" with other costs and benefits.[139]

For all of these reasons, section 30.8 is arbitrary and capricious and thus invalid.

VIII. EPA'S PROPOSAL WOULD DISPROPORTIONATELY HARM LOW-INCOME COMMUNITIES AND MINORITY COMMUNITIES

Not only is EPA's elimination of its use of critical human health research and studies that serve to protect and promote public health and the environment unlawful, but it is also discriminatory. The Proposed Rule has a disproportionately deleterious impact on low-income communities and minority communities – the overburdened populations that benefit most from the epidemiological studies used to set limits on air and water pollutants and to set safe exposure levels for pesticides and other toxics. By removing this critical category of studies from consideration when setting limits on pollutant and toxic exposure as well as standards for safe air and water, EPA is turning a blind eye to accessible and illuminating evidence that provides much-needed safeguards to the vulnerable communities most impacted by the laws EPA is charged with enforcing. These communities will disproportionately suffer as a result.

Since the 1987 landmark report *Toxic Wastes and Race in the United States*,[140] studies have confirmed again and again that communities of color and also economically disadvantaged

[139] Cass R. Sunstein, *The Real World of Cost-Benefit Analysis: Thirty-Six Questions (and Almost as Many Answers)*, 114 Colum. L. Rev. 167, 190 (2014).
[140] Dr. Benjamin F. Chavis, Jr. & Charles Lee, *Toxic Wastes and Race in the United States*, Commission for Racial Justice, United Church of Christ (1987),

populations are disproportionately located near toxic waste sites and other sources of pollution. And research has also found that overall air pollution exposure is more strongly concentrated in communities of color.[141] Pesticide exposure likewise disproportionately impacts low-income and minority communities: farmworkers tend to be poor,[142] and the vast majority are of Latin American origin,[143] and they have a higher incidence of pesticide poisoning than other workers.[144] For example, in California, the counties with the greatest use of the highly toxic pesticide chlorpyrifos are the counties with the highest poverty levels and largest Latino populations.[145] In April 2014, the California Department of Public Health issued a report showing that thousands of children, disproportionately people of color, attend school in close proximity to pesticide use.[146] Overall, the disproportionate burden of environmental exposure among these low-income communities and communities of color cannot be disputed.[147]

Fundamental to the research revealing the disproportionate impact of environmental harms on low-income and minority communities and the need to set appropriate standards is epidemiological data. Indeed, this category of science that EPA wants to eliminate has been foundational to establishing disparate harms from a variety of toxics in air, water, pesticides, and other environmental sources. For example:

- Epidemiological studies have shown that there is a persistent disparity in the blood lead levels measured in children of color compared to white children. These studies revealed that in 2011-2012, the mean level was almost 40 percent higher in black children 1-5 years old than in white children of the same age.[148]

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https://www.csu.edu/cerc/researchreports/documents/ToxicWasteandRace-TOXICWASTESANDRACE.pdf.

[141] Zwickl, *Regional Variation in Environmental Inequality* at 9-10; Ash, M. et al., *Is environmental justice good for white folks? Industrial air toxics exposure in Urban America*, 94:3 Soc. Sci. Q. 616, 616 (2013); Morello-Frosch, R. et al., *Separate and unequal: residential segregation and estimated cancer risks associated with ambient air toxics in U.S. metropolitan areas*, 114:3 Envtl. Health Persp. 386, 390-92 (2006).

[142] U.S. Department of Labor, *National Agricultural Workers Survey* (2011-2012), http://www.doleta.gov/agworker/naws.cfm (on average, a farmworker family earns an annual income ranging from $17,500-$19,999).

[143] *Id*.

[144] Geoffrey M. Calvert et al., *Acute Pesticide Poisoning Among Agricultural Workers in the United States, 1998-2005*, 51 Am. J. Indus. Med. 883, 890 (2008).

[145] Letter from Environmental Justice Organizations to Cal. EPA Assistant Secretary for Environmental Justice and Tribal Affairs Arsenio Mataka at 2-3 (Aug. 26, 2014).

[146] Cal. Dep't of Public Health, *California Environmental Health Tracking Program: Agriculture Pesticide Use Near Public Schools in California* (April 2014), http://cehtp.org/file/pesticides_schools_report_april2014_pdf.

[147] Mohai, P. et al., *Racial and Socioeconomic Disparities in Residential Proximity to Polluting Industrial*; Zwickl, K. et al., *Regional Variation in Environmental Inequality* at 20.

[148] Jain R.B., *Trends and Variability in Blood Lead Concentrations Among US Children and Adolescents*, Envtl. Science and Pollution Research, 23, 7880-7889 at 7884 (2016).

- While studies have shown that the mean blood lead level in black children is much lower than it was several decades ago, epidemiological studies have shown that even low levels of lead in the blood are harmful.[149]

- A 2011 peer-reviewed epidemiological study found that urine samples of children ages 6 to 24 months were more likely to have six organophosphate metabolites the closer the child lived to a pesticide application site.[150]

- Longitudinal cohort epidemiologic studies have shown that even low levels of exposure to the highly toxic pesticide chlorpyrifos can disrupt brain development in prenatally exposed children, leading to developmental delays, lower IQ, learning disabilities, and ADHD-like behaviors.[151]

- Epidemiological studies demonstrate that farmworkers have a higher rate of pesticide poisoning than any other workers[152]

Thus, it is clear that epidemiological studies have provided a consistent source of reliable data that has been critical to demonstrating disproportionate exposure to toxic chemicals. These studies in turn have been pivotal to setting air, water, and pesticide standards necessary to protect low-income and minority populations from harmful levels of exposure.

EPA's proposal to eliminate use of epidemiological studies will have a disparate impact on the most overburdened and vulnerable communities, eliminating the very source of data relied upon to provide protections crucial to their health and wellbeing. This Proposed Rule will perpetuate the environmental injustices that low-income and minority communities already face, as it will remove the primary tool used to study and address the inequitable environmental harms suffered by these populations.

IX. ADDITIONAL TOPICS FOR COMMENTS

A. Retroactive Application of the Law Would Be Unlawful.

EPA also requested "comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently

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[149] Lanphear B.P. et al., *Low-Level Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, Envtl. Health Persp. 113, 894-899 at 898 (2005).
[150] Asa Bradman et al., *Determinants of Organophosphorus Pesticide Urinary Metabolite Levels in Young Children Living in an Agricultural Community*, 8 Int. J. Envtl. Res. Public Health 1061 (2011).
[151] Rauh V.A., Garfinkel R., Perera F.P. et al., *Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children*, Pediatrics 118(6):e1845-59 (2006); Bouchard M.F., Chevrier J., Harley K.G. et al., *Prenatal Exposure to Organophosphate Pesticides and IQ in 7-Year Old Children*, Envtl. Health Persp. 21003185 (Apr. 2011); Rauh V.A. et al., *Prenatal exposure to the organophosphate pesticide chlorpyrifos and childhood tremor*, Neurotoxicology 51:80-86 (2015).
[152] Geoffrey M. Calvert et al., *Acute Pesticide Poisoning Among Agricultural Workers in the United States, 1998-2005*, 51 Am. J. Indus. Med. 883, 890 (2008).

introduce bias regarding the timeliness and quality of the scientific information available." 83 Fed. Reg. at 18,772. Like much of the rest of the Proposal, it is unclear what exactly EPA is asking or suggesting. Certainly, to the extent EPA uses the Proposed Rule to exclude important, valid scientific information, it will bias the quality of the scientific information available.

To the extent EPA suggests the Rule may be applied retroactively, there is simply no basis for doing so. It is well-established that an agency cannot apply a rule retroactively absent clear congressional intention for such application. *E.g.*, *Sierra Club v. Whitman*, 285 F.3d 63, 68 (D.C. Cir. 2002) (referring to "unusual ability to implement rules retroactively"); *Bowen v. Georgetown Univ. Hospital*, 488 U.S. 204, 208 (1988) ("Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result. By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms." (citations omitted)). EPA has not identified any such congressional intention in any of the statutes at issue, and thus retroactive application of the Rule would be unlawful.

Nor would the statutes upon which EPA relies support such an application. For example, as explained above, the Clean Air Act does not allow—and, as the D.C. Circuit has held, certainly does not require, *e.g.*, *American Trucking*, 283 F.3d at 372—applying the so-called transparency provisions of the Proposed Rule at all in rules subject to the procedural requirements of Clean Air Act § 307(d). Such rules include NAAQS. Further, far from suggesting that EPA could lawfully reopen long-settled NAAQS to apply a new and novel standard of review, the Clean Air Act requires EPA to review and revise air quality criteria and NAAQS at least every five years and to "promulgate such ***new*** standards as may be appropriate." 42 U.S.C. § 7409(d)(1) (emphasis added). This carefully chosen language confirms that Congress did not intend for EPA to apply rules like the Proposed Rule to undo existing NAAQS, but instead intended for regular reviews of scientific information to result in new NAAQS.

Even if EPA had statutory authority to apply the Proposed Rule retroactively, it could not do so rationally. *See Sierra Club*, 285 F.3d at 68 (if EPA had authority to implement a rule retroactively, "retroactivity must be 'reasonable,'"). Indeed, retroactive application of the Proposed Rule would undo well-settled rules in a tremendously unfair and irrational way, and would lead to widespread confusion about countless environmental and public health policies and protections.

B. Application of the Proposed Rule to Enforcement Actions, Individual Party Adjudications, or Permit Proceedings Would Be Unlawful.

EPA also seeks comment on whether provisions of the Proposed Rule should apply to enforcement activities, individual party adjudications, or permit proceedings. It should not. Application of the proposed provisions to such matters would be illegal and arbitrary for all the reasons set forth above, as well as for the following additional reasons.

First, with respect to enforcement actions, EPA has no authority to bar the courts or administrative adjudicators from considering relevant evidence merely because that evidence

hasn't passed an arbitrary test for transparency and peer review. The Clean Air Act, for example, vests authority over judicial enforcement actions to the courts, not EPA, and EPA has no authority to dictate to the courts what evidence they can and can't consider, or what weight to give such evidence. *See Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063-64 (D.C. Cir. 2014). Indeed, courts and administrative law judges are equipped with tools to separate out credible and non-credible scientific evidence, *see, e.g.*, Fed. R. Evid. 702; *Daubert*, 509 U.S. 579. Relatedly, whether a scientific study is sufficiently transparent or has been peer reviewed provides no bearing on administrative enforcement of these statutes, which provide enforcement authority over whether there has been a violation of specified requirements and prohibitions, *see, e.g.*, 42 U.S.C. § 7413(a)(1)-(5). It also is wholly irrelevant to determining administrative civil penalties. *See, e.g.*, *id*. § 7413(e). Though the Clean Air Act does allow consideration of "such other factors as justice may require" in setting civil penalties, EPA does not and cannot explain how its transparency and peer review tests could possibly be relevant to whether "justice" requires a different penalty for violation of a prohibition or requirement. If a defendant feels that a standard is unjust because of a lack of data transparency or peer review in supporting studies, the sole remedy is to seek review in the Court of Appeals within 60 days of the standard's publication. The validity of standards cannot be questioned in an enforcement proceeding. *See, e.g.*, 42 U.S.C. § 7607(b)(2).

Second, EPA does not explain how or where its Proposed Rule could be relevant in individual party adjudications. Though the administrative penalty provisions of the Clean Air Act provide for individual party adjudications, *see, e.g.*, 42 U.S.C. § 7413(d)(3)-(4), EPA's proposed procedures bear no relevance or applicability to such adjudications.

Third, the proposed procedures cannot lawfully or rationally be required in the context of EPA decisions to abate "imminent and substantial endangerments" ("ISEs") to human health and the environment. *See, e.g.*, 42 U.S.C. §§ 300(i)(a) (SDWA § 1431(a)), 6973(a) (RCRA § 7003(a)), 7603 (CAA § 303), and 9606(a) (CERCLA § 106(a)). None of these provisions set or authorize limitations on the studies that can be relied upon in identifying ISEs. To the contrary, both courts and the EPA have interpreted these statutes as precautionary in nature, allowing abatement action where there is only a risk of harm. *See, e.g.*, EPA, *Guidance On the Use of Section 303 of the Clean Air Act*, EPA-R08-OAR-2013-0556-0015, at 2-4 (1991) ("Section 303 Guidance"); *see also United States v. Vertac Chemical Corp.*, 453 F.3d 1031, 1045 (8th Cir. 2006) (describing § 9606(a)'s ISE standard as "cautionary" in sanctioning EPA's decision to issue a unilateral administrative order requiring cleanup of former manufacturing site). ISE authorities are so precautionary in nature that they may be used even when the risk of harm is uncertain. *See United States v. Conservation Chem. Co*., 619 F. Supp. 162, 194 (W.D. Mo. 1985) ("Both the courts and Congress have recognized that the evaluation of a risk of harm involves medical and scientific conclusions that clearly lie on the frontiers of scientific knowledge, such that proof with certainty is impossible."). EPA guidelines state that "[i]f the Agency can show a 'reasonable medical concern' created by the suspect emissions, it will have met the 'imminent and substantial endangerment' test of Section 303." Section 303 Guidance at 4.

EPA may be required to make an endangerment finding despite "some residual uncertainty." *Massachusetts v. EPA*, 549 U.S. at 534 (holding that EPA could not avoid its statutory obligation to regulate greenhouse gases by noting the uncertainty surrounding climate change unless the scientific uncertainty was so profound as to preclude EPA from making a reasoned judgment about the risk of harm); *see also Coal. for Responsible Regulation v. EPA*, 684 F.3d 102, 121 (D.C. Cir. 2012) ("existence of some uncertainty does not, without more, warrant invalidation of an endangerment finding. If a statute is 'precautionary in nature' and 'designed to protect the public health,' and the relevant evidence is 'difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge,' EPA need not provide 'rigorous step-by-step proof of cause and effect' to support an endangerment finding." (quoting *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976), a case regarding endangerment findings under § 211(c)(1)(A) of the Clean Air Act). For all the foregoing reasons, the language and purpose of the endangerment provisions would be flouted by a requirement that EPA be barred from (or forced to delay) relying on available peer reviewed studies to decide whether and how to remedy a hazardous substance release, contamination of drinking water, or other immediate threat.

Finally, to the extent EPA decides to apply this Proposed Rule in the context of enforcement, adjudicatory, and permit actions – which it should not – it must first issue a proposal setting out its basis for such a rule and provide opportunity for comment under the Administrative Procedure Act and Clean Air Act § 307(d). EPA cannot rely on the comment opportunity provided by its April 30, 2018 Proposal, as the Proposal provides no notice whatsoever of the substance of what EPA might or might not include in a rule applying to enforcement and other actions excluded from the regulatory text of the proposal. *See* 83 Fed. Reg. at 18,773 (proposed 40 C.F.R. § 30.3).

On Behalf Of:

Alaska Community Action on Toxics
Alianza Naciondal de Campesinas, Inc.
Altamaha Riverkeeper
Animas Riverkeeper
Appalachian Mountain Advocates
Atchafalaya Basinkeeper
Bayou City Waterkeeper
Boulder Waterkeeper
Breast Cancer Prevention Partners
Buffalo River Watershed Alliance
Cahaba Riverkeeper
Little River Waterkeeper
Living Rivers & Colorado Riverkeeper
Lower Susquehanna Riverkeeper Association
Matanzas Riverkeeper
Miami Waterkeeper
Milwaukee Riverkeeper
Missouri Coalition for the Environment
Missouri Confluence Waterkeeper
Mountain Watershed Association
MountainTrue
National Black Justice Coalition

California Communities Against Toxics
California Safe Schools
CATA - The Farmworker Support Committee
Center for Food Safety
Central Maryland Beekeepers Association
Clean Air Council
Clean Air Task Force
Community Alliance for Global Justice
Coosa Riverkeeper
CRLA Foundation
Defenders of Wildlife
Downwinders at Risk
Earthjustice
Environmental Health Strategy Center
Environmental Integrity Project
Environmental Stewardship
Family Farm Defenders
Farms Not Arms
Farmworker Association of Florida
Farmworker Justice
Food & Water Watch
Friends of the Earth
Government Accountability Project
Green Riverkeeper
Greenpeace USA
Hip Hop Caucus
Humane Society of the United States
Humboldt Baykeeper
Huron Environmental Activist League
International Society for Children's Health and the Environment
National Family Farm Coalition
Neighbors for Clean Air
OVEC-Ohio Valley Environmental Coalition
Partnership for Policy Integrity
PCUN
Peace Roots Alliance
Pesticide Action Network North America
Physicians for Social Responsibility
Pollinate Minnesota
Potomac Riverkeeper Network
Rural Empowerment Association for Community Help
Santa Barbara Channelkeeper
Save The Poudre: Poudre Waterkeeper
Save The River, Upper St Lawrence Riverkeeper
Save The Sound - Long Island Soundkeeper
Secular Coalition for America
Sierra Club
Snake River Waterkeeper
Suncoast Waterkeeper
Tennessee Riverkeeper
Tri-Valley CAREs (Communities Against a Radioactive Environment)
UFW Foundation
Union of Concerned Scientists
United Farm Workers
Upper Missouri Waterkeeper
Waterkeeper Alliance
Waterkeepers Chesapeake
Wayne Action for Racial Equality

Iowa Citizens for Community Improvement
Johns Hopkins Center for a Livable Future
Kids To The Country
Kootenai Environmental Alliance
Winyah Rivers Foundation, Inc.
Women's Environment and Development Organization (WEDO)
Worker Justice Center of NY
Yadkin Riverkeeper

U.S. Environmental Protection Agency

Attachment 2

Public Hearing on

Strengthening Transparency in Regulatory Science

9:00 a.m. to 5:45 p.m.

Tuesday, July 17, 2018

U.S. Environmental Protection Agency

1201 Constitution Avenue N.W.

Washington, DC 20460

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US EPA Panel Members:
MS. JENNIFER ORME-ZAVALETA (Hearing Official)
MR. CHRIS ROBBINS (Hearing Official)
MS. MARY ELLEN RADZIKOWSKI (Hearing Official)
MS. CAROLYN HUBBARD (Hearing Official)
MR. BRUCE RODAN (Hearing Official)
MR. KEVIN TEICHMAN
MS. MARIA DOA
MS. LYNN FLOWERS
MS. SUSAN BURDEN
MR. LOU D'AMICO

Non-EPA Panel Members:
Ms. LAUREN HALL, SC&A INC.
Ms. LESLEY STOBERT, SC&A INC.

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1 P R O C E E D I N G S
2 MS. ORME-ZAVALETA: So I want to say
3 hello, and I want to thank you all for coming. We
4 are now calling this public hearing into session.
5 My name is Jennifer Orme-Zevaleta, and I'm with
6 EPA's Office of Research and Development, and I'll
7 be one of the hearing officials today.
8 Kevin Teichman is also with me from the
9 Office of Research and Development, and we also
10 have some contract staff, Nanishka, Lauren, and
11 Lesley from SC&A Incorporated, who will be helping
12 with the logistics.
13 The purpose of today's hearing is to
14 accept public comments on EPA's proposed rule,
15 "Strengthening the Transparency in Regulatory
16 Science."
17 EPA is accepting comments on all aspects
18 of the proposed regulation. This public hearing
19 is a formal legal proceeding, and the testimonies
20 will become part of the administrative record on
21 which EPA will base its decision.
22 Public notice of this hearing was

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1 published in the Federal Register on April 30,
2 2018 (83 FR 18768), and EPA is proposing this rule
3 under the authority of 5 U.S.C 301, in addition to
4 the authorities that were listed in the proposed
5 rule document dated April 30th of 2018.
6 So my role today is to ensure that EPA
7 receives your comments in an orderly fashion, and
8 then -- although EPA panel members here may ask
9 clarifying questions, the intent of this hearing
10 is to hear from you and to listen to your comments
11 and not to discuss or debate the proposal.
12 So now, for a few housekeeping and ground
13 rules. Please refrain from interrupting speakers
14 or asking questions, shouting, noise making, or
15 any disruptive conduct which prevents speakers or
16 hearing officials from being heard are not
17 permitted. Please listen quietly so that we can
18 hear each testimony and to ensure that the court
19 reporter is able to record comments accurately,
20 and listeners on the phone can hear the oral
21 testimonies.
22 For everyone's awareness, the hearing is

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1 open to the press and we may have members of the
2 media present with us today. This event is also
3 open to any form of recording, video, audio, and
4 photos. We ask that you not cause any disruption
5 to those who are testifying or observing the
6 hearing.
7 There is no formal lunch break, so you
8 may leave for lunch and return to the hearing, but
9 just be advised that you'll need to clear security
10 again if you do that.
11 If you would like to make an oral comment
12 on today's hearing and did not preregister to
13 speak, please see the hearing staff just outside
14 here at the door at the registration table, and
15 they'll be able to sign you up.
16 If you would like to provide written
17 comments to the official record, you may hand-
18 submit it to EPA staff today, or mail it, fax it,
19 or e-mail it, your comment. So see the staff at
20 the registration table for instructions on how to
21 submit written comments.
22 There is a comment box at the

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1 registration table where you can leave hard copies
2 of your oral testimony, or written copies. All
3 comments received will be included in the official
4 docket.
5 If you submit written comments, it is not
6 necessary for you to give the same comments
7 orally. Written comments and oral testimonies
8 will receive equal consideration by EPA in
9 preparing the final rulemaking decision.
10 EPA has extended the comment period and
11 written comments must now be received on or before
12 August 16th of 2018. So EPA will only consider
13 comments related to the proposed rule,
14 "Strengthening Transparency in Regulatory
15 Science," so please refrain from making any other
16 comments that are not related to this action.
17 EPA will not provide responses during the
18 hearing, rather EPA will prepare a written summary
19 of comments received that include responses. The
20 Response to Comments document will be available at
21 the time EPA issues its final decision. EPA will
22 not make a final decision until all comments

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1 submitted during the public comment period have
2 been considered.
3 The hearing is being recorded by a court
4 reporter who will be preparing a verbatim record
5 of this hearing, so please speak clearly and
6 slowly into the microphone so that the court
7 reporter can record your comments accurately. A
8 copy of the transcript will be placed in the
9 docket. And this hearing is also being audio
10 streamed through Adobe Connect and via phone
11 lines.
12 The hearing is scheduled from 8:00 a.m.
13 to 8:00 p.m., or one hour after the last
14 registered speaker has spoken, whichever is
15 earlier. And it's divided into three sessions.
16 8:00 a.m. to 12:00 p.m., 12:00 to 4:00, and 4:00
17 to 8:00.
18 Public restrooms are located on both
19 sides down the hall, men's to the left, women's to
20 the right, and we will have staff escort you so
21 that you're able to get through the security point
22 and be able to come back. And please note the

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1 location of emergency exits, primarily as you come
2 in and you know, out where you entered this
3 morning will be the main emergency exit for you.
4 So please take a moment to silence your
5 cell phones. Speakers should have been given a
6 sticker on entry that lists your assigned session,
7 and if you plan to speak and have not received a
8 sticker, please go back to the registration table
9 so they can give you one.
10 For this session, the 8:00 a.m. to 12:00
11 p.m. session, the speaker sticker color is neon
12 green so we can see you. Speakers will be called
13 to the speaker's table, which is located right
14 across from us, and will be coming up in pairs to
15 that speaker's table. When it's your turn to
16 speak, please come up to the table. Watch your
17 step as you come up the steps over there, and
18 state and spell your name slowly so that we can
19 have that for the record. And if you are
20 appearing on behalf of someone else or some
21 organization, be sure to clear that -- make that
22 clear as well. If you are not in the room when

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it's your turn to speak, I will call you after all other speakers have made their oral arguments.

Each speaker is allotted five minutes for remarks, elected and appointed government officials may be provided additional time since they are representing large groups of constituents. Speakers will be notified when their time is ended. We have a time keeping system just over here. It runs by the yellow -- green, yellow, and red-light system. So when you begin to speak the green light will come on and you have five minutes. When you have one-minute left to speak you'll see a yellow light. And then when the red light appears, your time is up. At that moment I will ask you to wrap up your comments so that we can make room for the next speaker to come forward.

Speakers Numbers 1 and 2, if you could go ahead and please come on up and take your seat at the speaker's table. We will start with Speaker Number 1. And again, if I could ask you to please speak directly into the microphone and state and

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spell your name for the record.

And if I could ask, Speakers 3 and 4, if you could just stand at the steps so that you'll be ready, and we'll be able to keep this moving. So, Speaker Number 1.

MR. STEICHEN: Good morning. My name is Ted Steichen, and it's S-T-E-I-C-H-E-N, and I am representing the American Petroleum Industry.

API is the only national trade association -- boy, it's not very bright here. Sorry. The American Petroleum Institute is the only national trade association with all facets of the oil and natural gas industry which supports 10.3 million U.S. speakers (sic).

Sorry. I'm having a little trouble this morning.

All right. So, supports 10.3 million U.S. jobs and nearly 8 percent of the U.S. economy. Our 620 corporate members from large integrative oil companies to small independent companies comprise all segments of the industry. API members are producers, refiners, suppliers,

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retailers, pipe line operators, and marine transporters as well as service supply companies supporting most of the national energy.

The members of API are dedicated to continuous improvement in compatibility with their operations with the environment, while environmentally, economically developing energy resources, supplying high-quality products and services to consumers.

Our members recognize the responsibility to work with the public, the government, and others to develop and use natural resources in an environmentally sound manner that protects the health and safety of employees and the public.

API supports the use of sound science for a critical component of public policy, to the extent possible and consistent with the protections of other compelling interests, such as privacy, trade secrets, intellectual property, and other confidentiality protections, data and analysis used in establishing or evaluating environmental health, welfare and economic impacts

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should be transparent and reproducible and available as early as possible in the rulemaking process.

Transparency and reproducibility should be able to underly -- also be underlying data and information such as environmental and economic impact data and models that are utilized in protecting and predicting the costs, benefits, market impacts, and environmental effects of specific regulations.

API members are aware that there are obstacles to full transparency and reproducibility, and are committed to working with other stakeholders in developing practices and maximize science transparency while preserving existing confidential strictures.

The EPA -- as the EPA goes forward with this rulemaking, API recommends the following principles be followed. Openness to science and related findings underpinning the laws, regulations, standards, and guidance documents. Reproducibility of research and associated

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1 findings, including fully annotated data,
2 methodologies, model inputs, code and other
3 critical information that support the conclusions
4 of research. All of these should be available to
5 the public.
6 The inclusion of clear requirements to
7 ensure that the data underline the decision-making
8 are publicly available in a manner sufficient for
9 independent validation as much as practicable.
10 Privacy concerns are important, but advances in
11 encryption technology and blinding of data may
12 make it possible to enhance transparency while
13 ensure privacy as necessary to comply with the
14 law.
15 Protection for confidential business
16 information used in the regulatory process and
17 supporting actions should also be taken into
18 account, explicitly addressing and highlighting
19 uncertainties in data, models, and analysis when
20 utilizing those studies in decision-making. Broad
21 application of these principles to inform the use
22 of policy for setting scientific, economic, and

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1 environment impact requirements and models that
2 are designed to protect health and environment,
3 engaging stakeholders as early as possible in the
4 decision-making process to ensure application of
5 data transparency principles for studies to be
6 included, and to address how those studies have
7 not been reproduced or are not reproducible will
8 be considered in the process, application of these
9 principles as early as possible in the pre-rule
10 making stage, as technical support documents are
11 prepared.
12 In closing, as described above, API
13 supports the use of sound transparent science and
14 public policy making, and we plan to submit
15 written comments to the docket.
16 MS. ORME-ZAVALETA: Thank you.
17 MS. FELD: Good morning. My name is Jodi
18 Feld, J-O-D-I F-E-L-D, and I'm the Chief Scientist
19 in the New York City office of the New York State
20 Attorney General's Environmental Protection
21 Bureau.
22 On behalf of New York Attorney General,

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1 Barbara Underwood, I thank you for the opportunity
2 to speak before you today. The Office strongly
3 opposes EPA's proposed rule to limit the use of
4 science in agency rulemakings. The proposed rule
5 was developed without any input from the
6 scientific community and has been widely
7 criticized by the scientific and public health
8 communities. It is vague, poorly reasoned, and
9 violates fundamental legal requirements for a
10 valid rulemaking.
11 Most importantly, while the proposed rule
12 has the stated purpose of strengthening the
13 foundation of EPA's regulatory actions, it would
14 have the opposite effect. It would exclude
15 relevant probative scientific studies, models, and
16 other information from EPA decision-making that
17 have been validated by peer review, simply because
18 the underlying data are not available to the
19 public. The proposed rule broadly and squarely
20 conflicts with core EPA statutory duties. It
21 violates the very federal laws that EPA is
22 required to uphold by limiting EPA's access to the

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1 most current, best available, and generally
2 accepted science that these laws mandate be used
3 by EPA in developing new rules and standards.
4 Quite simply, it is bad science.
5 It departs abruptly from the best
6 practices of the scientific community and
7 disregards both well-established reasons why
8 public sharing of all study data is not possible
9 or necessary, and why studies relying on such data
10 demand consideration in agency decision-making.
11 The result of the proposed rule would be
12 to profoundly weaken EPA's science-based
13 regulatory decision-making, and ultimately its
14 protection of public health in the environment in
15 New York and elsewhere across the nation. We urge
16 EPA to abandon this damaging and misguided effort.
17 It appears that the proposed rule was developed
18 with a total absence of independent scientific
19 input. The proposal offers no rationale for the
20 premise that only studies for which the underlying
21 data are publicly available can be used for
22 decision-making, nor any evidence that EPA's

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current approach to selecting studies for decision-making is resulting in scientifically unsound decision-making, or is somehow overly protective of public health and the environment. Hence, at its core, the proposed rule is a solution in search of a problem.

Requiring that study data be publicly available as a prerequisite to its consideration by EPA would be an abrupt and unprecedented break from well-established best practices of the scientific community. The scientific community recognizes what the proposed rule ignores, that there are often very good reasons why some research data simply cannot be fully available to the public, such as the protection of personal privacy and confidentiality.

Within the scientific community the validity of research is judged on multiple grounds, including how well studies are designed, how clearly data are collected, how carefully analysis are performed and described, and how thoroughly findings of related studies are cited.

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In other words, within the scientific community studies are validated through rigorous expert peer review. They are not summarily judged and valid and discarded simply because all underlying data cannot be fully shared.

Perhaps the strongest indicator that the proposed rule is flawed as a matter of science is the overwhelmingly negative reception it has received from the scientific community. We are not aware of a single major independent scientific organization that has expressed support for the proposed rule, while many have urged EPA to stop and reconsider the proposal.

Contrary to EPA's position, the proposed rule would certainly hurt states. EPA standards and regulations are a fundamental important to states and actions that affect these standards and regulations directly affect us. In fact, many states, environmental laws, and regulations explicitly adopt EPA standards. By undermining the basis of EPA standards and regulations, the proposed rule would likely have direct damaging

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impacts on New York and other states' abilities to protect the health and environment of their residents. These impacts will be felt most historically by our most vulnerable populations, the young, the elderly, and the sick, and those living in communities that have borne a disproportionate share of environmental hazards, including communities of color and low-income communities.

From a legal perspective, the proposed rule fails to meet the most fundamental requirements for a valid rulemaking. It is exceedingly vague, creating many more questions than it answers. For example, exactly how, when, and to what the rule will be applied is entirely unclear. And critical information such as its actual cost is entirely missing.

In May, the New York Attorney General, joined by seven other attorneys general, wrote to then, Administrator Pruitt, expressing strong opposition to the proposed rule and calling for it to be withdrawn. Today, the State of New York

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renews our call to Acting Administrator Wheeler to withdraw the proposed rule.

I thank you for your time and for providing me with an opportunity to speak on this important matter.

MS. LAUREN HALL: Thank you. If we could have Speakers 3 and 4 come to the table, and then 5 and 6 on-deck?

MR. SUSSMAN: Good morning. My name is Bob Sussman, and I am a former EPA official in the Clinton and Obama --

MS. HALL: Could you bring your microphone --

MR. SUSSMAN: -- administrations --

MS. HALL: Yes, thank you.

MR. SUSSMAN: -- and now a consultant and an attorney.

I'm here today representing Safer Chemicals, Healthy Families, which leads a coalition of 450 organizations and businesses united by a common concern about toxic chemicals in our homes, places of work, and products we use

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every day.

I believe that the EPA proposal we are discussing today is flawed and misconceived. In the name of transparency, it will burden EPA scientists with unnecessary and costly procedures that run counter to the Agency's long-standing obligation to base public health decisions on the best available science.

The premise of the proposal is that unless EPA can guarantee full public access to a study's underlying data, the study must be deemed unreliable and should play no role in assessing a pollutant or chemical's effects on public health. This premise ignores the many ways in which the scientific community, regulators, and the public have traditionally determined the quality and relevance of scientific evidence.

Study reports typically explain the protocols use to gather data, the methods used for data analysis, the doses or exposure concentrations at which effects were and were not observed, the nature, severity, and incidence of

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such effects, and any unusual occurrences that may affect interpretation of the results.

This information plays an important role in the peer review process, informing the judgment of independent reviewers as to whether a study is worthy of publication in the scientific literature. Agency reviewers likewise consider these indicators of reliability in deciding how much weight a study deserves in making judgments about hazard and risk.

In principle, no one disputes the benefits of improving access to underlying data. The goals of open science have received support from several organizations in leading scientific journals and research institutions. These voluntary efforts, however, do not justify the unprecedented step of requiring EPA to guarantee access to the underlying data for every study it may use for decision-making, and to forfeit the ability to consider a study if this requirement has not been met.

EPA scientists working on risk and hazard

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assessments collect and review thousands of studies. Published reports of these studies typically do not include all underlying data. In such cases, EPA would need to contact the researcher, ascertain the nature and extent of underlying data, and put in place a mechanism for the public to access the data.

Even with diligent efforts by EPA, there are many reasons why disclosure of data sufficient to replicate a study may be impossible. The EPA proposal duly notes these obstacles to study replication and provides that exemptions may be granted on a case-by-case basis. But an exemption process will add to the considerable cost and effort required to implement the proposed rule and will undoubtedly result in disputes and even litigation over whether exemptions are justified. Is the damage it will inflict on the quality and timeliness of EPA scientists justified by the benefits of the proposed rule?

EPA leaders have painted a bleak picture of EPA reliance on quote, "secret science"

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developed behind, quote, "closed doors," based on data that has, quote, "been withheld from the American people."

This is not the reality that I experienced in my several years at EPA. I saw a very different reality. I saw EPA science assessments providing an exhaustive and critical review of relevant studies, and a full explanation of how they're being interpreted. I saw extensive information about each study being placed in the public record. I saw public comment and peer review of all EPA assessments. And of course, as part of public comment, members of the regulatory community had an opportunity at any time to replicate studies they deemed flawed.

In short, the problem that the proposed rule seeks to fix is imaginary. In conclusion, the Agency's leadership needs to fundamentally rethink the proposed rule. The stakes for EPA science and the protection of public health are simply too high to finalize a proposal which is deeply problematic and unnecessary. Thank you.

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MS. ORME-ZAVALETA: Thank you.

DR. ROSENBERG: Good morning. I am Dr. Andrew Rosenberg, R-O-S-E-N-B-E-R-G. I'm the Director of the Center for Science and Democracy at the Union of Concerned Scientists. And we advocate for the role of science and public policy.

I'm here today to ask that you rescind this proposed rule because it would only restrict EPA's ability to use the best available science to fulfill its mission of protecting public health and the environment, while doing nothing to improve transparency and decision-making.

First and foremost, the proposal is fatally flawed because it provides almost no justification of analysis of the impacts of the proposed change in policy. There is no cost-benefit analysis of the rule with respect to the agency, and external researches, nor how it would affect EPA's mission and critical work.

Additionally, the proposal would affect -- effectively prevent the EPA from using many

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kinds of scientific studies vital to its decision-making. This includes, but it is not limited to studies that rely on personal health data, confidential business information, intellectual property, or older studies where authors and data sources may not be accessible.

Without the ability to use this scientific information EPA would be unable to meet its mission and statutory obligations. This proposal would make it significantly harder for EPA to use the best available science to protect the public, including from harmful emissions of hazardous air pollutants, particulate matter and ozone, exposure to dangerous chemicals and commerce, drinking water contaminated with toxic chemicals, such as PFAS or lead.

Further, CBO has calculated that such restrictions would substantially increase costs and burdens to an agency that is already experiencing budget cuts, reorganizations and understaffing, thus undermining the ability of EPA to make decisions based on science.

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The proposed rule could also prevent the Agency from addressing the impacts of dangerous chemicals at low concentrations where direct measurements are very difficult. This would have the effect of leaving Americans unprotected, even when there was clear indication of harm to human health.

I have over 30 years of experience in government service, academia, and non-profit leadership. I've offered -- authored or reviewed hundreds of peer-reviewed scientific papers. As part of my government service I worked as a scientist and in a policy position at a regulatory agency, and universities as a faculty member and dean. I understand how agencies use science in policy making, how research at universities is conducted, and how these entities incorporate best practices of transparency into their scientific work. As a frequent peer reviewer, I do not review the raw data for studies, since that would tell me little. I review the research questions, the methods that summarize data, the results and

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conclusions in order to assess the quality of the work. EPA's proposed rule would do nothing to improve transparency for scientists, policy makers, or the public.

Crafting the rule without consulting with the scientific community is a fatal error for this proposal. Even the Agency's own Science Advisory Board has noted the need to consult with scientists in any further development of this proposal.

A further fatal flaw is that the proposed rule would replace scientific evidence with political judgment. The rule would grant the EPA administrator broad authority to exclude individual studies or entire decisions from being subject to its provisions. Decisions on which science is to rely on should be made by the Agency's scientific experts based on established criteria for best available science.

Five minutes is not enough time to cover all the problems with this proposal. At best, this proposed rule is a misguided attempt at

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transparency. At worst, it is a back-door attempt to prevent EPA from protecting public health. UCS supports real transparency reforms. We support scientific integrity policies that prevent political interference in scientific analysis and reporting. We do not believe researchers should be put in the absurd position of choosing between protecting study participant privacy or informing the EPA's effort to protect public health and safety.

On behalf of the Union of Concerned Scientists, and I have 500,000 supporters, I urge the EPA not to move forward with this rulemaking and to continue to allow agency scientists and policy analysts to use the best science available to inform their work. Thank you very much.

MS. HALL: Thank you. Would Paul Tonko and Suzanne Bonamici please approach the speaker's table. Speakers A and B, respectively. And Speakers 5, Daniel Greenbaum, and 6, Jennifer McPartland, please take your seats at the on-deck circle.

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MR. TONKO: Good morning.

MS. ORME-ZAVALETA: Good morning.

MR. TONKO: Can I begin? Okay. Thank you. Good morning and thank you for the opportunity to address the panel.

I am Congressman Paul Tonko. I represent the 20th Congressional District of New York State, more specifically the Capital Region and Mohawk Valley, an area rich in environmental stewardship.

As the Energy and Commerce, Environment Subcommittee ranking member, I have come here today to express grave concerns about the Environment Protection Agency's proposed rule published on April 30th of 2018, entitled "Strengthening Transparency in Regulatory Science."

This proposal would severely limit the types of research that EPA could take into account when developing policies. It has been cloaked in arguments about transparency. But let's all admit here that this emperor has no clothes. This has nothing to do with transparency. It is a thinly

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veiled campaign to limit serious and highly credible scientific research that supports critical regulatory action.

This administration has used this bad faith argument about transparency to say that the many studies, including many epidemiological studies that rely on private, personal, medical data should be excluded entirely from EPA rulemaking. Why would a science-driver public agency undertake such a radical departure from existing and widely accepted scientific standards? I have yet to hear a credible answer to this question that is not rooted in favors to industry polluters.

The current political leadership at EPA has shown a pattern of bad faith in pushing policies that undermine this Agency's -- EPA's mission, and the public trust.

Today's proposal and its false claims about transparency are consistent with that pattern; a fact that was put on full display when the administration realized its broad approach

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would hurt regulated industries too, since many EPA chemical reviews rely upon confidential business information. To get around this, the rule would give the EPA administrator complete discretion to exempt studies, especially or essentially guaranteeing that political interests will always matter more than science. That's why I refer to this policy as selective science.

This proposed rule would be used to erode landmark achievements in public health and environmental safety. For example, we know the Clean Power Plan would have led to reductions in pollution that were predicted to prevent some 3,600 premature deaths, 19,000 asthma attacks in children, and 300,000 missed school and work days each year. Many of these health benefits were partially determined by landmark clean air studies like the Harvard Six Cities Study.

Opponents of Clean Air Act protections would like nothing more than to see such landmark public health findings excluded from EPA reviews. I'm not here speaking alone. Nearly 1,000

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scientists in many leading scientific organizations are united in vocally opposing this policy. Countless everyday Americans stand with us too, with many more listening in and watching for news to see if anyone in a position to do something about this will finally admit the obvious; this is not about transparency. This is not about protecting human health or our environment. This emperor, again, has no clothes.

This rule would limit the scientific research available to EPA policy makers as they draft public protections and environmental guidelines. I implore EPA to put science and public interest ahead of political and special interests, and withdraw this rule, ill-conceived, that's based on -- its negative impacts on science and public health. A very discouraging and concerning proposal. And I just felt compelled to come here today and vehemently speak against it.

MS. ORME-ZAVALETA: Thank you, sir.

MS. BONAMICI: Thank you. Good morning.

MS. ORME-ZAVALETA: Good morning.

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MS. BONAMICI: And thank you to Acting Administrator Wheeler and Director Sinks. I am Suzanne Bonamici. I represent the First Congressional District of the State of Oregon. I serve on the House Committee on Science, Space, and Technology, where I am the ranking Democrat on the Subcommittee on Environment. I appreciate the opportunity to testify before you today.

I am opposed to the Environmental Protection Agency's proposed rule titled, "Strengthening Transparency in Regulatory Science." The proposed rule would impede, if not eradicate the EPA's ability to protect Americans from significant risks to human health and to the environment by limiting the scope of research that the EPA could consider in making decisions.

The proposed rule perpetuates the incorrect notion that the science the EPA relies on is somehow hidden. It is not. This misconception is based on conflating the meaning of secret and confidential. None of the information used by the EPA is secret. Some of

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the information may be confidential if, for example, it includes the personal health information of individuals who participated in a study.

As a cornerstone of its regulatory process, the EPA relies on peer-reviewed science. The EPA already publicly discloses studies that support regulatory action. The proposed rule simply attempts to block access to good science. Much of the science that is used to inform regulatory actions is developed outside of the agency. Scientific studies often include personal information and other confidential data. Because this data is legally protected from disclosure, the EPA would be forced to ignore valuable information discovered during their research, because it contains confidential information. This would have chilling consequences for the EPA and for every person who benefits from clean air and clean water.

It is also deeply troubling that the proposed rule is inconsistent with the Agency's

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statutory obligation to use the best available science as required in the Toxic Substances Control Act, Safe Drinking Water Act, and Clean Water Act. The proposed rule would preclude the use of a range of scientific research that has long been used to safeguard the public.

There is also tremendous uncertainty whether the proposed rule would retroactively apply to existing standards and regulations. Retroactive application would severely undermine existing public health and environmental protections that keep the public safe and healthy.

Transparency is a laudable goal, and it could be accomplished through collaboration with, and input from the scientific community. It is noteworthy that thousands of scientists and many leading scientific originations also propose this proposed rule. If the proposed rule is implemented it is possible, or even likely, that scientists, organizations, and research institutions will be less inclined to participate in EPA funded research because of the risk of

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1 improperly disclosing personal information. It
2 may also be more challenging for researchers to
3 recruit participants for their studies because of
4 the fear that personal data could be shared.
5 Over the last few years, the House
6 Committee on Science, Space, and Technology has
7 considered several iterations of legislation that
8 have many similarities to the proposed rule. I
9 have been a vocal opponent of these bills for the
10 reasons I just stated.
11 I also want to note that despite repeated
12 efforts by the majority, the so-called secret
13 science legislation has not passed both chambers.
14 Congress has the sole constitutional authority to
15 legislate, and this proposed rule is an
16 administrative attempt to circumvent the
17 legislative process. I strongly urge you to
18 withdraw this proposed rule. It will undermine
19 scientific integrity, jeopardize bedrock public
20 health and environmental standards, and endanger
21 the EPA's ability to protect the American people,
22 which is its mission.

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1 Thank you for the consideration of my
2 testimony.
3 MS. ORME-ZAVALETA: Thank you both for
4 coming.
5 MR. TONKO: Our pleasure.
6 MS. HALL: Would Daniel Greenbaum,
7 Speaker Number 5 and Speaker Number 6, Jennifer
8 McPartland, please approach the speaker's table.
9 And would Speaker Number 7, David Michaels and
10 Speaker Number 8, Paul Billings, please take a
11 seat in the on-deck circle.
12 MR. GREENBAUM: Let there be light. And
13 there was light.
14 My name is Daniel Greenbaum. That's
15 green, like the color, B-A-U-M. I'm the President
16 of the Health Effects Institute, and I'm very
17 pleased on behalf of the Health Effects Institute
18 to provide these brief oral comments today. We
19 are preparing and will submit much more detailed
20 written comments.
21 As many in this audience know, HEI has a
22 longstanding commitment to the principles being --

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1 attempting to be addressed by this proposal,
2 producing science of the highest integrity and
3 quality with special attention to issues of
4 reproducibility and transparency.
5 This includes rigorous research and
6 statistical design, subject to competition,
7 continuous oversight, data quality assurance
8 audits, and more, extensive efforts that test all
9 findings against a wide range of different
10 statistical techniques and assumptions, intensive
11 and independent peer review with all results
12 published, and an active data access policy which
13 for nearly 20 years has been working to ensure
14 access to underlying data for all HEI funded
15 studies.
16 In our view, reproducibility is a
17 critical challenge for science. Can the results
18 of an important study be reproduced? However, in
19 our view the most effective way to test
20 reproducibility and the validity of science is not
21 necessarily to simply reproduce the same results
22 in the same data sets. Rather it is most

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1 important to answer the question, “Are the results
2 consistent when tested in other independent
3 studies?” For example, studies that use new and
4 different data sets not affiliated with the
5 original studies. Studies that have different
6 investigators applying the same and/or alternative
7 statistical techniques. And studies that test the
8 sensitivity of the results against a wide range of
9 possible other explanations like smoking or
10 socioeconomic status.
11 In a limited number of cases where there
12 are not comparable studies, it may be useful to
13 gain access to the original study data and
14 analytic codes to allow for independent
15 evaluation. Can the original results be
16 replicated, and are they robust to a wide range of
17 alternative assumptions, models, and potential
18 confounders? This is, of course, exactly what the
19 Health Effects Institute did when we conduced an
20 independent rigorous reanalysis of the Harvard Six
21 Cities and American Cancer Society studies. And
22 I've attached and will submit the summary

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1 description of that reanalysis from HEI's final
2 report.
3 This approach can and did provide
4 comprehensive assurance of the quality, integrity,
5 and validity of the original results. However,
6 this is a highly cost-intensive and time-consuming
7 endeavor, which should only be applied in cases
8 where there are only one or just a few studies in
9 a particular arena.
10 HEI also agrees with the continued need
11 to enhance transparency and data access, but would
12 note that these issues are not new. We've had our
13 own data access policy for over 20 years, and have
14 been -- and they've been addressed now for over 15
15 yeas by administrations from both parties, and by
16 the scientific community. This is -- it included
17 guidelines for the Information Quality Act adopted
18 by OIRA in 2002, numerous actions by the
19 scientific community and journals to enhance
20 access, and most recently the requirements for
21 enhanced data access across the federal government
22 promulgated by OSTP in February 2013.

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1 We would strongly urge EPA to review the
2 progress already made under these several major
3 initiatives and to carefully consider whether or
4 not there are additional efforts that could
5 further enhance transparency and to do so before
6 proceeding with a final ruling.
7 Finally, access to private medical
8 information is essential to conducting high
9 quality and reproducible air quality and health
10 research. There are of course longstanding
11 federal rules for protecting the privacy of
12 individual medical information of the subjects of
13 studies. And gaining access to data from older
14 studies may be difficult, but given the privacy
15 commitments that were made to study subjects in
16 the past.
17 However, there are today, several means
18 to make such data available to investigators with
19 appropriate privacy protections. Medicare makes
20 it available, federal research data centers make
21 it available, and many investigators already have
22 been taking advantage of these.

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1 Although it is possible, as some have
2 suggested, to create a depersonalized data set by
3 stripping all personal identifiers, such as
4 address, date of birth, et cetera, it's not
5 possible to conduct a high-quality air pollution
6 and health study without knowing the location of
7 those being studied. I.e., Where do they live and
8 what are the sources and levels of their air
9 pollution exposure? So it can't be simply put on
10 a disk and handed out.
11 Thank you for this opportunity to
12 testify. We look forward to submitting our
13 detailed written comments, and would welcome the
14 opportunity to further assist EPA in these efforts
15 to ensure that the widest array of science is
16 available for decisions.
17 MS. ORME-ZAVALETA: Thank you.
18 MS. McPARTLAND: Good morning. My name
19 is Jennifer McPartland, M-C-P-A-R-T-L-A-N-D, and
20 I'm a Senior Scientist at Environment Defense
21 Fund.
22 EPA's proposed rule represents a

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1 disregard for the Agency's core mission,
2 protection of human health and the environment.
3 Under the guise of transparency, EPA's proposal
4 handcuffs the Agency's use of best available
5 science in violation of many of its statutes. If
6 finalized, the rule will erode critical public
7 health protections, and with them, the scientific
8 integrity and public trust of the agency.
9 EPA's censored science proposal would
10 prohibit EPA's use of critical scientific studies
11 in developing regulatory requirements unless all
12 the data underlying the studies have been made
13 public. As the authors of this proposal know
14 well, this unnecessary and unworkable standard
15 would effectively bar the Agency from using high-
16 quality scientific research in studying public
17 health safeguards.
18 The data underlying many scientific
19 studies are not publicly available and cannot be
20 made publicly available. For example, research
21 involving human subjects often rely on medical or
22 other personal information; information that

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1 researchers cannot make public.
2 Additionally, advances in data science
3 have made it increasingly more challenging to
4 effectively deidentify study subjects and protect
5 their privacy. In other instances, studies may
6 have been published decades ago and the underlying
7 data are no longer available. It is exactly these
8 types of studies that EPA and other authorities
9 use to protect people from harmful environmental
10 exposures like lead, formaldehyde, methylene
11 chloride, benzyne, arsenic, and perchlorate, just
12 to name a few. It is the science generated by our
13 most prestigious scientific institutions. It is
14 the knowledge we rely on to ensure our water is
15 safe to drink, our air is safe to breath, and our
16 land is safe for our children to play.
17 Beyond jeopardizing critical public
18 health protections, the proposed rule completely
19 disregards established effectiveness mechanisms
20 used to vet scientific research including peer-
21 review, data sharing agreements, and consensus in
22 findings across multiple studies. Indeed, EPA

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1 provides no explanation or justification, showing
2 that this proposal would improve upon these
3 established mechanisms.
4 The proposed rule also raises several
5 troubling concepts that are contrary to scientific
6 best practices and chemical assessment, as
7 discussed extensively in the Seminole National
8 Academy's report, Science and Decisions.
9 Specifically, the proposed rule ignores
10 the report's conclusions that thresholds of effect
11 for chemical exposures are the exception rather
12 than the rule, given by a logical and exposure
13 variability across the population. The rule also
14 seeks to demote the use of health protective
15 defaults and risk assessment, again at odds with
16 the recommendations of the National Academies.
17 Additionally, the proposal gives more
18 value to studies in employ of a variety of dose
19 response models, an approach that can be
20 misleading. Multiple bad analysis does not make a
21 study more credible.
22 More broadly, the proposed rule seeks to

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1 codify scientific practices and irregulation. It
2 is a consistently frowned upon approach given the
3 continuously evolving nature of science. EPA's
4 development of the proposal also represents a
5 total disregard for process. The Agency
6 sidestepped review by its external Scientific
7 Advisory Board, which has now voiced serious
8 concerns about the proposal and has recommended
9 that it undergo full SAB review before possible
10 finalization.
11 The White House OMB review of the
12 proposal was also quite dubious, involving a
13 revision to the original date its review had been
14 completed to seemingly align with the fact that
15 former Administrator Pruitt had signed the
16 proposed rule a day prior. The final OMB review
17 process took course over just a few days, an
18 impossible amount of time for any legitimate
19 interagency review of the complex scientific
20 issues at stake in this rulemaking, even though
21 they have implications for all other federal
22 agencies that rely on sound science.

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1 Not surprisingly, the proposed rule does
2 not grapple with the challenging steps necessary
3 for legitimate effort to support greater data
4 availability. It does not consider the digital
5 infrastructure that would be required to make
6 underlying study data publicly available in a
7 secure manner, nor the resources needed for
8 researchers in the Agency to use and maintain such
9 a system.
10 Indeed, the congressional budget office
11 estimated that a similar piece of legislation
12 would cost millions of dollars. Americans need
13 and expect the EPA to use the best available
14 science. Right now, Americans across the country
15 are drinking water contaminated with per- and
16 polyfluoroalkyl substances, or PFASs.
17 In May, EPA publicly committed to
18 initiating steps to regulate two of the most well-
19 studied, PFOA and PFOS, toxic substances linked to
20 cancer, thyroid effects, and reproductive harm.
21 Some of the best available data on PFOA comes from
22 the C8 Health Project, which involved a community-

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1 wide assessment of 69,000 residents living around
2 Parkersburg, West Virginia, who had been exposed
3 to PFOA for decades. Studies resulting from the
4 project will be critical to EPA as it takes steps
5 to address PFOA and PFOS, yet the censored science
6 proposal would make it difficult, if not
7 impossible for EPA to rely on those studies.
8 EPA's censored science proposal serves
9 the interest of polluters, not the public. It is
10 designed to undermine EPA's use of critical
11 research, EDF supports, meaning full transparency
12 and science, and the ongoing efforts in the
13 scientific community provide that transparency.
14 But this proposal is not about transparency. It
15 is about rolling back public health protections
16 and environmental protections.
17 EDF strongly recommends that EPA withdraw
18 the proposed rule. Thank you.
19 MS. HALL: Thank you. Would Speaker
20 Number 7, David Michaels, and Speaker Number 8,
21 Paul Billings, please approach the speaker's
22 table. And Speaker Number 9, Gary Timm, and

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1 Speaker Number 10, Tyler Smith, please take a seat
2 in the on-deck chairs.
3 MR. MICHAELS: Good morning. My name is
4 David Michaels, M-I-C-H-A-E-L-S. I'm an
5 epidemiologist and Professor of Environmental and
6 Occupational Health at the George Washington
7 University School of Public Health. I'm also
8 submitting a longer set of comments, copies of
9 which I have available.
10 From 2009 to January 2017, I served as
11 Assistant Secretary of Labor for OSHA, the longest
12 serving in OSHA's history. From 1998 to 2001, I
13 was Assistant Secretary of Energy for Environment,
14 Safety, and Health, charged with protecting the
15 workers, community, residents, and environment in
16 and around the nation's nuclear weapons complex.
17 As a scientist who has been deeply
18 involved in promulgating regulations that protect
19 the public's safety, health, and environment, I
20 recognize the importance of open science and using
21 the best available science. However, the proposed
22 rule does not accomplish these goals. Instead, it

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1 would make it more difficult for EPA to use
2 scientific findings to protect public health. I
3 have no doubt it would result in more people made
4 sick by pollution or toxic chemicals that would
5 have been prevented in the absence of this new
6 regulation.
7 This cynical approach proposed by EPA can
8 be best described as weaponized transparency.
9 Decades ago, when studies started to show that
10 smoking killed not only smokers, but also their
11 non-smoking spouses, the tobacco industry
12 recognized the government would use this evidence
13 to reduce smoking. In response, the tobacco
14 industry demanded access to the raw data of these
15 studies.
16 Big tobacco turned transparency, an
17 important scientific principal, into a weapon.
18 The strategy worked for tobacco for years, helping
19 to delay regulation and increase the death toll
20 from smoking related illness. Since then,
21 polluters and manufacturers of deadly products
22 have followed big tobacco's playbook. First

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1 supporting legislation, and then when that was
2 unsuccessful, this proposed rule.
3 If promulgated, this regulation would
4 permit the EPA administrator to deny the Agency
5 use of findings of any study unless the raw data
6 and other related materials are provided to the
7 Agency and posted on the Agency's website. There
8 are no constraints on the administrator. She or
9 he is not required to provide any rationale for
10 rejecting a study because the underlying
11 information is not publicly available.
12 The underlying justification for this
13 quote/unquote, "transparency proposal," is a
14 caricature of how science really works. It is not
15 sound science. It is something that sounds like
16 science, but isn't.
17 While in theory, most studies could be
18 reproduced, they rarely are because it's a waste
19 of resources. The scientific enterprise involves
20 approaching the same question in different ways to
21 determine if the results support each other.
22 Reanalyzing the same study over and over is little

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1 different from checking on a surprising newspaper
2 article by buying additional copies of the same
3 newspaper to see if it says the same thing.
4 Under the provisions of the
5 Administrative Procedures Act, the EPA
6 administrator does not have the authority to
7 refuse to consider any comments submitted to the
8 agency. If he or she thinks it's not valid,
9 inaccurate, or inapplicable, she or he must
10 explain why. Under the EPA submissions, including
11 scientific studies, cannot arbitrarily or
12 capriciously be discarded because the underlying
13 data are not provided.
14 When I was an OSHA administrator, we
15 wanted to protect the integrity of the science
16 used in setting regulations, so we explored asking
17 for conflict of interest disclosures, similar to
18 those requested by every leading scientific and
19 medical journal.
20 Our legal experts determined that we
21 could request this disclosure, but we could not
22 reject submissions that failed to include them.

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1 This is a comparable situation; rejecting
2 submitted studies because the underlying data are
3 not available is prohibited under the EPA.
4 Furthermore, many of the EPA's
5 authorizing laws require the Agency to use the
6 best science. For example, the Clean Air Act
7 mandates that air quality criteria accurately
8 reflect the latest scientific knowledge. In the
9 past the EPA has considered all available studies
10 in issuing these criteria without consideration of
11 the availability of the underlying data.
12 Promulgation of this proposed rule would be a
13 violation of these provisions of the Clean Air
14 Act.
15 When the loss similar to this NPRM was
16 first considered by congress, the EPA told the
17 Congressional Budget Office that it estimated the
18 cost of gathering, redacting, and posting the data
19 on the public website, at $250,000,000 annually.
20 The cost estimate made by the current
21 administration for a substantially similar law
22 dropped to $1 million a year from $250,000,000 a

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1 year, because in the candid shocking words of the
2 CBO, EPA officials explained this approach would
3 significantly reduce the number of studies the
4 Agency relies on when issuing or proposing covered
5 actions.
6 In summary, by turning scientific
7 transparency into a virtual weapon, the EPA will
8 inflict severe damage to the nation's scientific
9 enterprise. It will undermine the credibility and
10 application of scientific evidence and impose
11 costs and impediments that will discourage
12 scientists from undertaking studies of great
13 importance. Limiting the EPA's use of scientific
14 evidence in the name of increased transparency
15 will impede its ability to protect the health,
16 safety, and environment of the nation. This
17 proposal must be withdrawn.
18 MS. ORME-ZAVALETA: Thank you.
19 MR. BILLINGS: Good morning. I am Paul
20 Billings, B-I-L-L-I-N-G-S, National Senior Vice
21 President Public Policy at the American Lung
22 Association. The American Lung Association is the

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1 nation's oldest voluntary health agency. Our
2 volunteer leaders take great pride in that our
3 work is always grounded in the best available
4 science. The American Lung Association opposes
5 this rule and we urge the EPA to withdraw it.
6 Make no mistake, this proposal is not an
7 effort to strengthen transparency or improve
8 regulatory science. As I will discuss, this
9 proposal is an effort to exclude important studies
10 whose conclusions, especially studies that shows
11 particulate air pollution causes premature death,
12 are inconvenient. Together with the efforts to
13 discount or exclude benefits from pollution
14 reductions, this is a coordinated effort to ignore
15 the science that is inconvenient to EPA's agenda
16 to roll back regulations that reduce air pollution
17 and save lives.
18 The EPA Science Advisory Board has asked
19 to review the rule under the authority vested in
20 it by the Environmental Research, Development and
21 Demonstration Authorization Act. The SAB sent a
22 letter to the EPA administrator, raising many of

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the same scientific issues of confidentiality, feasibility, and the need for a clearer definition of crucial concepts, such as replication and validation. We urge the EPA to fully consult with the SAB before moving forward with this rule.

After the SAB review is complete, EPA should either withdraw the proposal, or provide an additional opportunity for public comment based on that SAB review.

We are disappointed that the EPA has made this proposal. This is not a new fight. It started in the early 1990s, when the tobacco industry tried to undermine the science that supported EPA's landmark risk assessment that showed that second-hand smoke kills. The tobacco industry and its allies lost a decade-long fight about whether or not second-hand smoke causes lung cancer, heart disease, asthma attacks, and other adverse health effects.

We know many of the details the tobacco industry's efforts, because -- as a result of the landmark tobacco litigation, nearly 90 million

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pages of tobacco industry documents are housed at the University of California, San Francisco, Truth Tobacco Industry Documents library. Now we know the truth.

Within this archive are documents that show how PR firms, lawyers, and front groups attempted to undermine the credibility of EPA science. The documents show the tobacco industry launched this effort in the name of sound science that not only attacked the second-hand smoke risk assessment, but EPA's efforts to protect the public from ozone air pollution, radon, pesticides, and more. Remember, in 2006, the big tobacco companies were found guilty of civil racketeering for their decades-long conspiracy to defraud the public about the health risks associated with smoking.

The attack on science continued throughout the 90s, when EPA set the first standard for fine particulate matter. The PM2.5 standard. That national ambient air quality standard has saved thousands of lives. This was a

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concerted effort by industry and the tobacco industry and their allies, and make no mistake, tobacco industry did not only focus on second-hand smoke. They attacked all of EPA's science. The other polluters came along for the ride and now we're leading that effort.

There was a concerted effort to undermine the Six Cities Study, and the American Cancer Society study. To address the questions being raised, and we just heard from the Health Effects Institute, the HEI, while protecting patient confidentiality, conducted an independent review of the data and these studies. The HEI reaffirmed the results from those studies. These landmark studies were key to informing the rules that cut PM2.5 pollution over the past two decades. Thousands of people are alive, and millions are breathing easier because of those efforts.

These studies depend on patient participation. Protecting patient confidentiality must be paramount and is key to recruiting study participants. This proposal will censor science,

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will exclude important well-done peer-reviewed studies that are informing EPA actions, or will threaten that patient confidentiality. This is an unacceptable choice. EPA must use the best science, with within established frameworks, and not limit access to the best science to inform regulatory decisions. We urge the EPA to withdraw this proposal. Thank you very much.

MS. HALL: Thank you, both.

Would Speaker Number 9, Gary Timm, and Speaker Number 10, Tyler Smith, please come up to the speaker's table. Would Speaker Number 11, Eugenia Economos, and Speaker Number 12, Anne LeHuray, please take your seat in the on-deck chairs.

MR. TIMM: Good morning. My name is Gary Timm, G-A-R-Y T-I-M-M. I worked at EPA for 38 years and retired in 2011.

I was Chief of the Chemical Testing Branch in the Office of Pollution, Prevention, and Toxics for 10 of those years. The Chemical Testing Branch is responsible for implementing the

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1 testing provisions of Section 4 of the Toxic
2 Substances Control Act.
3 Today, my remarks will focus on three
4 things. Our studies traditionally used in support
5 of regulation, and vis-à-vis, the proposed
6 transparency policy, it's interaction with TSCA
7 Section 4, and its interaction with our
8 obligations to accept studies conducted in
9 accordance with OECD test guidelines.
10 Let us be clear, if EPA had adopted this
11 data transparency limitation and past risk
12 assessments, EPA would not have been able to take
13 many of its historic actions to protect children,
14 families, and the environment. No reduction or
15 elimination of the exposure to children to lead
16 and paint, gasoline and drinking water, no air
17 quality standards for particulate matter and other
18 air pollutants, and the list goes on and on.
19 The proposed policy would affect
20 assessments that will soon be carried out under
21 TSCA Section 6. TSCA gives EPA the authority to
22 regulate the manufacture, processing, distribution

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1 and commerce, use, and disposal of chemicals. The
2 problem formulation documents, which set forth
3 EPA's approach for assessing the first 10
4 chemicals under the amended TSCA are open for
5 public comment now.
6 How these chemicals are assessed will be
7 the model for future assessments. The proposed
8 policy would in fact make it impossible for EPA to
9 consider the full array of well-conducted and peer
10 reviewed scientific studies of the health and
11 environmental effects of pollution. It would bias
12 the body of information in favor of industry
13 supplied studies, since they would all have the
14 means to provide the underlying data.
15 Assessment of all relevant scientific
16 information is essential in making sound judgments
17 about protecting human health and the environment.
18 And it is a legal requirement in all major
19 environmental legislation.
20 TSCA also contains provisions to require
21 chemical manufactures to test the chemicals that
22 they manufacture and process. To require industry

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1 to test chemicals under Section 4, EPA must make a
2 set of legal findings. It is the data inadequacy
3 finding that we are interested in today, for it is
4 the nexus between TSCA Section 4, and the proposed
5 transparency policy.
6 To make this finding, EPA conducts a
7 thorough literature search and usually issues a
8 rule to require studies that have not been
9 published to be submitted to the agency.
10 Typically, the bulk of information considered,
11 however, is studies published in the peer reviewed
12 scientific journals. Despite being accepted by
13 the scientific community, these studies do not
14 meet the transparency requirements of the
15 published rule, since it requires that all raw
16 underlying data and the models used to analyze the
17 data supporting their study are available for
18 public review.
19 Thus, if the Transparency Rule were in
20 effect, under TSCA Section 4's second finding, EPA
21 would have to judge studies from peer reviewed
22 journals as inadequate. Ignoring this large

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1 category of information would cost industry
2 hundreds of millions of dollars to repeat
3 perfectly good scientifically acceptable studies,
4 which the public would ultimately pay for through
5 higher prices. And it would significant delay, or
6 in some cases preclude assessment and regulation
7 of risks to human health and environment.
8 Another aspect not discussed in the
9 proposed transparency policy is the obligation of
10 the U.S. to accept data generated in accordance
11 with the Mutual Acceptance of Data treaty. The
12 U.S. and other Organizations for Economic Co-
13 operation and Development member countries realize
14 that differences in testing requirements on
15 countries, meant that companies would in some
16 cases have to retest a chemical in order to market
17 it in other areas. This was needlessly costly and
18 resulted in a delay in obtaining information
19 needed for regulatory assessment.
20 As a result, the OECD member nations
21 agreed to accept, for regulatory purposes, data
22 generated in accordance with the OECD test

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1 guidelines. Submission of underlying data is not
2 a requirement of the Mutual Acceptance of Data
3 treaty. Therefore, the proposed policy which
4 requires underlying data to be made available to
5 be used for risk assessments would run counter to
6 our obligations under the Mutual Acceptance of
7 Data treaty.
8 In short, the proposed policy is a trojan
9 horse. I can only conclude that this proposal
10 constitutes fraud, as it is deceptive. Waste,
11 rejecting perfectly valid studies and abuse, for
12 it is arbitrary and capricious.
13 Thank you for giving me the opportunity
14 to provide comments this morning.
15 MS. ORME-ZAVALETA: Thank you.
16 MR. SMITH: Good morning. My name is
17 Tyler Smith. I'm a staff scientist at
18 Earthjustice. We are the largest non-profit
19 environmental law organization in the country.
20 EPA's proposed rule is an attack on the
21 science used to protect children's health. Simply
22 put, it would weaken risk assessments for

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1 chemicals that harm kids. These chemicals include
2 organophosphate pesticides like chlorpyrifos,
3 which EPA scientists long ago concluded present
4 grave risks to children.
5 Earthjustice therefore urges the Agency
6 to reconsider its approach and withdraw the
7 proposal immediate. Under the Food Quality
8 Protection Act, EPA is required to abide by an
9 additional safety factor of 10 when setting the
10 level of exposure to a pesticide that may harm
11 infants and children. It is well established that
12 children are more susceptible to the toxicity
13 caused by pesticide exposure than adults. The law
14 therefore requires that EPA take this into account
15 and ensure that the most vulnerable among us are
16 protected.
17 Under the statute, EPA may decide to
18 apply a different safety factor if, and only if it
19 concludes on the basis of reliable data that such
20 margin will be safe for infants and children. The
21 most reliable data, including epidemiological
22 studies conducted in three different perspective

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1 cohorts clearly establish that prenatal exposure
2 to chlorpyrifos and other organophosphates, harms
3 the developing nervous system. This exposure
4 reduces IQ, and it increases the risk of
5 developmental disorders, such as ADHD.
6 All of this science was peer reviewed
7 prior to publication, and EPA scientists and the
8 independent experts who serve on the FIFRA
9 Scientific Advisory Panel reviewed it extensively
10 and repeatedly over many years. Accordingly,
11 chlorpyrifos risk assessments conducted in 2014,
12 and again in 2016, included the required safety
13 factor, and both assessments found that exposures
14 exceeded the identified levels of concern.
15 Accordingly, the EPA proposed banning all
16 uses of chlorpyrifos on food in 2015. But last
17 year, political appointees at the Agency
18 disregarded this science and announced that the
19 Agency would not finalize the proposed ban. EPA
20 now may wait years to reconsider. And it appears
21 that the same political appointees who disregarded
22 the science, now want to weaken the chlorpyrifos

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1 risk assessments in advance of their next review.
2 Indeed, the pesticide industry responded
3 to EPA's conclusions on chlorpyrifos by proposing
4 novel requirements that are strikingly similar to
5 what the Agency now proposes to do for all
6 science. CropLife America, an industry trade
7 association, asked EPA to quote, "Require access
8 to raw data as a prerequisite to relying on any
9 study to support regulatory decisions," unquote.
10 And Dow AgroSciences, which manufactures
11 chlorpyrifos, also complained in comments that the
12 Agency is not quote, "Secured and shared the raw
13 data underlying the epidemiology studies,"
14 unquote.
15 Now EPA did seek a study -- or, I'm
16 sorry, did seek data from a study conducted at
17 Columbia University. However, Columbia determined
18 that it could not provide all of the requested
19 data without violating its obligations to the
20 mothers and children who had participated in the
21 research.
22 Notably, EPA did not respond to these

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concerns by refusing to consider the Columbia study. Rather, scientists from the Agency and Columbia met to discuss the study in greater detail, and the University produced extensive supplemental analysis in response to agency questions.

Furthermore, Columbia offered to make all of the data available to agency scientists for analysis in a secured facility on Columbia's campus. Now these efforts suggest there are numerous alternatives to the rigid requirements the proposed rule would impose on the use of science and agency rulemaking.

As epidemiologic studies of chlorpyrifos support retaining the safety factor to protect infants and children, EPA may believe that such studies fall within the vague definition of dose response data and models contained in the rule. If so, EPA may believe that the continued efforts by Columbia to protect the hundreds of mothers and children who participated in its research preclude the use of these data because they cannot be made

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publicly available.

EPA may believe this precludes the use of other epidemiologic studies as well. As a result, this proposal could be used to avoid protecting infants, children, and others from exposure to chlorpyrifos and more than two dozen other organophosphate pesticides. It is simply outrageous that EPA, an agency charged with utilizing science to protect public health, would do the bidding of the pesticide industry it regulates, and try to circumvent its own scientific conclusions by choosing to ignore the best available science.

I urge the Agency to reconsider this proposal and withdraw this deeply flawed rule. Thank you.

MS. HALL: Thank you. Would Speaker Number 11, Eugenia Economos, and Speaker Number 12, Anne LeHuray, approach the speaker's table. And Speaker Number 13, Diana Van Vleet and Speaker Number 14, John Auerbach, please take a seat in the on-deck chairs.

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The speakers are reminded to please speak into the mic, and also state who you're speaking for. Thank you.

MS. ECONOMOS: Hi. I am Eugenia Economos, E-U-G-E-N-I-A E-C-O-N-O-M-O-S. I am with the Farmworker Association of Florida. We are a grassroots farmworker organization that's over 35 years old. I say that because it's important to understand that our organization was co-founded by a man who was a farmworker himself. Our staff are almost all former farmworkers. Our board of directors are farmworkers. They're from farmworker families. And I'm here on behalf of our communities who are mostly African/American, Hattian, and Hispanic farmworkers who harvest the food that feed all the rest of us, the food that we eat is harvested by farmworkers in the field who are exposed regularly to pesticides. And I’m here on their behalf.

Our organization is very involved in pesticide health and safety, and in doing that we have participated in community based participatory

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research projects, including a four-year project with Emory University that we did. It was funded by NIOSH, and in that study, we looked at farmworkers and in the nursery industry that did ornamental plants in Central Florida, and farmworkers in the fernery industry, which are also ornamental plants.

And we looked at the reproductive health effects of occupational exposures, including occupational exposure to pesticides. We are well-trusted in the community because we are based in our communities and because we are of, by, and for the farmworker communities. And we're able to do these studies because we have the trust of our community members.

In that study with Emory University, we did surveys with 260 women of reproductive age. One of the things we looked at was -- we additionally did urine samples on 100 women, including women that were pregnant, looking at levels of organophosphate pesticides and the pesticide, mancozeb, in their urine.

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One of the reasons we chose mancozeb, because that is a fungicide that was implicated in birth defects that happened in Omokollee, Florida in 2004 and 2015, and we wanted to look at the levels of the pesticide in the urine of the women that we studied.

The results of that study showed very high levels of organophosphate pesticides and mancozeb in the urine of the women that we studied, much higher than the NHANES national averages.

We used that information in order to both develop a training for the women about how to protect themselves from pesticides. But we also used that information to write up a paper about -- because mancozeb is coming up for re-review, and we think it's very important to understand the levels that we found of the mancozeb in the urine.

I say that because we would not be able to do that study if we did not have the trust of the people. And we had that trust because we ensured their confidentiality. We would not be

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able to do this if there was any sense at all that their confidentiality could be compromised. You're talking about people who are minorities. Many of them are immigrants. They're already under attack in their communities for many other reasons, and if we could not assure their confidentiality, we would not have participation.

I have people come to me all the time with different complaints from their work environments. And it's heartbreaking to me when people come to me and talk about being exposed to pesticides, and then they're afraid to make a report because they're afraid of losing their job, or they're afraid of retaliation.

We would -- we cannot, we would not, we would never engage in studies if we could not ensure that our people, our community would be protected from any kind of revelation of their identities or of their information. So that's why we are opposed to this proposed rule. We're also concerned about that epidemiological data is really important to look at synergistic and

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cumulative effects of pesticide exposure, and you cannot find that without doing epidemiological studies. So we are also concerned that we're -- I'm sorry. We're also looking at the body burden of pesticides in the farmworkers that we study, and farmworkers are exposed to multiple different kinds of pesticides. And if you're not looking at epidemiological studies to look at that, then you are ignoring an important role of science in the farmworker community.

I am saying that, I am sitting here, and I just want you to know that even though I'm sitting here, behind me are tens of thousands of farmworkers in Florida and around the country, and I'm here on their behalf. And on their behalf, I'm asking you to reject this rule. Thank you.

MS. ORME-ZAVALETA: Thank you.

MS. LeHURAY: Good morning. My name is Anne LeHuray, L-E-H-U-R-A-Y. And that's Anne, with an E. And I am here as the Executive Director of the Pavement Coatings Technology Council, also I'll call it PCTC.

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PCTC, their members manufacture products that are used in pavement maintenance programs to extend the useful life of an asphalt parking lot, for example. Airport surfaces, and the like.

Our members are almost exclusively small family-owned businesses, and their customers, who we also represent, are virtually 100 percent small family -- small and maybe even say micro family owned businesses.

So at PCTC, we strongly support the concept of what EPA is proposing in the "Strengthening Transparency in Regulatory Science" rule, however we urge EPA to go beyond what it has proposed with a goal of improving on EPA's current procedures which lack any meaningful remedies when the Agency relies on science that has been shown to be unreproducible.

The Council supports the efforts of the Agency to ensure that scientific studies, data, and models on which it relies in developing regulations, guidance, and policies are sufficiently transparent. Doing so helps ensure

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that others can attempt to reproduce the results in which the Agency bases its regulation, guidance, and policies.

However, the council believes the proposed rule does not go far enough. PCTC has witnessed first-hand the distortions and bad public policy that can result from what has been called in other venues, secret science, by which we mean, science that has been shown not to be reproducible.

And EPA has contributed to this problem. They were not the source of the unproducible science, but they've contributed to the problem by using that unreproducible science, because to use the Agency's words, it is fit for purpose. Meaning, we suppose, that it suits the Agency's desire to regulate, even if the science says that the regulation is unwarranted.

So PCTC's experience causes it to be concerned that the Agency proposes to restrict its increased focus on transparency to only dose response data and models, to only final

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regulations, and to only pivotal studies as narrowly defined the proposed rule.

We would note that worldwide scientists and science organizations have recognized the crucial rule of transparency to the very crux of the scientific enterprise, which is, science has to be falsifiable. That means that it has to be reproducible.

At a minimum, the Agency should be as concerned as the publishers of peer reviewed science journals, that all the science it considers is possibly key or pivotal to a right to a regulatory purpose, any regulatory purpose meets the standard of transparency.

EPA's role is to translate and distill research results into regulations, guidance, and policies that have significant impacts in the real world. It is therefore the obligation of EPA to ensure that it uses the best available science, which by definition includes science that has been shown to be reproducible on any issue of any important EPA policy making.

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Now to promote the idea of use of reproducible science and transparency, and an understanding in all agency actions, PCTC has two specific recommendations. One is that it gives preference to studies, not just when industry submits a study as part of let's say registering a pesticide, this requires that that study has to follow GLP, Good Laboratory Procedures -- Good Laboratory Practices.

GLP is a formal program. It relies on, like OECD, guidance, methods, test methods. But there's also a thing called the Spirit of OECD, which simply means following good standard scientific practice.

So we recommend and go into detail in our written comments about that the GLP should be given preference in all science that all -- that EPA considers in any of its policy making decisions. And we also have a specific recommendation about how the Office of the Science Advisor should consider combining the roles of the information quality function at EPA, and the

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Office of Scientific Integrity, and I thank you very much for your attention and we expand on this in our written comments.

MS. HALL: Thank you very much.

Would Speaker Number 13, Diana Van Vleet, and Speaker Number 14, John Auerbach, please come up to the speaker's table. And Speaker Numbers 15, Harvey Fernbach, and 16, Joseph Stanko, please take a seat on the on-deck chairs.

MS. VAN VLEET: Hello. My name is Diana Van Vleet, D-I-A-N-A, Van Vleet, V-A-N V-L-E-E-T. I work for the American Lung Association, but I am sharing comments on behalf of Health Care Without Harm today.

As the organization leading the global movement for sustainable healthcare, Health Care Without Harm strongly opposes the proposed rule, “Strengthening Transparency in Regulatory Science.” The rule would impede the Agency from upholding its mission to protect human health and the environment by limiting the use of scientific research.

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It was the EPA's conclusions regarding the human health impacts of dioxin that lead the formation of our organization in 1996. Since then, we have led the charge to transition the U.S. healthcare sector away from medical waste incineration, the leading source of dioxin pollution.

In the United Sates, more than 5,000 medical waste incinerators were in operation in the mid-90s. Today, fewer than 16 medical waste incinerators remain. This work would not have been possible without the EPA relying on sound science to make determinations about the toxicity of dioxin pollution for human health.

Currently, Health Care Without Harm works with hospitals and health systems to transition to renewable energy and to prepare for the impacts of climate change. We look to the EPA to heed the science regarding the human health effects of fossil fuels and climate change when making decisions so that our hospitals are in the best position to protect their patients.

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By artificially limiting the research it considers when making decisions, the EPA would endanger health and put lives at risk. We urge the EPA not to adopt this proposed rule.

MS. ORME-ZAVALETA: Thank you.

MR. AUERBACH: Good morning.

MS. ORME-ZAVALETA: Good morning.

MR. AUERBACH: My name is John, that's spelled A-U-E-R-B-A-C-H.

I am a public health practitioner. I've been a leader in the public health field for about 30 years. I was a city health commissioner, a state health commissioner, and an official at the Centers for Disease Control, and currently I am the President and Chief Executive Officer of Trust for America's Health, or TFAH.

TFAH is a non-profit, non-partisan public health and science-based organization that promotes optimal health for every person and community, and makes the prevention of illness and injury a national priority.

TFAH has been focused on issues like

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clean air and clean water, because they are fundamental to ensuring that all Americans have the opportunity to live long and healthy lives. This is particularly crucial since we know that unhealthy air or contaminated drinking water disproportionately affect some of our more vulnerable subpopulations, including children, older adults, and lower income Americans who are more likely to include racial and ethnic minorities.

As a component of our mission to promote health we issue a series of reports every year that examine some of our nation's most pressing health issues, and we rely heavily on all available research and evidence to develop recommendations for decision makers on how they can most effectively respond to improve health.

For example, in 2011, TFAH and the Environmental Defense Fund released a report that analyzed the savings and health care spending associated with four different EPA regulations. In so doing, we relied on the EPA's own regulatory

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impact analysis that measured reduced mortality, reduced incident of chronic bronchitis, reduced incident of heart attack, and decreased hospital emissions and emergency room visits. These studies estimated that nearly half a million lives could be saved by these four EPA standards alone.

Because of the importance of having access to such scientific data in order to protect the public's health, we oppose the “Strengthening Transparency and Regulatory Science” proposed rule. Research and evidence is the foundation of EPA's policies and has been necessary for success of laws like the Clean Air Act and improving and in saving lives from the dangers of air pollution.

Congress intentionally directed EPA to consider peer reviewed research under the Clean Air Act, and mandates regular reviews of the science to ensure that EPA is reviewing and considering the most up to date science. We believe that the proposal would prevent EPA from using the best science to inform decision-making, and the result would be weaker standards at the

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expense of American's health. For example, the proposal would exclude several landmark air quality studies from the evidence base that EPA is permitted to consider, largely on the basis that these studies include confidential patient information that would make them less transparent under the constructs of the proposed rule.

The practical result would be weaker air pollution standards, despite the fact that the science behind these studies is pointing us in the opposite direction. The current methodology and system for review is sound, reliable, and has operated effectively for years. And that's why we have joined with the American Lung Association, the American Academy of Pediatrics, the American Public Health Association, and over 70 additional public health, medical, and academic organizations in opposing this regulation, this proposal.

As a long-term public health practitioner and the President of TFAH, I remain committed to ensuring that federal health policy and practices are guided by the evidence in a transparent and

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accountable manner. EPA and other federal agencies should be no exception. We at TFAH look forward to working with congress, with the EPA and others, as we continue to advocate for policies and practices that uphold these principles and protect and promote the health of every American. Thank you very much.

MS. HALL: Thank you very much. If I could ask those that are in the room to please refrain from talking. There's a lot of whispering and it's distracting. If you do need to have a conversation, please step outside the room. Thank you.

Would Speaker Number 15, Harvey Fernbach and Speaker Number 16, Joseph Stanko, please approach the speaker's table. And Speaker Number 17, Peter Lurie and Speaker Number 18, Jamie Wells, please take a seat in the on-deck chairs.

What speaker number are you?

MR. STANKO: Sixteen.

MS. HALL: So, do we have Speaker Number 15? Harvey Fernbach?

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[No audible response.]

MS. HALL: Okay, so we'll move ahead.

[Discussion off the record.]

MS. HALL: Number 17, Peter Lurie, would you like to take a seat up here? And then Speaker Number 19, Ami Zota, please take a seat in the on-deck chairs. Thank you.

MR. STANKO: Thank you. My name is Joseph Stanko, S-T-A-N-K-O. Thank you for the opportunity to address EPA's proposal entitled, “Strengthening Transparency in Regulatory Science.” My name is Joseph Stanko, and I am counsel to the NAAQS Implementation Coalition.

The Coalition is comprised of trade associations, companies, and other entities who confront challenges in permitting and operating manufacturing and other facilities under increasingly stringent National Ambient Air Quality Standards.

Our members --

MS. ORME-ZAVALETA: If we could ask you to move the microphone a little bit more in front.

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MR. STANKO: Sure.

MS. ORME-ZAVALETA: No, the other way. There you go.

MR. STANKO: All right.

MS. ORME-ZAVALETA: Thank you.

MR. STANKO: Our members, and the companies they represent have a proven record of working with states and regional EPA offices on implementing emissions reduction strategies to attain NAAQS.

However, increasingly more stringent NAAQS have caused demonstration requirements for Clean Air Act permits to exceed the limits of current tools and policies for NAAQS implementation. This makes it increasingly more difficult for companies to attain the approvals needed for new state of the art projects that create jobs and bring much-needed tax revenue to local communities.

Without a transparent NAAQS process, underlying studies lack robust external review, leading to standards that may not provide

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1 objective public benefit. In certain cases,
2 increasingly stringent standards have pushed NAAQS
3 to concentrations at or near background levels,
4 beyond the feasible limits of implementation.
5 While inaccurate assumptions in both setting and
6 implementing NAAQS could be more readily absorbed
7 under prior less stringent NAAQS levels, recent
8 more stringent standards have eroded such
9 tolerances.
10 Addressing this new reality starts with
11 an inherently forward-looking NAAQS review process
12 that assesses science and policy in a rigorous and
13 holistic manner. The transparency proposal
14 fosters such an open-source approach to pivotal
15 regulatory science, one that enables the public to
16 more meaningfully comment on the science
17 underlying NAAQS review. This can foster a more
18 effective NAAQS implementation that still meets
19 the Clean Air Act's mandate to protect public
20 health.
21 While we support the principles behind
22 the transparency proposal, its sound policy goals

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1 should be balanced with legal and ethical
2 obligations to protect private, sensitive, and
3 confidential information. As the transparency
4 proposal is implemented, efforts must be made to
5 address protected health information under the
6 Health Insurance Portability and Accountability
7 Act, or HIPAA.
8 Disclosure limitations also exist for
9 proprietary information and trade secrets. We
10 agree with EPA that dose response data and models
11 should be exempt from public review as necessary
12 to protect private, sensitive, and confidential
13 information. However, we believe that EPA can
14 protect such information while still seeking
15 maximum possible transparency.
16 As the transparency proposal notes, many
17 generally acceptable techniques exist to
18 deidentify personally identifiable information.
19 Where such deidentification is not possible, EPA
20 could facilitate review of sensitive data sets by
21 a diverse group of experts subject to HIPAA
22 compliant nondisclosure agreements.

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1 If all other options to expand review
2 have been exhausted, EPA could decide that a study
3 could not be subject to outside review and
4 verification, and consider the study accordingly
5 without excluding it from a rulemaking proceeding.
6 Administrations -- administrators pardon
7 me, have regularly taken similar methodological
8 considerations into account when assessing studies
9 in past NAAQS reviews. EPA could further balance
10 transparency and privacy by appropriately
11 tailoring the transparency proposal according to
12 the type and scope of the regulatory decision
13 involved. For this reason, we agree with EPA that
14 the transparency proposal should be limited to
15 pivotal regulatory science that is involved in
16 significant regulatory actions that result in
17 substantial costs.
18 To that end we note that because Clean
19 Air Act regulations have accounted for the vast
20 majority of costs and benefits cited in rules over
21 the last decade across the entire federal
22 government, such regulations are particularly well

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1 suited for the transparency proposal's high
2 standard of robustness.
3 As this process moves forward, we
4 encourage EPA to further detail how the
5 transparency proposal will protect private,
6 sensitive, and confidential information, be it
7 personally identifiable or proprietary
8 information, trade secrets, or other similar
9 information. To that end, EPA should explicitly
10 state that any final regulations arising from the
11 transparency proposal do not support or assert
12 authorization under the law to disclose such
13 currently protected information, and that any
14 claim to do so must be independently based on a
15 statutory grant of authority from congress.
16 In conclusion, the transparency proposal
17 would increase replicability and verification in
18 the scientific process, thereby testing critical
19 methodological assumptions and mitigating biases
20 in key studies upon which the Agency relies in
21 developing regulations. It recognizes that
22 transparency can go beyond simply maximizing

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disclosure to better contextualizing studies through replicability and verification.

In doing so, the public can more meaningfully take part in EPA notice and comment rulemaking processes. As EPA advances the transparency proposal, it can and should implement these sound policy goals in concert with obligations to protect private, sensitive, and confidential information.

The NAAQS Implementation Coalition appreciates EPA's efforts on the transparency proposal, as well as the opportunity to present its view on the topic.

MS. ORME-ZAVALETA: Thank you.

MR. LURIE: Hear me? Good morning. My name is Dr. Peter Lurie. I'm a physician, an epidemiologist, and now the President for Center for Science in the Public Interest. We are an independent science-based health advocacy organization with over 500,000 members.

Before I joined CSPI, I served at the FDA as an associate commissioner and in fact, for

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several years I led the Agency's transparency initiative. Over the course of my career I've authored close to a dozen academic articles on the topic of transparency, and nobody ever asked me for the underlying data for any of those studies.

We at CSPI are firm advocates of scientific transparency and have had a number of projects along those lines over the years. But EPA's proposed rule is not about transparency or strengthening science. Instead, it is a wolf of pro-industry bias hiding in the sheep's clothing of transparency in science. Proposal should be withdrawn.

Transparency is not about restricting the use of sound science, as this proposal would do. Suddenly, the more transparent a government agency can be about the nature and limitations of the data underlying a decision, the better. But the failure to meet some abruptly and arbitrarily elevated standard for disclosure cannot and should not be the grounds for the summary exclusion of data that were rigorously gathered and reported.

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The surest tests of any scientific transparency policy are two. One, was it generated in a transparent fashion? And two, will it actually promote the transparent rigorous science-based decision-making that it claims to? This proposal fails on both counts. Let's start with the procedural matter.

This proposal violates fundamental tenents of transparency rulemaking. EPA failed to consult with relevant stakeholders, such as science, research, or health professional associations, did not consult with other federal agencies who would be affected by this, and did not even make the proposed rule available to its own Scientific Advisory Board for review.

In addition, the proposal lacks critical citations and documentation, or even an adequate justification for why it was proposed. Rather than furnishing the evidentiary support required for administrative action, the Agency has merely adopted a legislative initiative that failed to (indiscernible) despite support from the energy,

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chemical, manufacturing, and other key industries.

Moreover, despite its professed (indiscernible) to cost effectiveness in rulemaking, the proposed rule provides no cost-effectiveness analysis whatsoever. It simply blithely asserts that, quote, "EPA believes the benefits of this proposed rule justify the costs." I wish we could have gotten away with that at FDA.

But the rule would be costly indeed. Analysis of an earlier version of the legislation predicted costs of $250 million over the next few years. But even more important, the proposal does not meet its purported scientific goals and will instead undermine the scientific basis for decision-making at EPA.

Since its inception, EPA has developed rules with demonstrable efficacy in protecting the public by relying in large part upon the kinds of data that EPA would now preclude from consideration. Some of EPA's greatest public health accomplishments, such as eliminating lead and gasoline, classifying second-hand smoke as a

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cause of cancer were based on the kinds of data that would be discarded under the proposal. Such data are widely used in rulemaking proceedings by other U.S. government agencies and around the world. And I can say, at FDA, we would not have had the rules that we ultimately developed or proposed on mercury in fish, on arsenic in rice, on dental amalgam, or in sodium targets from a nutritional perspective. None of those could have been done if data of these kinds were eliminated.

In particular, it's also especially troubling that the proposal also opens the door to a reconsideration of past rules which would be utterly inappropriate under prevailing principles of administrative law. In fact, the proposal would have an effect opposite to its claimed purpose. It would address -- it would suppress important and relevant science conducted in large part by the best minds in academia and government, thereby unduly restricting the evidence available to EPA and potentially favoring data developed by industry.

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Further evidence of the pro-industry orientation of this proposal is its discussion of the dose response function and the assault on linearity. Quite aside from the merits of that discussion, which I think are few, the real question is, what is this discussion doing in this proposal in the first place. It has nothing to do with transparency whatsoever, and it's simply there as a marker, in my view, of the pro-industry bias that this entire enterprise represents.

Let me close with a question with which EPA should have started. What exactly is the problem that this proposed rule seeks to fix? Where indeed is the study for which the lack of access to raw data resulted in misinterpretation or in the promulgation of an inappropriate regulatory standard?

To the contrary, the record is replete with studies that form the basis of health and life saving regulations that would now be precluded from use, and that might even provide a basis for the revocation of rules enacted in the

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distant past. Thank you.

MS. HALL: Thank you. Would Speaker Number 18, Jamie Wells, and Speaker Number 19, Ami Zota, please come up to the speaker's table. And Speaker Number 20, Surbhi Sarang and Speaker Number 21, Laura Bloomer, please take a seat in the on-deck chairs. Thank you.

Please, quick reminder to speak into the mic and state your organization.

MS. WELLS: My name is Dr. Jamie Wells, J-A-M-I-E W-E-L-L-S, and I'm the Director of Medicine for the American Council on Science and Health, and I'm here on behalf of our president, Hank Campbell.

In the past, peer-reviewed journal publication ha been considered authoritative, but that has inherent weakness if they can't be replicated. Knowing the potential for error, and even misuse, replication is vital, but we recognize that that's not always possible. A safety valve for that is a higher level of scrutiny when it is not possible. Studies that

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can't be replicated should at least make sense within the pattern of available data, which in the case of EPA will often include hundreds of other studies done according to federal guidelines.

However, there are also occasions where replication is not possible and new claims or outliers from the consensus of many other studies. And in those cases, they should still absolutely be used if EPA risk scientists, without breaking confidentiality, can obtain the additional information needed in order to conduct their own analysis.

EPA risk scientists are charged with protecting public health, and the American Council on Science and Health has argued since 1978 that the judgment over which epidemiology and/or toxicology data to use for risk or safety assessment should always include risk scientists. The public's interest is best served when science is replicable and consistent with other information.

On occasions, when studies cannot be

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1 replicated, or when such studies are not
2 consistent with other information, use of those
3 studies depends on having access to the underlying
4 data for independent analysis. When the
5 underlying data are not provided, it is difficult
6 to make a credible risk assessment, much less
7 national rulemaking, as you know. So risk experts
8 should be involved.
9 You should have received a more extensive
10 written document as well.
11 MS. ORME-ZAVALETA: Thank you.
12 MS. ZOTA: I'm Dr. Ami Zota, that's A-M-
13 I, last name Z-O-T-A. I am a health scientist and
14 Professor of Environmental and Occupational Health
15 at the George Washington University Milken
16 Institute School of Public Health. I am also
17 speaking as part of Project Tender. We are an
18 alliance of scientists, health professionals, and
19 advocates with expertise in protecting children
20 from exposure to toxic chemicals that can
21 contribute to neurodevelopmental problems, such as
22 ADHD and learning disabilities.

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1 I oppose EPA's proposed rule. The
2 proposed rule prohibits the Agency from setting
3 regulations that are support in part or whole that
4 is for data that is publicly available for
5 reanalysis or cannot be replicated.
6 Since the proposed rule is retroactive,
7 it could lead to the dismantling of many important
8 existing EPA regulations that safeguard our
9 children and families -- children and families
10 from toxic chemicals.
11 I would like to spend my time identifying
12 some of the major problems with this rule that
13 warrant consideration before the Agency moves
14 forward. The scientific sources cited for the
15 basis of this rule do not support the proposed
16 rule. EPA did not consult with critical
17 stakeholders in the development of this proposed
18 rule, including scientists, health professionals,
19 and affected communities.
20 EPA does not present any analysis of
21 benefit-cost, children's environmental health
22 risk, or environmental justice in support of the

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1 rule which are required under executive orders
2 12291, 13045, and 12898. The terms, pivotal
3 regulatory science, replication, reproducible, and
4 research data are not defined or are problematic.
5 The rule's requirements for specific types of
6 defaults, test methods, dose response models,
7 and/or analysis are not supported by current
8 science.
9 The rule is counter to the mandates in
10 the reformed Toxic Substances Control Act, or
11 TSCA, to use the best available science and
12 systematic reviews for chemical evaluations.
13 Data deidentification and masking
14 techniques cannot ensure confidentiality and can
15 degrade the accuracy of data for further analysis.
16 The rule is inconsistent with medical ethics and
17 existing legal requirements to ensure the privacy
18 and/or confidentiality of human data.
19 For example, in many cases individuals'
20 participant data cannot be made public because of
21 confidential requirements legally mandated by
22 institutional review boards and/or the Health

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1 Insurance Portability and Accountability Act of
2 1996, or HIPAA.
3 In conclusion, EPA should withdraw this
4 proposed rule immediately. EPA should focus on
5 implementing existing initiatives and guidelines
6 for improving data sharing and transparency at the
7 federal government. Thank you.
8 MS. HALL: Thank you.
9 Would Speaker Number 20, Surbhi Sarang,
10 and Speaker Number 21, Laura Bloomer, please come
11 up to the speaker's table. Would Speaker Number
12 22, Ms. Nsedu Obot Witherspoon, and Speaker Number
13 23, Joanne Zurcher, please take a seat in the on-
14 deck chairs. Thank you.
15 Speakers, please remember to speak into
16 the mic and state your organization.
17 MS. SARANG: My name is Surbhi Sarang,
18 spelled S-U-R-B-H-I S-A-R-A-N-G, and I'm a legal
19 fellow at the Environmental Defense Fund.
20 I appreciate this opportunity to provide
21 public testimony on the proposal and hope that
22 everyone who wises receives an opportunity to be

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1 heard. We urge EPA to hold hearings in additional
2 locations to allow affected Americans in other
3 communities who cannot travel to be here today, an
4 opportunity to provide input as well. I'm
5 testifying here today to raise our serious
6 concerns of the proposed rule and to ask that the
7 EPA withdraw the proposed rule immediate.
8 Communities across America rely on EPA
9 safeguards to protect their health and wellbeing.
10 But this rule would greatly restrict the body of
11 scientific information that EPA draws on when
12 setting these safeguards. Instead of being
13 informed by all available science, in many cases
14 EPA would be forced to operate in the dark. By
15 obliging EPA to disregard scientific research that
16 would otherwise alert the Agency to taking strong
17 protective actions, this rule endangers the health
18 of all families and communities. Had this rule
19 been place previously, we would likely currently
20 be facing greater exposures to air pollutants,
21 water contaminants and toxic chemicals.
22 In the proposal, EPA completely ignores

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1 the practical effects of the proposed rule and how
2 it fundamentally conflicts with EPA's mandate to
3 use the best available science as it develops
4 safeguards.
5 Agency decisions must be informed using
6 the best available science. Public deserves
7 nothing less when health and safety are on the
8 line. This value is core to EPA's mission and
9 should be placed at the forefront.
10 But the proposal takes an unsupported and
11 unprecedented leap by suggesting that this mission
12 allows EPA to only use science where the
13 underlying data and models can be made and are
14 made publicly available for independent
15 validation. Much of the data underlying
16 scientific studies concerning human health cannot
17 be made publicly available for legitimate privacy
18 and confidentiality reasons. In many cases, it is
19 impossible even to redact information in a manner
20 that allows independent validation while
21 respecting privacy and confidentiality.
22 Thus, the proposal would seriously

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1 restrict EPA's ability to use the best available
2 science as it sets critical safeguards. Nor does
3 EPA explain why such restrictions on the use of
4 science are necessary. EPA does not point to any
5 instance in which a failure to disclose data
6 resulted in an EPA decision or standard that lacks
7 scientific integrity.
8 EPA does not explain why other means of
9 vetting that are used by the scientific community
10 and that protect privacy and confidentiality, such
11 as review by EPA's independent Science Advisory
12 Board, peer review, and corroboration through
13 independent studies are insufficient to ensure the
14 integrity of the science EPA relies on. And EPA
15 does not explain why it is appropriate for an
16 agency tasked with basing its decisions on best
17 available science to now discard otherwise valid
18 science simply because a disclosure is not
19 possible.
20 Indeed, courts that have examined the
21 issue have made clear that it is entirely
22 reasonable for EPA to rely on scientific studies

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1 which data cannot be disclosed. While EPA states
2 in the proposal that many organizations have
3 endorsed data disclosure as a means to increasing
4 transparency, the reality is the proposed rule
5 completely departs from good scientific practice.
6 None of the organizations EPA identifies in the
7 proposed rule have endorsed the practice of
8 disregarding studies where data disclosure is not
9 possible, or that have been subjected to other
10 means of validation, or suggested that regulatory
11 agencies should exclude such studies when using
12 science to inform regulatory actions.
13 To the contrary, organizations that are
14 deeply committed to transparent science have come
15 forward to stress that policies to promote
16 transparency must be developed within the
17 scientific community and to oppose the notion of
18 disregarding otherwise valid science, simply
19 because the underlying data cannot be disclosed.
20 Indeed, EPA's own Science Advisory Board,
21 which it failed to consult before issuing this
22 proposal, has raised concerns similar to those we

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raise here, noting that EPA provided no analysis of the impact of losing the ability to run on these studies, and that there are other ways to assess the validity of studies without access to data. Not only did EPA skip over review by the Science Advisory Board, but then EPA allowed for only a 48 (indiscernible) review process for the proposal.

This hastened process seriously calls into question the validity of the proposal. The proposal would not even increase transparency. By allowing the administrator to grant exemptions based on vague and discretionary criteria, the proposal would allow EPA to selectively apply this disclosure policy with no public record of the decision or its basis. The risk that the rule will artificially restrict and distort the scientific basis for EPA's decisions is only heightened by its many gaps.

The proposal fails to explain critical details, such as what mechanisms would be used to make data public, what the cost of the Agency and

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to researchers would be, and how the peer review provision would fit into EPA's existing peer review requirements. It is not even clear how EPA would determine that a given study is publicly available in a manner sufficient for independent validation. This underscores concerns that this proposal would undermine the integrity and transparency of EPA decisions rather than enhance them.

It is also important to note that this rule was posed under former Administrator Pruitt who actively obscured transparency goals by directing the removal of scientific information from EPA's websites, refusing to publicly release his full and accurate schedule, using secret e-mail addresses, and spending tax payer money in violation of federal laws.

While Pruitt is now gone, this proposal unfortunately suffers from the same disregard for scientific integrity and transparency that infused the former administrator's tenure.

We thus call on Acting Administrator

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Wheeler to recognize the redeemably flawed basis for this proposed rule and withdraw it immediately.

MS. ORME-ZAVALETA: Thank you.

MS. BLOOMER: My name is Laura Bloomer, B-L-O-O-M-E-R, and I'm a student at Harvard Law School and the Kennedy School of Government. I am interning at EDF, Environment Defense Fund this summer. I am here testifying on my own behalf.

I am the daughter of two parents who grew up near auto industry towns in Michigan. My mom was born in Flint. Her parents, my grandparents, grew up in Flint and chose to raise their four children there.

Though I'm a proud Texan, as my family moved to Houston when I was in elementary school, most of my family continues to call Michigan home. The Flint water crisis was personal for us.

My aunt, a dental hygienist, volunteered and delivered water to Fling residents after the story broke. She understood the heart wrenching fear a mother would experience when she found out

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her child had been drinking contaminated water. She understood the outrage of her home community when they found out that the government they trusted did not care enough to keep their drinking water safe. She understood what it might feel like to have a fundamental safeguard, like clean water, suddenly disappear.

But the water crisis in Flint did not disappear when it left the nightly headlines. Just last week, my mom went to her favorite hotdog shop in Flint and sent me a photo of a poster from the restaurant. It was an advertisement for healthcare, aimed at mothers of children who grew up drinking contaminated water. My mom was devastated.

And though the Flint water crisis is more salient and more visible than this proposed rule, the impacts are far too similar. For decades the EPA has relied on first-rate science to establish protections for our air and water, and most importantly for our public health.

It is because of these safeguards that I

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have never experienced the type of pollution my mom describes from her childhood. It is because of incredible researchers and scientific discoveries that many of our communities will never experience a water crisis like Flint is still experiencing. It is because EPA regulates lead in our drinking water, and arsenic in our drinking water, and the many other contaminants that harm our most vulnerable populations that my friends and I grew up in a healthy environment.

It is because EPA has a responsibility to seek out and utilize the best available science at every step of the way, that the next generation of children will be protected from threats to their health as well.

Yet right now, in 2018, when our science has never been more advanced, and when EPA is considering revising the Lead and Copper Rule for drinking water, EPA would choose to voluntarily ignore the best available science. This proposed rule would severely limit the studies on which EPA could rely. It would threaten the enormous amount

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that EPA and engaged citizens have accomplished, and it would hamstring any progress we hope to make in the future.

This rule isn't about transparency, and it was not developed with people like my family and me in mind. For the safety of all of us and for future generations, I respectfully ask that this rule be withdrawn. Had this rule been in place decades ago, more communities might be suffering from the same threats to public health that Flint is now facing. Many of EPA's drinking water standards rely on epidemiological studies. Often these studies last decades and follow hundreds, if not thousands of patients, collecting confidential health data, as well as other personal data, like the people's addresses, ages, and genders.

For most of these studies the underlying data cannot be made public, even in redacted form, without sacrificing the participants' privacy. These studies are monumental and state of the art. These are the studies that EPA should hope to rely

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on, not the type of studies the EPA should shun. These are the studies that will guarantee that communities don't suffer from the devastating impacts of dirty water and polluted air. Studies like these establish the original limits for lead, and this research continues to essential today.

This proposed rule may seem abstract, but it is anything but that. And it is extremely significant. It will have far-reaching -- far-reaching impacts on the ability of EPA to protect all of us and our families. And it could affect our most important environmental safeguards. It is extremely personal, for my mom, for my family, and for me.

I am here today to ask you to withdraw this proposed rule and recommit to EPA's mission of protecting human health and the environment. Thank you for the opportunity to speak today.

MS. Hall: Thank you. Would Speaker Number 22, Ms. Nsedu Obot Witherspoon, and Speaker Number 23, Joanne Zurcher, please come up to the speaker's table. And Speaker Number 24, Michelle

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Endo and Speaker Number 25, Jenny Xie, I think, please take a seat at the on-deck chairs.

[Substitution of panel members.]

MR. ROBBINS: Good morning. I'm Chris Robbins. I'm the Acting Deputy Assistant Administrative for Management in the Office of Research and Development.

MS. ORME-ZAVALETA: Good morning.

MR. ROBBINS: Thank you.

MS. DOA: Good morning. My name is Maria Doa , I am in the Office of Research and Development.

MS. WITHERSPOON: Good morning. I'm Nsedu Obot Witherspoon. I'm the Executive Director for the Children's Environmental Health Network. My name is spelled N-S-E-D-U O, B as in boy, O-T W-I-T-H-E-R-S-P-O-O-N.

For over 26 years, the Children's Environmental Health Network, also known as CEHN, has been a national voice committed to protecting all children from the harmful effects of environmental hazards, and to promoting a

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healthier environment.

CEHN educates decision makers and advocates for evidence-based child protective policies. We also ensure that those who care for children, personally or professionally, have the information they need to take the steps to reduce children's exposures to harmful toxicants.

As the Executive Director, and on behalf of CEHN, I appreciate the opportunity to provide these comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science."

CEHN is strongly opposed to the rule and is concerned that it will adversely affect EPA's ability to use the best available science in decision-making, and negatively influence existing and future protections for children's health, such as clean air, clean water, and the prevention of toxic exposures.

The exposed rule sets transparency standards that are too rigid and impossible to meet. It requires that all data used in

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rulemaking be publicly made available, and allows EPA to exclude data that relies on confidential patient information. Critical studies which have led to significant advancements in protective policies, for example from the NIEHS, EPA's Children's Environmental Health, and Disease Prevention Research Centers may very well be excluded.

The scientific research that EPA uses already undergoes a long-established transparent review process, and makes available the scientific studies it relies on to inform policy. Sometimes studies contain private medical data that legally can't and should not be made public. In those cases, independent review bodies have also examined the studies and weighed in on the research. No legitimate reason exists to exclude those studies and their critical important findings.

Health based research involves people and often the collection of private information. There are no systems in place to protect this

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information. The federal government must continue to protect private information about patients, and not allow this information to be made public. Otherwise, patients will not participate in these important studies.

Further, redacting personal information actually sounds easy, however, it is cumbersome and quite costly. EPA will not likely have the resources to redact personal information resulting in exclusion of critical studies.

The proposed rule would restrict EPA's ability to set regulations informed by confidential data that cannot be replicated. This is of serious concern because for many older, long-standing landmark studies, the original data sets were either not maintained, or stored in out of date formats. These could be eliminated under this proposed rule.

The proposed rule could block the use of studies on the harmful impacts of toxic exposures and pollution. Studies which were instrumental in the Clean Air Act, the Safe Drinking Water Act,

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and the -- excuse me, Food Quality Protection Act, among many others. We do request that you withdraw this proposal, "Strengthening Transparency and Regulatory Science." If the proposed rule is implemented, an inevitable consequence is that children that could have been protected from chemical exposures will lose those opportunities.

Irreversible damage to children in their growth and development, loss of intelligence, behavior modifications, and overall life achievement is the future ahead, and I would hope, not the legacy that this EPA would like to preserve. Thank you very much.

MR. ROBBINS: Thank you.

MS. ZURCHER: My name is Joanne Zurcher, J-O-A-N-N-E Z-U-R-C-H-E-R, and I'm representing the National Environmental Health Association.

Good morning. Thank you for the opportunity to speak to you on behalf of the environmental health professionals from across the country who've vigorously opposed the Censoring

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science rule.

My name is Joanne Zurcher, and I am the Director of Government Affairs for the National Environmental Health Association, NEHA.

Environment health is profoundly local. Simply put, it's the cleanliness of the water from the kitchen faucets. It's the safety of the food we feed our families, our friends, and ourselves. It's the air the children breath during the 1,600 hours they spend inside their schools. It's the cleanliness of our community beaches that our families are spending the summer enjoying.

When things go well, environmental health is not on the front page of the New York Times, because environmental health professionals keep us safe every single day.

NEHA has over 7,000 members. Our members anticipate, recognize, evaluate, and control hazards that are likely to cause harm, serious illness, or even death to American families. Examples include lead, radon, legionella viruses, harmful algae blooms, PFOA, PFOS, Zika viruses,

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and many other natural and man-made risks. Our members possess strong science and math backgrounds. They must take over 30 units of undergraduate math and science just to sit for our exam. They have the unique ability to work with clinical and nonclinical professionals. They know and work with the regulated community. They are credentialed members of the profession, and the NEHA credential is considered the gold standard.

EPA science is the foundation for informed decision-making for our members. Our members turn to the EPA for best practices. Our members rely on EPA research to promote their community's health.

Our communities see EPA as the shelter of scientific certainty in an era of uncertainty. Our members rely on EPA expertise, whether it's continuing -- excuse me, containing mercury spills in their homes, setting standards to keep toxic chemicals out of drinking water, or cleaning up super fund sites, just to name a few of the few activities we do together. EA professionals work

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closely with the EPA every step of the way.

The EPA has administered successfully, the Clean Water Act, and the Clean Air Act, and these acts should be expanded based on scientific research. The EPA should not be working to undermine scientific research. Instead, this EPA should be working to provide running water to the 630,000 American families who do not have running water in their homes.

Let's be clear, this proposed rule undermines the EPA's mission to protect human health. Now is not the time to compromise health of our nation by casting a shadow of uncertainty on the integrity of the EPA -- of EPA's research.

EPA research is globally recognized as the foundation for informed decision-making that affects every person the plant. NEHA and it's 7,000 members are in every community and territory in the nation. Every EH professional relies on EPA research to ensure constituents meet human -- meet their human potential.

The current research system works, which

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at once protects the identity of every research participant, while promoting the health of every American. Health research sometimes includes sensitive data from patients, such as medical history and geographic location, which must be continued to be private and protected. Crucial volunteers will cease to come forward for scientific research if their medical history and geographic information will be made public, thus putting critical scientific research at risk. Please do not destroy a national gem, our EPA research, because you, your family, and your community deserve no less than a fully functional research system that protects and identifies research subjects while promoting the health of the nation.

NEHA and the environmental health professionals from across the United States vigorously oppose the censoring scientific rule. Thank you for this opportunity to be heard on this important topic, and please remember, do no harm.

MR. ROBBINS: Thank you.

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MS. HALL: Would Speaker Number 24, Michelle Endo, and speaker Number 25, Jenny Xie, come up to the speaker's table. And Speaker Number 26, Ann Mesnikoff, and Speaker Number 27, Roy Gamse, please take a seat at the speaker's -- well, at the on-deck chairs.

Speakers are reminded to speak into the mic and state your organization.

MS. ENDO: My name is Michelle Endo, E-N-D-O, and I'm speaking in a personal capacity, but I'm an intern at the Environmental Defense Fund.

So my name is Michelle Endo, and I'm a second-year student at Georgetown Law. I'm also a legal intern at the Environmental Defense Fund here in Washington, D.C. I'm here today to offer comments on my own behalf and to present my grave concerns with EPA's proposed rule, “Strengthening Transparency in Regulatory Science.”

I’m a fourth generation Southern Californian who lived the first 18 years of my life in Northern Los Angeles County. And while I'm proud to be from the Golden State, it also

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means that I grew up breathing some of the worst air pollution in the nation. Despite tremendous improvement, 70 percent of Californians live in an area with unhealthy air. As a result, I also grew to be familiar with the dangers of air pollution and the importance of health-protective regulation.

My family lives in a town that, like much of LA County, is in the United States 98th percentile for tropospheric ozone, according to EPA's own Environment Justice Screen.

Tropospheric ozone, commonly referred to as smog, is the visible layer of air pollution that gives LA sunsets their famous striped hues. Several studies have consistently reported there is a significant association between ozone pollution and premature death. According to the American Lung Association, long-term exposure to ozone pollution is also linked to developmental harm, reproductive harm, cardiovascular harm, and increased susceptibility to infections.

While I never had a snow day before

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moving to D.C., like most SoCal kids, I'm very familiar with bad air days. Instead of playing outside and building snowmen, children in Southern California lose all outdoor playtime on bad air days in order to avoid the harmful effects of smog. Coughing, impaired athletic performance, eye irritation, chest pain, nausea, headaches, and respiratory congestion.

Smoggy days can also worse asthma, heart disease, bronchitis, and emphysema.

My sister and I enjoyed the early years of childhood with fewer complications relative to my neighbor peers. But before even starting high school we both had missed days of school for nose bleeds that were likely triggered by the irritating smog that settled in the valley, and because ozone forms by the interaction of sunlight with hydrocarbons and nitrogen oxides emitted from cars and trucks, bad air days tended to worse each year, our Southern California summers, broke standard heat records of years before.

Shortly after my sister joined the high

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school soccer team, my family started to notice that her once limitless stamina on the field was wearing down. One particularly hot and hazy day, she had no choice but to walk off the field in the middle of the match. Clutching her chest, she struggled to breath. We later learned that she had developed asthma from LA's unhealthful smog, like many of our friends and family in the area.

It was experiences like this that motivated my decision to study environmental policy in college, and that continued to drive my legal career. Having witnessed first-hand the way in which the geography of where one lives, plays, learns, works, and grows determines one's health outcomes, I could not have chosen another path in good conscience.

When I first chose this path, over eight years ago, my hope was to strengthen the laws and regulations that did not go far enough to protect my family and our environment.

Under the Clean Air Act, EPA was required to establish and regularly update federal

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1 standards for hazardous air pollutants, including
2 asthma-causing particulate matter and ozone.
3 These standards and the National Ambient Air
4 Quality Standards or NAAQS, form the backbone of
5 our nation's air quality protections. Although
6 the NAAQS did not prevent my sister's asthma, they
7 have and continue to bring about substantial
8 improvement in our nation's air quality since
9 their first formulation.
10 The EPA's proposed rule would have
11 excluded peer review studies that form the
12 scientific basis of NAAQS. For example, peer
13 reviewed studies would be excluded because the
14 underlying data and models cannot be disclosed,
15 even in partial form. In fact, the standards
16 would not have been issued had the proposed rule
17 been in place when they were first enacted in the
18 1970s, because EPA would have tossed out the
19 underlying studies, tying its hands from taking
20 action in imminent public health concerns.
21 Without a doubt, many more Southern
22 Californians would have had their lives altered,

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1 or even cut short by dangerous levels of air
2 pollution.
3 If adopted, the proposed rule would
4 deprive EPA policy makers from real world evidence
5 and studies that are vital to the EPA's review of
6 the NAAQS into the future. Further, the proposal
7 directly contravenes the comprehensive federal and
8 state regulatory program congress envisioned when
9 drafting the Clean Air Act of 1970. It reduces
10 our public health legislation to mere
11 declarations, as EPA would severely delayed if not
12 rendered entirely unable to establish future
13 standards using the best available science.
14 Generations before me, through
15 legislation like the Clean Air Act, recognize that
16 public health and environmental pollution required
17 strong federal leadership and expert agencies like
18 EPA. Departing from the Agency's practice of
19 scientific review for over the last 40 years,
20 practices aligned with national and
21 intergovernmental bodies, like the Royal Society
22 of Medicine, and the World Health Organization,

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1 jeopardizes EPA's ability to utilize its expertise
2 with high cost to people's health.
3 It is therefore troubling that the Agency
4 has proposed to take this action under the guise
5 of scientific integrity without consulting its own
6 panel of scientific experts, the Science Advisory
7 Board, and against the advice of leading
8 scientific journals and organizations. It is even
9 more troubling when considering the Agency's
10 recent practices toward the public and the press,
11 which have been far from transparent.
12 To me, it is clear the proposal's
13 purported goal of transparency is a pretext for
14 the Agency's attempt to shirk its statutory
15 command. For the health of my sister, my friends,
16 and all Americans, I urge EPA to abandon this
17 proposed rule. Thank you.
18 MR. ROBBINS: Thank you.
19 MS. XIE: Good morning. My name is Jenny
20 Xie, J-E-N-N-Y, last name X-I-E, and I'm a policy
21 intern at the Environment Defense Fund, but I'm
22 here today speaking from a personal capacity to

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1 express my personal opposition to EPA's proposed
2 rule, "Strengthening Transparency in Regulatory
3 Science."
4 Many of the activities that I am involved
5 in on campus involve holding the university
6 accountable for its environmental goals that it
7 has set. I'm currently a student at Cornell
8 University, studying English and Environmental
9 Sustainability Sciences.
10 In fact, one of the main initiatives that
11 I am involved in calls for the University to
12 disclose as a financial investments and fossil
13 fuels in order to increase transparency, have
14 accountability, and maintain integrity as it works
15 towards its carbon neutrality. It is therefore
16 incredibly disheartening to hear that this EPA
17 administration is championing a proposed rule that
18 claims to be for increased transparency, when in
19 fact the purpose and the fact of the proposed
20 would be to bar EPA from considering rigorous
21 public health science and reduce the transparency
22 of EPA's scientific analysis.

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The proposed rule would require the EPA base some of its most important regulatory decisions only upon does response studies where the underlying data can be disclosed. The reality is that key scientific studies backing our nation's critical clean air safeguards which protect our health and environment are based on confidential patient data that in many cases cannot be disclosed in any form.

These rigorous peer-reviewed state of the art studies could be improperly discarded should this rule be finalized. As many scientists have noted, this would undermine and not promote the use of sound science in EPA decisions. Just because the data underlying a study isn't published does not mean that the study cannot be verified using other means.

For example, the American Cancer Society’s Cancer Prevention Study II, tracked air pollution, exposure, and personal medical histories of nearly 670,000 people for more than two decades to understand the exact risk of air

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pollution on death.

The study was based on private patient information that cannot be publicly disclosed, and yet the study has been subject to reanalysis and its conclusions have been upheld. And allowed under the scientific journal does response, the authors listed 16 key studies alone which supported the original conclusion of the Cancer Prevention Study 2.

Even more concerning is the fact that the proposed rule provides the administrator with broad discretion to make exception to the policy on a case-by-case basis. Former Administrator Pruitt may be out of office now, but Acting Administrator Wheeler's record as a fossil fuel lobbyist for corporations like Murray Energy leaves me and others incredibly skeptical that this rule would be applied fairly with no concrete criteria guiding decision to grant an exception.

This part of the proposal raises a serious risk that this or future administrations could selectively waive the policy to build a

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distorted scientific record that is designed to reach a desired result. In fact, just a few weeks ago I was in Pennsylvania where I'm from, talking to an Uber driver. He's a father with a daughter who has asthma, and we talked about the EPA. He had worked in public service before and expressed to me how frustrated he was with the current administration, with the EPA, and how it seemed that despite the endless promises the administration has made to protect its citizens and better our lives, many of those promises were not being fulfilled.

I can't help but think how disappointed he would be if he knew that the EPA has proposed a rule which will make it more difficult for EPA to use the best science to protect the health of him and his family. Citizens are watching and aware, from parents, to scientists, to students like me who advocate for good policy on their own college campuses.

The EPA hastily shuttled this rule past even the OMB, but it must pause to hear the

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concerns of the public. EPA's proposal will lead to censored science, not transparent science. Thank you for the opportunity to testify on the proposed rule today.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 26, Ann Mesnikoff, and Speaker Number 27, Roy Gamse, come up to the speaker's table. And Speaker Number 28, Jennifer Sabb (sic), and Speaker Number 29, Paul Miller, please take your seat at the on-deck chairs.

MS. MESNIKOFF: Hi. I'm Ann Mesnikoff. It's M-E-S-N-I-K-O-F-F, and A-N-N, no E.

Good morning. I'm Ann Mesnikoff. I'm the Federal Legislative Director for the Environmental Law and Policy Center.

ELPC works throughout the Great Lakes and the Midwest, protecting public health and special places under the belief that environmental protection and economic development can be achieved together.

ELPC appreciates the opportunity to

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1 testify in opposition to EPA's proposal to censor,
2 or otherwise constrain the science it will
3 consider in issuing essential standards that are
4 meant to protect public health and our
5 environment. The Midwest and the Great Lakes
6 region, with its industrial and agricultural
7 heritage is impacted by environmental and public
8 health challenges to air, land, and water, and we
9 depend upon EPA to effectively implement
10 environmental laws to protect the public and our
11 environment.
12 There is no basis in existing bedrock
13 environmental laws that authorizes EPA to limit
14 science considered in rulemaking processes. EPA
15 cites several key laws in its justification for
16 this proposal. Nowhere in the cited statutes is
17 there a basis for demanding access to raw data,
18 nor does this relate sensibly to any definition of
19 best available science. Rather, this undermines
20 the use of best available science called for in
21 environmental statutes, including the Clean Air
22 Act.

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1 Further, there is no basis for
2 politically appointed administrators to choose
3 which science will be considered, and which may
4 not be. EPA should continue to apply the rigorous
5 standards the Agency has used for decades, and
6 that stakeholders engage in the process that is
7 full and open with regards to science.
8 EPA's Science Advisory Board voted to
9 review this action during its June 1st meeting.
10 This proposal has also prompted, as we've heard
11 today, vehement reaction from the scientific
12 community. EPA's proposal is not about
13 transparency. It is about undermining public
14 health. The negative effects of this proposed
15 rule on EPA's programs could be far reaching
16 across the Midwest. Midwesterners are exposed to
17 unhealthy levels of air pollutants, including
18 particulates, ozone, and toxic emissions from our
19 industries and agricultural operations.
20 Achieving and maintaining health air to
21 breath remains a challenge. EPA just finalized
22 not attainment designations for Midwest's biggest

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1 cities. There are millions of people -- where
2 millions of people live, work, and play.
3 Foundational studies about the impact of air
4 pollution to public health are essential. These
5 studies have been reviewed numerous times. Yet,
6 under EPA's proposal, they would be ruled out of
7 bounds, compromising the Agency's ability to truly
8 assess the impacts of air pollution and to set
9 standards are a level that will protect public
10 health as the Clean Air Act requires.
11 Weaker standards will mean dirtier air in
12 our communities. The elimination of these studies
13 would also skew the evaluation of cost and
14 benefits, leading to less protective rules that
15 will not be based on a true accounting of the
16 public health costs of pollution. We're also
17 concerned about how EPA's proposal to censor
18 science will impact a range of other significant
19 concerns across the Midwest and Great Lakes, from
20 using the best available science and its review of
21 toxic -- the toxic insecticide, chlorpyriphos, the
22 impacts of growing problems of harmful algael

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1 blooms in Lake Erie and other places across the
2 Great Lakes on public health, and in setting
3 standards for lead in water, soil, and in homes.
4 EPA has shown time and again that
5 achieving cleaner air, and water, and a healthier
6 environment go hand-in-hand with economic growth.
7 Our children's health across the Midwest depends
8 on EPA continuing to do its job and not let
9 industry-driven agenda undermine its essential
10 role. We respectfully ask EPA to withdraw this
11 proposal. We will be submitting more detailed
12 comments to the record. Thank you.
13 MR. ROBBINS: Thank you.
14 MR. GAMSE: I am Roy Gam -- I am Roy
15 Gamse, G-A-M-S-E, no S on the end. Formerly EPA
16 Deputy Assistant Administrator. Reading the
17 comments of John Bachmann of the Environmental
18 Protection Network. He served EPA for 33 years,
19 was Associate Director of Science Policy and New
20 Programs for the Office of Air Quality Planning
21 and Standards.
22 John's comments. "I appreciate the

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1 opportunity to provide the comments on the
2 proposed rulemaking on strengthening transparency
3 on behalf of EPN. EPN will submit the detailed
4 written comments on the proposal later."
5 "This proposal would not strengthen
6 transparency of regulations. Instead, it would
7 preclude the assessment and use of best scientific
8 information available as required by all major
9 statutes administered by EPA. The process by
10 which it was developed, the misuse of references
11 that ultimately do not support its arguments and
12 the lack of specifics, what EPA actually intends
13 to do are an embarrassment to the agency."
14 "The new acting administration should
15 withdraw it from consideration as soon as
16 possible. EPA's proposal is a solution in search
17 of a problem. A proposal asserts it's dealing
18 with a replication crisis, but does not cite a
19 single instance where a study used by EPA for any
20 type of major rule was shown to be flawed due to a
21 lack of access to the underlying data. In fact,
22 EPA and the industry funded an independent

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1 reanalysis of the two air pollution studies that
2 were criticized for not releasing confidential
3 health information, and both were successfully
4 reproduced with the results published in 2000.
5 Moreover, their key findings have been replicated
6 dozens of times since then by other investigators
7 using different health and air quality data."
8 "The proposal to exclude important peer
9 reviewed studies is wholly inconsistent with
10 scientific practice and EPA's past use of science
11 and regulatory decisions, where studies with novel
12 results appear, EPA's assessments have noted
13 limitations and some cases supported reanalysis."
14 "EPA's science policy related assessments
15 are, themselves, peer-reviewed by the SAB or CASAC
16 to further ensure study evaluations consider all
17 of the relevant scientific literature."
18 "As noted by the SAB workgroup, the EPA's
19 proposal downplays valid concerns about the risks
20 of providing access to the confidential
21 information of subjects in epidemiology studies.
22 The SAB group noted some of the largest most

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1 useful health effects data sets cannot be made
2 fully public because certain personal information
3 of age, sex, health, and location could be used to
4 identify participants, or because of agreements
5 made with study participants in advance."
6 "EPA failed to mention various ways to
7 assess the validity of fire epidemiology studies
8 without access to data, nor that the rule may
9 preclude continued use of studies published many
10 years ago."
11 "The proposal includes a provision for
12 the administrator to waive this requirement. No
13 clear decision criteria provided to allow EPA
14 scientists and stakeholders to understand when and
15 how the waivers would be granted. It appears that
16 requirement could be applied in an arbitrary and
17 capricious manner that does not reflect sound
18 science judgment. Critical decisions like these
19 must be made on the basis of science, not
20 politics. Otherwise, highly relevant studies for
21 which data can't be publicly shared, even if
22 published in the best peer reviewed journals and

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1 replicated may be judged to be inherently
2 untrustworthy."
3 "The rushed, mostly secret process EPA
4 followed in developing the proposal displays a
5 complete disinterest in transparency, much less in
6 science. In developing this proposal EPA
7 leadership did not provide a role for zone career
8 science experts in crafting the proposal, never
9 included the rule on its regulatory agenda, did
10 not notify of consult with the SAB, much less
11 request the review as required by law. Did not
12 solicit the advice of the NAS on provisions that
13 would change does response models used in risk
14 assessment from those previously recommended by
15 NAS, did not ask for review to solicit the views
16 of other federal agencies that conduct research or
17 use health effect science in developing
18 regulations. Finally, the Agency originally only
19 allowed a 30-day comment period on this remarkable
20 unvetted departure from the past practice."
21 "In suggesting potential cost of the rule
22 would be minimal, EPA ignored the cost to

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1 researchers who would have to pay to set up and
2 maintain data sharing for their previously
3 published studies to be considered, to EPA for
4 conducting the multiple reanalysis required in
5 Section 30.6 of the rule, and to public health for
6 the disbenefits of undermining existing
7 regulations. Having done no assessment, EPA has
8 no basis for its claim that the benefits of the
9 rule exceed its cost. Scientists and scientific
10 publications that EPA cites as evidence for
11 support for this rule have rejected the proposal's
12 preemption of existing studies based on
13 availability of raw data. Professor John
14 Ioannidis reacted strongly to the proposal in an
15 editorial noting that, quote, 'If the proposed
16 rule is approved, science will be practically
17 eliminated from all decision-making processes.
18 Regulation would then depend uniquely on opinion
19 and whim.' End quote."
20 "Editors of four major scientific
21 journals whose policies EPA cited as support
22 jointly stated, quote, 'It does not strengthen

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1 policies based on scientific evidence to limit the
2 scientific evidence that can inform them.
3 Excluding relevant studies simply because they
4 don't meet rigid transparency standards will
5 adversely affect decision-making processes.'"
6 "Finally, EPA should immediately withdraw
7 this flawed proposal from consideration, given the
8 fatal flaw of establishing unnecessary regulation
9 for science assessment that would elevate
10 transparency over any other criterion. We're
11 unable to offer any suggests for improving it."
12 MR. ROBBINS: Thank you.
13 MS. HALL: Would Speaker Number 28,
14 Jennifer Sabb (sic), and Speaker Number 29, Paul
15 Miller, come up to the speaker's table. And
16 Speaker Number 30, Matthew McKinzie and Speaker
17 Number 31, Anne Mellinger-Bird (sic), take a seat
18 at the on-deck chairs.
19 Please remember to speak into the mic and
20 state your organization.
21 MS. SASS: Hello. My name is Jennifer
22 Sass, S-A-S-S. I'm with NRDC, the Natural

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1 Resources Defense Council.
2 And I'm here to talk about the concern
3 that scientists and environment health and medical
4 professionals have with this rule. In one of his
5 last acts of aggression against the public before
6 resigning, the corrupt and disgraced EPA
7 Administrator Scott Pruitt, proposed the rule to
8 restrict the scientific studies that EPA could
9 rely on to set safety standards for toxic
10 chemicals.
11 Ironically, the rule is called science
12 transparency when in truth public health will be
13 seriously harmed. That's why over 40 doctors and
14 scientists released a letter today which was
15 submitted to the docket, raising alarm about the
16 rule and the harms that it would bring about.
17 In the letter, they say as scientists and
18 health professionals we recognize the importance
19 of data sharing and replicability in scientific
20 practice and discourse. The experts are part of
21 Project Tender, and their letter is also publicly
22 available.

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1 They say the proposed rule is about
2 stiffing science used by EPA, not improving it.
3 They all have careers devoted to protecting
4 children and their families from exposures to
5 neurotoxic chemicals. They say the proposal could
6 also undercut existing safeguards. Regulations
7 that have led to protections against toxic air
8 pollution, lead and drinking water, and dangerous
9 pesticides, such as chlorpyrifos.
10 Dr. Phil Landrigan, a globally renowned
11 expert on childhood harm from chemical pollutants
12 warned that if you implement this proposed rule
13 the inevitable consequence is that chemicals with
14 potential to damage children's brains and nervous
15 systems will remain longer on the market, and many
16 thousands of children born, and not yet born, who
17 could have been protected against these chemicals,
18 will be unnecessarily exposed. Brain damage with
19 loss of intelligence, disruption of behavior, and
20 diminished lifetime achievement will be the
21 result. Is this the legacy that EPA wishes to
22 leave for America's children?

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The Economist also wrote about the rule, very bluntly in an article titled, "Swamp science: Scott Pruitt embarks on a campaign to stifle science at the EPA." In that Economist article they emphasized that the proposal rule is really about blocking information used by EPA to protect our health. The rule prohibits the Agency from setting regulations that are supported in part or whole by data that is not publicly available for reanalysis or that cannot be replicated. It will hamstring EPA's use of scientific information, which could only harm EPA's work quality and public credibility.

There are many reasons why a study cannot be made fully public or replicated. For example, the original raw data may no longer be -- exist. Or the original exposure conditions may no longer exist, such as lead exposures from leaded gasoline, and patient protection and privacy rules may prevent full disclosure of the raw data, or information. EPA already has long-established and transparent methods for evaluating data in these

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situations.

This rule would block the studies used to set air pollution regulations that will have prevented more than 30,000 premature deaths by 2020, with benefits valued at 30 times the cost of the Clean Air Act, according to EPA scientists and technical experts.

The rule would also block the studies that protect children from lead poisoning in air, water, and soil, and would block the studies of harmed children that support an EPA proposed ban on the neurotoxic pesticide chlorpyrifos, which President Trump and former Administrator Pruitt have already rolled back those proposals.

This may be the most unpopular proposal from an already unpopular EPA administration to date. It is a rule that fundamentally purports to solve a problem that doesn't exist, and it should be abandoned. It cannot be fixed. Thank you.

MR. ROBBINS: Thank you.

MR. MILLER: Hello. My name is Paul Miller. It's M-I-L-L-E-R. I am Deputy Director

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of the Northeast States for Coordinated Air Use Management, or NSCAUM. NSCAUM is the regional association of state air agency air quality control agencies in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

My comments today reflect the majority view of NSCAUM's members, while individual members may hold some views different from the majority consensus.

In sum, we are concerned that should this proposal lead EPA to not fully consider the best available science in rulemakings, it will endanger public health and the environment.

The EPA invokes strengthening transparency as a primary driver for this proposal, but fails to describe how a perceived lack of transparency has hampered past rulemakings. It provides no examples of work, quote, "EPA has not previously implemented these policies and guidance in a robust and consistent manner," end quote, nor what are the specific

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quote, "Agency culture and practices regarding data access," end quote. That requires changing.

The Agency also provides no cost analysis of this proposal. Without additional clarity from EPA we are having difficultly identifying the problem EPA seeks to address. Therefore, for the following reasons we request that EPA withdraw the proposed rule.

First, the proposal is too vague as written to provide the public with meaningful opportunity to comment. EPA solicits comments across a long list of topic areas, but fails to provide the Agency's own sufficient detail and rationale on the solicited comment areas as required by the Administrative Procedure Act.

We are left to speculate on EPA's views, and on those of other commenters that would presumably shape EPA's final rule. It is well settled law that this approach fails to provide adequate notice for informed public comment.

Second, EPA must describe how the proposed text in Sections 30.5, 30.7, and 30.9

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1 affect current practice. Section 30.5 states that
2 the Agency shall ensure that those response data
3 and models underlying pivotal regulatory science
4 are publicly available in a manner sufficient for
5 independent validation.
6 Section 30.7 states, EPA shall conduct
7 independent peer review on all pivotal regulatory
8 science used to justify regulatory decisions.
9 EPA, however, does not describe what constitutes
10 in its view, independent validation and
11 independent peer review.
12 Furthermore, Section 30.5 includes
13 qualifying language that EPA will take all
14 reasonable efforts to make data available unless
15 it is not possible due to other constraints, such
16 as legal protections of privacy and
17 confidentiality.
18 EPA provides no examples of where and
19 how, in the Agency's view, past rulemaking
20 specifically failed to make these same efforts,
21 nor how EPA would change past practice in this
22 context. Adding to the vagueness of Sections 30.5

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1 and 30.7, Section 30.9 would provide the
2 administrator with broad authority to exempt
3 regulatory decisions from the proposed disclosure
4 provisions on a case-by-case basis if he or she
5 determines that compliance is impracticable. The
6 proposed rule fails to provide specific criteria
7 for determining when compliance is impracticable.
8 Lacking clear guidelines for transparent
9 decision-making, the administrator's discretion
10 would appear to be unbounded in application and
11 potentially based on haphazard and non-transparent
12 rationales.
13 Third, EPA has provided no meaningful
14 cost estimate for the proposed rule. The costs
15 are likely quite significant, however, based on a
16 congressional budget office cost estimate of the
17 similar congressional proposal.
18 In addition to lack of cost information,
19 EPA offers no accounting of foregone benefits
20 should a broad application of this proposal limit
21 the use of the best available science in setting
22 public health standards and preventing adverse

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1 health outcomes.
2 In conclusion, EPA's proposal has far-
3 reaching consequences on the future use of science
4 by the agency. These consequences, however
5 significant they may be, are indeterminate in
6 light of the proposal's vagueness. The proposal
7 fails to clearly articulate the problem EPA seeks
8 to address, the specific proposed rule
9 requirements, and its cost and benefits.
10 These are well understood and basic
11 elements that federal agencies must include to
12 ensure informed public comment. Given that these
13 elements are missing from this proposed, EPA
14 should withdraw it. Thank you.
15 MR. ROBBINS: Thank you.
16 MS. HALL: Would Speaker Number 30,
17 Matthew McKinzie and Speaker Number 31, Anne
18 Mellinger-Bird (sic) come to the speaker's table.
19 Would Speaker Number 32, Erica Bardwell, and
20 Speaker Number 33, Jennifer Reaves, take a seat at
21 the on-deck chair.
22 MR. McKINZIE: Good morning. I'm Matthew

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1 McKinzie, M-C-K-I-N-Z-I-E. I'm a nuclear
2 physicist with the Natural Resources Defense
3 Council, NRDC, and I'm very pleased to talk today
4 about this proposed rule. My remarks will focus
5 in on the radiation protection aspect of the
6 proposed rule.
7 NRDC, just as background, is a national
8 non-profit organization of scientists, lawyers,
9 and environmental specialists. We are dedicated
10 to protecting the public health and the
11 environment.
12 NRDC has been engaged with the
13 environmental issues surrounding nuclear energy
14 and nuclear weapons since our founding. There's
15 something strange about the proposed rule in that
16 it does not use the word radiation, and it does
17 not cite the EPA's authority under the Atomic
18 Energy Act.
19 Nevertheless, the language of the
20 proposed rule seems to clearly implicate radiation
21 protection standards. In particular, appears to
22 undermine the basis, a fundamental basis of

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1 radiation protection standards, the linear no-
2 threshold dose response model. And so that's what
3 I'll focus on with my five minutes.
4 The science in radiation epidemiological
5 studies has repeatedly demonstrated over decades
6 that linear no-threshold dose response, LNT,
7 provides the most reasonable description of the
8 relation between the low dose, low radiation dose
9 exposure, and the incidence of solid cancers that
10 are induced by that ionizing radiation.
11 EPA bases its regulatory limits and
12 nonregulatory guidelines for population exposure
13 to low-level ionizing radiation on this linear no
14 threshold model. EPA's radiation protection
15 standards are based on the premise that any
16 radiation does carries some risk, and that risk
17 increases directly with dose.
18 This method of estimating risk is called
19 LNT. For over 40 years, the LNT dose response
20 model has been commonly utilized when developing
21 practical and prudent guidance on ways to protect
22 workers and members of the public from the

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1 potential for harmful effects from radiation in
2 that balance, with commercially justified and
3 optimized uses of radiation. EPA derives the LNT
4 model from reports by authoritative scientific
5 bodies, including the National Academy of
6 Sciences, NAS, the National Council on Radiation
7 Protection and Measurements, NCRP, and other
8 bodies.
9 The NCRP published its last commentary on
10 the LNT issue only weeks ago, in April of 2018,
11 reinforcing this -- the LNT as the basis for
12 radiation protection standards.
13 Epidemiological studies of humans provide
14 evidence that is critically important in
15 establishing potentially causal associations of
16 environmental factors with disease. NAS and other
17 studies that EPA has long relied upon in the
18 radiation standard setting process are
19 epidemiological human cohort studies. EPA's
20 proposed rule, if implemented, would limit EPA
21 staff from basing regulatory actions on precisely
22 these types of studies by requiring that the

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1 underlying data of these studies should be
2 publicly shared, fully publicly shared. This
3 would be a nearly impossible task for the agency.
4 Data for some of the radiation
5 epidemiological studies are accessible to users,
6 with a detailed description of how a user can
7 access the information. However, public sharing
8 of personally identifiable information is
9 restricted. These are profoundly important
10 studies on radiation health effects that have been
11 peer reviewed for decades, and the science that
12 has emerged from them has been validated multiple
13 times. But these are not studies where the
14 entirety of the public data can be shared or
15 independently replicated.
16 Replication of these studies is
17 impossible as this data comes from individuals
18 exposed to significant, acute, and protracted
19 doses of radiation. Pruitt's proposed rule would
20 throw out the data from the atomic bomb survivors
21 of World War II. That's a profound, very profound
22 thing.

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1 Adverse consequences for EPA would affect
2 federal guidance reports, nuclear field cycle
3 standards and regulations, minimum amount --
4 minimum allowed concentrations of radiation in
5 drinking water, soil clean up for super fund
6 sites, radioactive waste disposals, as well as the
7 fundamental concept of ALARA, As Low As Reasonably
8 Achievable, in radiation protection standards.
9 In conclusion, I urge the EPA to abandon
10 the proposed rule as it fundamentally calls into
11 question basic radiation protection standards that
12 are scientifically founded and have protected the
13 public for many years. Thank you.
14 MR. ROBBINS: Thank you.
15 MS. MELLINGER-BIRDSONG: Hi. My name is
16 Anne Mellinger-Birdsong, M-E-L-L-I-N-G-E-R, dash,
17 B-I-R-D-S-O-N-G.
18 Thank you for allowing me to speak today.
19 My name is Anne Mellinger-Birdsong, and I am a
20 fellow of the American Academy of Pediatrics and a
21 specialist in environmental public health. I have
22 worked at city, county, state, and federal public

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1 health agencies, and Indian health service
2 facilities.
3 I'm here to speak in opposition to this
4 proposed rule and to state that this proposed rule
5 is unnecessary and it would harm EPA's ability to
6 evaluate health impacts of environmental
7 pollutants. It should not be finalized or
8 implemented.
9 This proposal has wording that makes it
10 appear noble and well-meaning, but it is a sheep
11 in wolf's clothing. This proposal will severely
12 hamper EPA's ability to use past and future
13 research on health effects of human exposure to
14 environmental chemicals and toxicants. It should
15 be withdrawn.
16 Both the HIPAA and the federal
17 regulations on human subjects research address
18 privacy as a concern of people who participate in
19 research. It's not as simple as redacting data
20 such as name, birth date, medical record number,
21 et cetera. You also have to not have data that
22 can be used to intuit or figure out who a study

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1 subject is. So you have a study of Town A and
2 people who had heart attacks in July. If there is
3 age or zip code data associated with that, the
4 people that live in Town A could figure out, oh,
5 that's Mr. X down the street. So it would really
6 hamper the ability to use data, and environmental
7 health data often has zip code and year and a lot
8 of stuff that can be used to put together and
9 figure out who people are.
10 So that's how it would work. And I just
11 would like to say also that children have even
12 more health protections than adults because of
13 being smaller, and we have to be more concerned
14 for them. And especially living human subjects of
15 research who will continue to live, we need to be
16 extra careful to protect their privacy. And this
17 rule would either require data made public, or it
18 would prohibit using a lot of data that would
19 enable -- that would inhibit privacy protection.
20 So also it would decrease people's trust
21 in participating in research if they are fearful
22 of their personal identifiers being released or

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1 people being able to know that they participated
2 in a study. They may not participate, so we would
3 have worse data for studies in the future because
4 of this rule.
5 And I would like to say that children do
6 not choose where they live, or where they go to
7 school, or what kind of water quality their water
8 they drink is, or the air that they breathe. It's
9 up to we, who are adults, the adults who are their
10 caretakers who choose where they live, and we who
11 set policies to make these decisions to keep
12 children healthy. And this rule would severely
13 harm children because it will throw out a lot of
14 data, and a lot of data that has been used to
15 form, already, established rules.
16 So I ask, why was this rule proposed? It
17 would eliminate use of scientific studies and
18 hamper future research. The rule was completely
19 unnecessary. We have mechanisms within scientific
20 institutions to transfer data so it's HIPAA
21 compliant and IRB approved, so we can verify
22 research and reevaluate it and confirm it. We

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1 don't need this rule and it is, again, it's a rule
2 that's unnecessary and would hamper and harm EPA's
3 ability to carry out its functions.
4 So I'm going to end with a quote by a
5 professor from Carnegie Mellon University, Granger
6 Morgan. He used to chair the EPA Science Advisory
7 Board under George W. Bush. He said, “this
8 proposed rule is an attempt by people who aren't
9 interested in using science to find the truth to
10 raise doubts about what, at this stage, is very
11 clearly established and well-reviewed science.”
12 And I urge the EPA to withdraw this
13 proposed rule and not implement it at all.
14 MR. ROBBINS: Thank you.
15 MS. HALL: Would Speaker Number 32, Erica
16 Bardwell, and Speaker Number 33, Jennifer Rebeb
17 (sic), come up to the speaker's table. And
18 Speaker Number 34, Molly Rauch, and Speaker Number
19 35, Barbara Gottlieb, take a seat at the on-deck
20 chairs.
21 Speakers are reminded to speak into the
22 mic and state your organization.

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MS. REAVES: Hi. My name is Jennifer Reaves. Reaves spelled R-E-A, V as in Victor, E-S. I represent Moms Clean Air Force, Maryland.

Am I supposed to speak first? Oh, okay.

My name is Jennifer Reaves. I live in Hyattsville, Maryland. Thank you for this opportunity to offer comment. As a member of Moms Clean Air Force, Maryland, I am here today to speak out in opposition to Acting Administrator Andrew Wheeler's attempts to censor science in the name of transparency.

This dangerous censoring sign plan to limit the scientific information EPA can use to identify public health threatens and future and safety of our children. This proposal will essentially require researchers to make private personal medical information public in order for the EPA to use their research in its decision-making.

This proposal also includes loop holes that would exempt industry from having to disclose details of their own studies. It is designed to

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favor the fossil fuel and chemical industries, limiting EPA's ability to protect us from toxic pollution and chemicals. High quality science is crucial to understanding the risk of our families face every day, especially when it comes to air pollution and toxic chemical exposure.

This proposal means that many studies on populations, such as elderly, young people, and people of color, groups who are often suffer disproportionately from pollution would be excluded from EPA consideration because making the data public could identify and participating -- identify the participating individuals. Including this important data from consideration means that implementing this proposal could even further exuberate negative environmental impacts on these and other vulnerable communities.

This proposal puts our children's bodies on the line by censoring research, making even low levels of pollution with significant health impacts instead of cleaning up their act. Polluting industries want these kind of studies to

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simply disappear.

My family and my fellow Marylanders are counting on the sound and transparent science the EPA has used for decades. And we are counting on our medical records remaining private. I strongly urge the EPA to stop this radical proposal for the health and safety of all Americans. Thank you.

MR. ROBBINS: Thank you.

MS. BARDWELL: All right. Excuse me. Thank you. My name is Erica Bardwell. Can you hear me? Okay.

I am a local registered nurse. I work at a local hospital. I'm also a member of Physicians for Social Responsibility. Thanks for taking time today.

Mr. Scott Pruitt is no longer here as EPA administrator, but it does seem that this proposal preserves the hallmark of his tenure. By that I have to say, I mean a complete lack of shame.

This proposal masquerades as an attempt to strengthen science, and by extension, public health. But this is a bald, even shameless lie.

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It would actually make public health research impossible, or much, much more difficult, which obviously is the real point.

If someone can't participate in medical research without worrying that their identities or parts of their medical records are going to be rampaging around the public record, then they simply won't do it. Which again, is the point.

Basically, shameless people say that to themselves behind their scenes. But to us they say that they're really concerned about us and public transparency, but it's not true.

I saw a reference to a replication crisis. Last I heard, the replication crisis was mostly social sciences. There's not a huge replication crisis in epidemiology. Certainly not to the point where basic facts are in doubt. There is no doubt that air pollution kills people, that poison in water makes people sick, that toxic soil grows toxic food. This is not in contention. There's no replication crisis here.

So the only purpose of this rule could be

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to avoid adding to the already damning weight of this existing evidence. Basically, to make it cheaper for a few people to literally poison people for profit, which is ultimately a tragedy for everybody.

I think the thinking is that sciencing debates are going to bore the public, and most other people have to work on a random Tuesday. I swapped a shift to be here, but most people don't have that option.

MS. DOA: Can you speak into the mic a little bit more?

MS. BARDWELL: Sure. Okay.

MS. DOA: That's better. Thank you.

MS. BARDWELL: So, the true public interest may not be represented here because people have to work. But if this rule is finalized, the public is going to howl once they actually feel its effects and lose the protection that they need from these studies. And I wouldn't want to be the person left holding the bag when that travesty happens.

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Finally, as my grandmother used to say, what sauce is for the goose is sauce for the gander. If exposing personal information is really required to have quality medical research, I eagerly await the day this administration proposes similar restrictions on, say, pharmaceutical research. I wait for the day that Pfizer can't get approval for its nth blood sugar pill without revealing incredibly invasive information about all of its research subjects. I don't think that day is ever going to come, because protecting people or advancing science isn't really the goal.

Thanks for your time.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 34, Molly Rauch, and Speaker Number 35, Barbara Gottlieb come to the speaker's table. And Speaker Number 36, Lyndsay Alexander, and Speaker Number -- is there a Speaker Number 37 in the room? What's your name?

MS. BENDER: Laura Bender.

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MS. RAUCH: Hi. I'm Molly Rauch. Name is spelled M-O-L-L-Y R-A-U-C-H. I'm Public Health Policy Director with Moms Clean Air Force. We're a national organization of more than a million moms and dads fighting air pollution and climate change for the sake of our children's health.

Thanks for this opportunity to offer comment. On behalf of our more than 1 million members, I am here today to strongly oppose the administration's attempts to censor the science used in public health decision-making. This intentionally misleading proposal is being sold by EPA leadership as an effort to increase transparency. But the facts suggest that the real motivation is simply to sweep under the rug the scientific evidence disfavored by polluting companies.

The proposal would prevent EPA from using studies that are based on personal medical data, thereby eliminating some of the most important long-term epidemiological studies, investigating the impacts of pollution on public health, and

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hundreds of scientists have already spoken out against this proposal.

Indeed, this flimsy proposal was designed without adequate input from the scientific community, according to the members of EPA's own Scientific Advisory Board. It was rushed through the regulatory process. It was originally proposed with a gallingly short public comment period that suggested an intention of casting less light on the rulemaking process, not more.

For a proposal that posits a sweeping change in the health-based rulemaking that is the foundation of the EPA, it was quite the slight of hand.

As a public health expert who has been closely following EPA's rulemaking process for more than a decade, it is evident to me that this is a cynical ploy to bolster polluting industries that don't like the results of longitudinal research.

Who does this benefit? Who really benefits from this charade? I must call it a

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1 charade. Not the families everywhere who want to
2 breathe clean air and drink clean water. Not
3 frontline communities dealing with multiple
4 pollution exposures from many industrial sources.
5 Not the millions of children in the U.S. with
6 asthma across the country whose disease can be
7 worsened by small changes in air quality day to
8 day, not the elderly, not those with underlying
9 health problems whose likelihood of being admitted
10 to the hospital, of having a stroke, of having a
11 heart attack, even of dying, could depend on the
12 levels of particulate pollution in the air. It
13 does not benefit these people.
14 I have a master's degree in public
15 health. One of the most valuable things that I
16 studied in graduate school was how to evaluate the
17 reliability of epidemiological studies. We learn
18 the importance of considering many different
19 criteria in making these evaluations. Whether the
20 raw data was available to me, personally, to
21 review, was never grounds for automatically
22 discounting the credibility or reliability of any

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1 given study.
2 The idea that an entire library of
3 research would be rejected wholesale, based simply
4 on that one external criteria, represents a crude
5 approach, to put it kindly.
6 We also, in grad school, learned about
7 the iron-clad importance of treating study
8 subjects ethically and with respect. And this is
9 a touchstone of public health practice. All
10 research on humans must be approved by
11 institutional review boards, and they prioritize
12 the privacy and consent of study subjects. There
13 are laws about this.
14 When study subjects are disrespected
15 terrible things can happen, which is why we were
16 required to learn about things like the, “Tuskegee
17 Study of Untreated Syphilis in African/American
18 (sic)Men,” when we were in public health school.
19 We cannot go back to the time when the study
20 subject was a mere pawn in someone else's game.
21 Treating study subjects ethically requires
22 protecting their privacy.

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1 Finally, we studied the tactics of
2 polluting industries and their shameful legacy of
3 attempting undermine science, whether it was the
4 tobacco industry or the lead industry, we learned
5 about the deliberate, expensive, decades-long
6 campaigns to protect corporate profits, and
7 meanwhile people were literally dying as a result.
8 This is an old story. We've heard it before, and
9 we're hearing that story again. Public health
10 professionals are trained to recognize history and
11 call it out, which is what we are doing today.
12 This proposal is an excuse to hamstring
13 researchers to weaken public health protections,
14 and to pad the profits of polluting industries.
15 As a public health professional, as a mother, and
16 on behalf of the 1 million members of Moms Clean
17 Air Force, I strongly urge the EPA to stop this
18 proposal for the health and safety of all
19 Americans. Thank you.
20 MR. TEICHMAN: Thank you.
21 MS. GOTTLIEB: Good morning. My name is
22 Barbara Gottlieb, G-O-T-T-L-I-E-B. I'm the

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1 Director for Environment and Health at Physicians
2 for Social Responsibility.
3 On behalf of our 33 members, I'm here to
4 express our opposition to the proposed rule --
5 "Strengthening Transparency in Regulatory
6 Science."
7 The U.S. EPA plays a critical role in
8 keeping our nation and our families safe from
9 environmental exposures that can cause illness and
10 death. We thank you for that - and we count on you
11 for it. Because your role is vital to our health
12 and well-being, the nation relies on you to
13 formulate and enforce the most effective
14 protections possible, based on the best available
15 science. The medical and scientific studies that
16 underlie the EPA's decisions must be objective,
17 vetted, and present a full and accurate assessment
18 of the threats to health posed by the pollutants
19 under study.
20 To provide those full and accurate
21 assessments, studies need to relate exposure
22 levels to actual health outcomes in real human

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1 beings, and to amass large data bases so that
2 researchers can draw valid conclusions.
3 In order to have reliable data and large
4 sample sizes, researchers frequently study the
5 records of patients treated in hospitals. Hospital
6 records, of course, include personal identifiers,
7 and disclosure of those identifiers would violate
8 privacy and confidentiality laws. Thus, the best
9 available data for many health studies cannot be -
10 in the literal sense -fully and openly shared.
11 However, to refuse to consider scientific
12 studies simply because they include personal
13 identifiers -- would be a great mistake, nor is it
14 necessary. Reviewers wanting to reproduce a study
15 in order to validate it can arrange to have
16 confidential access to key data. Furthermore,
17 scientists can assess the merits of published
18 research without seeing its data by considering
19 such published features as the study's research
20 design, the methods used for data collection and
21 analysis, and comparison with previous results.
22 In any case, to exclude credible peer-

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1 reviewed scientific studies because the personal
2 identifiers cannot be released under the law, is
3 to exclude from the EPA's consideration many
4 important and valid studies. This would greatly
5 hamper our ability, your ability, to understand
6 the impacts of serious, even deadly, pollutants.
7 I'd like to cite, as example, three
8 studies that could be lost to consideration under
9 the proposed rule, on a topic I haven't heard
10 referred to today. These studies reveal
11 statistical correlations between exposure to
12 emissions from fracturing, or fracking, for oil
13 and gas, and serious health outcomes.
14 So the first is a study by University of
15 Pennsylvania and Columbia University researchers
16 and published in 2015 in the journal, PLoS ONE,
17 found that drilling and fracking activity in
18 Pennsylvania was associated with increased rates
19 of hospitalization for cardiology, neurology,
20 cancer, skin conditions, and urological problems.
21 In communities with the most wells, the
22 rate of cardiology hospitalizations was 27 percent

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1 higher than in control communities with no
2 fracking. These findings are obviously of great
3 concern; we would not want them to be lost to the
4 EPA as you consider regulation of fracking related
5 emissions.
6 Yet because the data includes such things
7 as patients' names, diagnoses, addresses, and zip
8 codes, this valuable study could be, under the
9 proposed rule, excluded from EPA consideration.
10 Another study conducted in Pennsylvania
11 between 2005 and 2012, found that living near
12 fracking operations significantly increases asthma
13 attacks. This study was conducted by researchers
14 at Johns Hopkins University and it was based on a
15 study of 35,000 medical records of people with
16 asthma. This is just the sort of study that we
17 want EPA to base its health-protective regulations
18 on: a robust database conducted by researchers at
19 a respected institution and published, as this one
20 was, in the Journal of the American Medical
21 Association Internal Medicine.
22 Yet should the proposed rule be adopted,

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1 this study could be disallowed because its 35,000
2 medical records cannot easily be scrubbed of
3 personal identifiers.
4 Third example, a study by the Johns
5 Hopkins Bloomberg School of Public Health and
6 other researchers, used data from the Geisinger
7 Health System on over 9,000 pregnant women and
8 their over 10,000 newborns between January 2009
9 and January 2013. The researchers found that the
10 pregnant women who live near active fracking
11 operations in Pennsylvania were at a 40 percent
12 increased risk of giving birth prematurely.
13 Premature birth is the leading cause of infant
14 death in this country.
15 So we're talking about data that indicate
16 that fracking operations could put newborn babies
17 at risk of death. This was a study published in
18 the peer review journal, Epidemiology.
19 Our families should have the benefit of
20 these studies and many more that might be
21 disregarded under the proposed rule. To exclude
22 them would be to weaken the scientific record and

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1 undercut an accuracy and strength of EPA's
2 regulatory process, and to endanger human health.
3 For that reason, Physicians for Social
4 Responsibility opposes the proposed rule. Thank
5 you.
6 MR. ROBBINS: Thank you.
7 MS. HALL: Would Speaker Number 36,
8 Lyndsay Alexander, and Speaker Number 37, Laura
9 Bender, come up to the speaker's table.
10 And would Speaker Number 38, Liz
11 Borkowski, and Speaker Number 39, Janice Nolen,
12 take your seat at the on-deck chairs.
13 MS. ALEXANDER: Good morning. My name is
14 Lyndsay Alexander, A-L-E-X-A-N-D-E-R. I direct
15 the National Health Year Campaign at the American
16 Lung Association. I am also the mother of a
17 thriving toddler, who like all children, deserves
18 healthy air to breath, and safe water to drink
19 that won't make him sick or die prematurely.
20 I am here to ask EPA to withdraw this
21 proposed rule because I'm very concerned that
22 rather than foster transparency in regulatory

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1 science, this rule promotes a callous effort to
2 suppress and censor the science used to inform EPA
3 policy to the detriment of millions of Americans'
4 health and well-being.
5 EPA's ability to effectively fulfill its
6 mission and protect public health from dangers,
7 such as air pollution, hinges on the ability of
8 its scientists to first evaluate the best
9 available scientific evidence of the health
10 threats of air pollution. Recognizing that
11 scientists' understanding of the relationship
12 between air pollution and public health would
13 continue to evolve, congress wisely required EPA
14 to review the latest evidence and revise air
15 pollution limits for six key pollutants every five
16 years. And then to work with states to reduce
17 pollution to meet the limit.
18 While more work remains, this basic
19 approach has worked exceedingly well at reducing
20 ambient air pollution, saving lives, and improving
21 health by preventing asthma attacks, heart
22 attacks, and many other negative health outcomes

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1 from air pollution.
2 This proposed rule would require EPA to
3 exclude many of the best available peer-reviewed
4 and rigorously scrutinized studies from
5 consideration during decision-making, such as its
6 upcoming air quality standard reviews for ozone
7 and particulate matter.
8 Excluding studies for which raw data are
9 not available due to concerns over patient
10 confidentiality, or which do not meet vague
11 standard of reproducibility because studies were
12 conducted over long periods of time, or connected
13 to real world events beyond the control of
14 researchers, would greatly narrow the body of
15 evidence and the quality of the information that
16 EPA can consider. This would undoubtedly lead to
17 weaker protections and EPA's ability to estimate
18 the true threats of air pollution on human health,
19 and the benefits of reducing pollution, and thus
20 result in weaker air pollution limits.
21 In 1993, researchers at Harvard
22 University published a landmark air pollution

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1 study, showing that particulate matter air
2 pollution was linked to premature death. The
3 Harvard Six Cities Study, as it is known, tracked
4 the health of 8,111 adults, and 14,000 children in
5 six small cities in the United States, beginning
6 in the 1970s.
7 This study found that people in cities
8 with cleaner air were living two to three years
9 longer than those living in cities with dirtier
10 air. Residents of Steubenville, Ohio, the city
11 with the dirtiest air, were 26 percent more likely
12 to die prematurely than were citizens of Portage,
13 Wisconsin, the city with the cleanest air.
14 What surprised researchers was that the
15 culprit was particulate matter, not sulfur-
16 dioxide, as they had thought. This was a very
17 important scientific discovery. This study, and
18 countless others since, have helped EPA to
19 understand that particle pollution in the air we
20 breathe, resulting from activities such as burning
21 coal for electricity, or diesel exhaust from
22 vehicles, harms human health in profound ways in

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1 communities across the nation and has paved the
2 way for stronger air pollution limits designed to
3 protect public health.
4 But the data for the Harvard Six Cities
5 Study are not publicly available, and the study
6 was conducted over a long period of time that make
7 it very difficult to reproduce. Industry, and
8 their allies in congress previously challenged the
9 findings of this study and other similarly
10 important studies. Instead of blocking the
11 studies, as this proposal would do, EPA took a
12 logical step and referred them to an independent
13 third-party, the Health Effects Institute, for a
14 deep dive review.
15 There, autonomous reviewers examined the
16 data and developed a report that confirmed their
17 original findings. Other research has since
18 confirmed similar findings, including some studies
19 that use publicly available data sets. Critically
20 important studies, such as the Harvard Six Cities
21 Study would likely be excluded under this proposal
22 to the detriment of health protections. This

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1 proposal would also affect other protections
2 currently in place, such as limits on certain
3 toxic air emissions from tail pipes and smoke
4 stacks, and information on the health effects of
5 many of these; more than 150 chemicals come from
6 older studies built on confidential patient or
7 private business data that cannot be made public.
8 This could -- this proposal could also
9 cull the use of research that includes
10 confidential business information or older studies
11 that has data stored on older technology that
12 can't be recovered, just to name two other
13 limitations.
14 Thank you for the opportunity to speak
15 today. The American Lung Association will submit
16 more detailed written comments.
17 MR. ROBBINS: Thank you.
18 MS. BENDER: Good morning. My name is
19 Laura Bender, L-A-U-R-A B-E-N-D-E-R, and I'm the
20 National Director of Advocacy of the American Lung
21 Association's Healthy Air Campaign.
22 The lung association's mission is to save

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1 lives by improving lung health and preventing lung
2 disease. And as you know, we strongly oppose
3 EPA's so-called, "Strengthening Transparency in
4 Regulatory Science," proposal.
5 Today you've heard from many
6 representatives at the public health and medical
7 community about the ways this proposal would
8 undermine human health. I'd like to take a few
9 minutes to highlight the Lung Association's
10 concerns about the lack of transparency in EPA's
11 work on this rule.
12 The administration has attempted to rush
13 this rule forward at every turn, consistently
14 sacrificing expert analysis and public health
15 along the way. This is a sweeping proposal that
16 will impact a wide range of public health
17 safeguards, essentially affecting every future
18 decision at EPA based on science. And yet, EPA's
19 process in issuing it has been haphazard, rushed,
20 and anything but transparent.
21 First, back in April, then Administrator
22 Scott Pruitt, prematurely announced the proposal

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1 while it was still undergoing interagency review
2 at the White House Office of Management and
3 Budget. Then, when media inquired about this
4 discrepancy, OMB actually backdated the clearance
5 by several days. This means that OMB only
6 reviewed the proposal for 48 hours. That's a
7 staggering tight timeline for such a sweeping
8 rule.
9 In a similar vein, EPA initially only
10 allowed a 30-day comment period with no public
11 hearing. The Lung Association was among the
12 organizations who requested 60 additional days and
13 a hearing. We greatly appreciate the additional
14 time and today's public hearing.
15 That additional time is crucial,
16 particularly because EPA has failed to complete a
17 regulatory impact analysis that explains the
18 impacts of the proposal, putting the burden on
19 commenters to do so instead.
20 EPA ignored another important opportunity
21 for review when it failed to consult the Agency's
22 own Science Advisory Board. The SAB, which

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includes appointed members from this administration, voted at its May meeting to request to review the proposal.

In a letter to EPA last month, they said that they were only made aware of the rule through the press, and when it was published in the Federal Register. The SAB said unequivocally, quote, "The proposed rule merits review by the Board."

We strongly encourage the Agency to move forward with the SAB review of the proposal. To refuse their request to do so would be unprecedented and in direct contradiction of the Agency's stated claim of wanting the best science to inform its decision-making.

EPA rushed out this proposal after an inadequate review process, and it shows. The proposal falls short in several key ways. First, EPA fails to provide any evidence that the changes outlined in the rule are needed. EPA's existing approach towards science, with its detailed review and deliberation of the research, is already

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transparent and has worked well for decades.

First, independent science has revealed that studies prior to publication by recognize journals, then independent and EPA staff scientists reviewed them again and question every aspect of the research in depth. And they do these reviews in wide open processes, including publication, public hearings, and comment periods.

EPA does not acknowledge the rigor of this process in its proposal. Instead, it attempts to justify this rule by claiming that the Agency is following in the footsteps of scientific journals. But last month as other commenters have noted, several scientific journals issued a joint statement highlighting their concerns with EPA's proposal and pointed out that even though many peer-reviewed publications have recently adopted transparency policies, they are still able to assess and use studies for which the underlying data cannot be made public.

Second, EPA fails to define its requirement that studies must be replicable. Does

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EPA mean that the Agency couldn't consider a study that looked at health impacts of a one-time event, like a major oil spill?

The SAB also raised questions about EPA's failure to define this and other terms.

Finally, EPA did not explain how the Agency would implement the rule. The proposal offers no process for public hearing, or even consultation with the SAB over implementation. What process would EPA use to review and assess the existing research and revisions? What guidance would the administrator receive to avoid arbitrary decision-making over the fate of this research?

And where would the massive staff time and resources the EPA would need for such a massive additional workload come from? What would have to be sacrificed?

EPA's rushed process, its inadequate review, its false attempt to claim that its policy is supported by scientific journals, and its many unanswered questions about how the proposal would

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work, all underscore a core problem with this rule. It would not improve the use of science of EPA. It would not make the Agency's science-based rules more transparent. It would permanently damage EPA's ability to do its job to protect the public.

On behalf of the millions of people with lung disease that we serve who will be hurt by the weaker pollution protections that would result from this proposal, we urge EPA to withdraw this rule to censor science. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 38, Liz Borkowski, and Speaker Number 39, Janice Nolen, come up to the speaker's table. And Speaker Number 40, Albert Donnay, you're already at your seat. Excellent. Also, if Speaker Number 15, Harvey Fernbach, is in the room, you can take a seat at the on-deck chairs. Last call.

MS. BORKOWSKI: Thank you for the opportunity to present comments. My name is Liz Borkowski, and I'm the Managing Director of the

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Jacobs Institute of Women's Health, which is at the Milken Institute School of Public Health at the George Washington University.

The Jacobs Institute is concerned about EPA's proposed rule, "Strengthening Transparency in Regulatory Science," due to the harmful impact it would have on women's health and reproductive justice.

We urge EPA to withdraw it based both on its detrimental impacts, and on the lack of a demonstrated need for such a rule. EPA has failed to demonstrate that its current processes for considering science and regulation are inadequate. It has not provided examples of any instances in which insufficient transparency has resulted in outcomes contrary to its statutory mandates or executive orders.

Given extensive existing procedures used by EPA and the scientific community at large to ensure the quality of research, EPA has failed to make a case that additional public access to data is necessary.

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The theoretical, but as yet undemonstrated benefits of EPA's proposed rule, must be weighed against the extensive and unequally distributed costs of such an approach. Failing to consider the best available evidence because the underlying data are not publicly available, would result in regulations that fail to sufficiently protect public health. The consequences would fall most severely on sensitive groups not adequately protected by current rules, which include racial and ethnic minorities, those with low socio-economic status, the elderly, and pregnant individuals and their eventual children.

My comments provide a few examples related to reproductive health. First, neurotoxicants are of particular concern to pregnant people and the parents of young children. In regulatory activities, to reduce exposure to neurotoxicants, such as lead and methyl mercury, EPA has relied on an extensive body of research. This research includes longitudinal studies of individuals who are exposed in utero or as young

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children to higher levels of lead or methyl mercury than would typically occur in the U.S. today. It would not be ethical to publicly release data from these studies, and it would not be feasible, particularly for older studies that used incompatible storage media to locate all participants and obtain their permission.

EPA's use of research on lead and methyl mercury also has implications for other agencies that address these substances. For instance, the Department of Housing and Urban Development relies on EPA's renovation, repair, and painting rule in its regulation of renovators working in housing units, receiving HUD housing assistance where lead paint is present.

EPA calculated the reference dose for methyl mercury that EPA and the Food and Drug Administration used to create guidelines on fish consumption, including recommendations for pregnant and breast-feeding women.

It does not appear that EPA has undertaken the required interagency review process

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to assess the implications of its rule for other agencies.

Another neurotoxicant of concern for reproductive health is the pesticide, chlorpyrifos. Researchers followed a cohort of children exposed to this pesticide before the current ban on indoor use and found lower IQ and working memory to be associated with higher levels of prenatal chlorpyrifos exposure.

In a rulemaking process regulating agricultural use of chlorpyrifos, EPA requested the underlying data from the Columbia Center for Children's Environmental Health. The response from Columbia University explained that because of the detailed sociodemographic and health-related elements their data set contains, they did not believe they could submit extensive individual-level data to EPA in a way that would ensure participants' confidentiality.

Such concerns are not uncommon with the kids of longitudinal data sets that allow identification of long-term consequences of

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environmental exposures. Often, the combination of variables used in an analysis provides enough information to identify individual participants and may include sensitive information, such as diagnosis of neurodevelopmental delays.

In addition, endocrine disrupting chemicals are of great concern and reproductive health and EPA has regulated some of these, such as PCBs and PBDEs, under the Toxic Substances Control Act.

Under reformed TSCA, EPA must make decisions based on the weight of the scientific evidence, but it is not clear how it can do so if studies may be eliminated from consideration because data sets are not publicly available.

If EPA moves forward with the rule it has proposed, it will undermine science and regulatory decision-making by making it difficult and potentially impossible to consider the best available science. This will have detrimental impacts on reproductive justice, health equity, and women's health. The Jacobs Institute of

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Women's Health urges EPA to withdraw this rule.

MR. ROBBINS: Thank you.

MS. NOLEN: Hi. Thank you. My name is Janice Nolen. It's J-A-N-I-C-E N-O-L-E-N, and I am the National Assistant Vice President for Policy for the American Lung Association.

The American Lung Association turns 114 years old this year. For more than a century we have fought to save lives for protecting lung health and preventing lung disease. We oppose the proposed rule.

Many years ago, in the early 1980s, my mother-in-law asked me to help her recruit participants in a major new study that they were doing. She worked for the American Cancer Society then. They were looking to create a huge database of ordinary Americans would be willing to provide them with confidential information about their health and medical experiences, and would allow them to track those for years to come.

I was so pleased that two men from my church choir in Nashville agreed to participate.

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They completed the forms and other paperwork, and became two of the more than half million participants in the cancer prevention study too.

Fast-forward a decade or so and I learned that their data were now part of a landmark study, the American Cancer Society study that revealed the risks to human health from breathing air pollution that I and my colleagues at the lung association were working hard to clean up.

Their data and private health and medical information, from hundreds of thousands of others were -- from hundreds of thousands of other people, who were pointing the way, the need to clean up emissions from power plants, from diesel engines and fuels, and many other sources. I never dreamed when my mother-in-law made her first request to me that EPA scientists and other researchers would mark that study as one of two seminal studies that helped reshape our understanding of the health risks from particulate matter air pollution.

None of us then would have ever dreamed

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that the information these two men provided would have helped to identify and underline the threat to human life posed by microscopic particles in the air we breathe.

Furthermore, that study and the Harvard Six Cities Study became examples, not only of ground-breaking research, but of how questions about that research can be reviewed and resolved without having to lose the entire study.

Unfortunately, that is an example that this proposal clearly fails to understand. These two studies with decades-old patient data and others in the long list of studies that found evidence of harm from industrial emissions are unique events that no one hopes to replicate, like gulf oil spills, clearly appear to be targets of this proposed rule.

Studies that have been -- long been targets of industry polluters and their allies, remains so in this proposal.

Once published, these studies raised alarms in the public health community about the

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1 increased likelihood of premature death from
2 particulate matter, widespread in the nation. The
3 studies raised alarms within industry too, about
4 the increased likelihood that their polluting
5 sources would have to clean up their emissions.
6 Industry kicked in messaging developed by the
7 tobacco industry, to challenge the science using
8 the same arguments we have in this proposal.
9 I have in my office, a page from a 1999
10 U.S. News and World Report article on the
11 challenges to these studies that could have been
12 written this year.
13 Scientists are working to become more
14 transparent in their research. More researchers
15 use publicly available information, but some
16 studies cover populations that are so limited in
17 size or specialized in their characteristics that
18 these data could not be posted on the web for all
19 the world to see. Anyone who has an account on
20 Facebook should have a visceral knowledge of how
21 important keeping confidential data confidential
22 can be.

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1 Meanwhile, EPA could readily review
2 historical data and studies in ways that respect
3 patient confidentiality and the gifts of data from
4 people like my two choir member friends.
5 So far, EPA has failed to show any reason
6 that these changes are needed in the current
7 system. Failed in its own transparency on this
8 issue, in fact since EPA has not sought SAB review
9 of this, and has not provided sufficient rationale
10 for why EPA needs this change, much less how they
11 would this rule going forward.
12 We request EPA to withdraw this proposal.
13 Thank you.
14 MR. ROBBINS: Thank you.
15 MS. HALL: Would Speaker Number 40,
16 Albert Donnay, come to the speaker's table. And
17 Speaker Number 41, Mona Sarfaty.
18 MR. DONNAY: Thank you. My name is
19 Albert Donnay. My comments are based on
20 experience gained from 40 years working on
21 regulatory science as an environmental health
22 engineer and toxicologist, as a research

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1 scientist, public health activist, clinician,
2 consultant, peer-reviewer for academic journals,
3 environmental groups and government agencies at
4 all levels, including EPA.
5 I'm glad I get to follow the last two
6 speakers because I want to highlight that although
7 EPA's proposal to “Strengthen Transparency in
8 Regulatory Science” is needed, did not give any
9 examples of regulations that had been undermined
10 by a lack of such transparency.
11 I want to remind everyone here what's at
12 stake and what happened the first time EPA,
13 congress, and environmental groups had to decide
14 whether it was okay to base regulatory standards
15 on published scientific studies whose achieves
16 were no longer available for review.
17 They got the answer right then, and I
18 hope they'll get it right again now. It was May,
19 1983, 35 years ago, and the EPA was about to
20 publish a new national ambient air quality
21 standard for carbon monoxide based on nine studies
22 by a distinguished cardiologist at the VA, Dr.

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1 Aronow. When the Washington Post reported that
2 he'd been barred by FDA a year earlier for
3 submitting a wave of false medical experiments
4 after he admitted, quote, “fudging his lab reports
5 in human drug studies.”
6 Although EPA's head of the Office of Air
7 Quality Planning and Standards said the Agency
8 had, quote, "No reason to believe anything was
9 wrong with Aronow's CO studies," whose data Aronow
10 claimed at the time, "are excellent and can't be
11 questioned." EPA nevertheless appointed a special
12 team of agency and outside scientists to review
13 his work, quote, "When we read that Aronow had
14 done some kooky things."
15 A month later, The Post reported the
16 shocking results under the headline, "EPA Probe
17 Criticizes a Study Used in Air-Quality Standard."
18 The team had said, quote, "Could not resolve the
19 issue of possible falsification of data because,"
20 quote, "no data were available." Aronow told them
21 he'd discarded the archives of all of his CO
22 studies after first storing them in his garage for

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1 years, and offering it to EPA because they didn't
2 want it.
3 The investigators noted considerable
4 concerns about the validity of the results
5 reported, quote, "Raw data were lost or discarded.
6 Adequate records were not maintained, available
7 data were of poor quality, and quality control was
8 nonexistent."
9 And Aronow's published results were
10 consistently too good to be true. They found it,
11 quote, "Rather remarkable that in 10 years of
12 research his papers showed," quote, "not even one
13 missing data point." They concluded that EPA,
14 quote, "Cannot rely on Aronow's data due to the
15 concerns we've noted." And they recommended the
16 Agency commission new research to attempt to
17 replicate Aronow's findings.
18 Congressional hearings and the GAO
19 investigation followed, after which Administrator
20 Ruckelshaus agreed that EPA would not rely on any
21 of Aronow's studies in future rulemakings, but
22 only on studies whose archives were still

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1 available for review.
2 In coordination with the California Air
3 Resources Board and the Health Effects Institute,
4 EPA commissioned a series of new controlled human
5 exposure studies on CO, and since 1994, has based
6 the CO NAAQS exclusively on just six of them, all
7 of which published their individual results in
8 deidentified form so they would be available for
9 public review in perpetuity.
10 And it's a good thing they did since all
11 the larger archives of these studies were
12 eventually discarded by their authors without
13 being offered to EPA. This history shows that EPA
14 can and should base regulations solely on studies
15 whose methods and data are available for review.
16 To base regulations on studies that can't be
17 reanalyzed is not science, and there is no need
18 for it. Even federal rules that are based on
19 older epi studies, like the last particulate NAAQS
20 rule in 2013 that cited just six studies could and
21 should be based on more recent research that
22 better reflects current air quality.

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1 Over 500 studies a year are now published
2 on particulate epidemiology, and many are in high
3 quality journals that require authors at least to
4 make all their deidentified data and methods
5 available to reviewers, if not to all readers from
6 the posting of supplemental material.
7 Given EPA's interest in basing
8 regulations on more transparent research, EPA
9 should start requiring all the researches it
10 funds, intermural and extramural, to publish their
11 results in such journals. Hopefully this will
12 prompt less rigorous journals that don't require
13 the posting of supplemental material to update
14 their policies.
15 In conclusion, the Aronow scandal shows
16 EPA cannot rely exclusively on traditional peer
17 review to detect misconduct. Aronow reviewers at
18 11 leading journals, as well as EPA staff and
19 their scientific advisors on the CASAC, who also
20 review the studies before recommending that nine
21 be cited as the basis for the CO NAAQS.
22 Unfortunately, despite all this publicity, none of

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1 Aronow's studies were retracted, and the EPA has
2 started citing them again, most recently in the
3 2010 integrated science assessment of the CO
4 literature.
5 EPA's proposal to strengthen transparency
6 and regulatory science could stop this from
7 happening again, which is why I support it and
8 encourage my colleagues to do so as well. Thank
9 you.
10 MR. ROBBINS: Thank you.
11 MS. SARFATY: Can you hear me?
12 MR. ROBBINS: Yes.
13 MS. SARFATY: Yeah. Okay. Respected EPA
14 panelists and fellow citizens, my name is Mona
15 Sarfaty. I'm a physician trained in family
16 medicine and public health. I practice primary
17 care medicine and taught medical and public health
18 students in three different academic medical
19 centers for 35 years.
20 Today I direct a program in climate and
21 health at George Mason University in Fairfax,
22 Virginia. I also direct a consortium of physician

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1 societies called the Medical Society Consortium on
2 Climate and Health, whose 550,000 members are more
3 than half the physicians in the United States.
4 The Consortium seeks to inform the public
5 and policy makers about the health harms of
6 climate change, and the health benefits of climate
7 solutions. I'm submitting the formal comment of
8 the consortium in written form in a separate
9 document.
10 The EPA is proposing to change the rules
11 that dictate what evidence must be considered as
12 the basis for protecting the public's health. As
13 a physician who spent a summer in Southern
14 California during college and didn't see Mount
15 Wilson looming in front of me for an entire week
16 because of smog, I am incredulous.
17 I remember well the pain in my chest when
18 trying to play tennis on those smoggy days. This
19 was the early 70s, when a republican president was
20 creating the EPA. Now, 50 years hence, tremendous
21 evidence has accumulated that validates my
22 symptoms and the negative effect that unhealthy

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1 hair -- air, has on people who must breathe it.
2 After that summer, as a practicing
3 physician, I took care of people with asthma and
4 chronic lung disease who were at greater risk on
5 bad air days. So it is shocking to me that the
6 EPA would propose putting aside huge amounts of
7 thoroughly reviewed evidence on the causal
8 connections between air pollution and poor health,
9 claiming that the basis for this conclusion was
10 secret.
11 Today, I lead a consortium comprised of
12 the country's largest medical societies whose
13 doctor members are highly concerned about the
14 health harms of climate change. The similarities
15 between the current EPA willingness to disregard
16 established science about the connection between
17 carbon dioxide and global warming, and the
18 willingness to disregard solid evidence about the
19 impact of air pollution on health, are glaring.
20 Despite overlapping evidence from every
21 country in the world, and the entire U.S. climate
22 science enterprise, not to mention major federal

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1 agencies like NOAA and NASA, the EPA leadership
2 does not accept or recognize reality.
3 To all of us whose lives are dedicated to
4 helping people get and stay healthy, there is a
5 secret lurking in the science of air pollution and
6 global warming. It is not what we have long-known
7 about how burning fossil fuels creates waste
8 products that damage and inflame our lungs. This
9 has been validated by voluminous overlapping
10 research studies. The secret is not that carbon
11 emissions from burning fossil fuels are warming
12 our climate, exacerbating the health harms of air
13 pollution, and causing other dangers to our
14 health, from heat waves, wild fires, pollen, and
15 storms.
16 The secret is hiding in plain sight.
17 Fighting air pollution is the greatest public
18 health opportunity of our time. It's the greatest
19 public health opportunity of our time.
20 Reducing polluting fumes and emissions
21 from fossil fuels will rapidly improve our health
22 and fight climate change.

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1 When an EPA's not so secret agenda is to
2 promote fossil fuels, two things follow. The fact
3 that fossil fuels are the major contributor to
4 both air pollution and global warming must be
5 undermined or denied. And the research that
6 documents this reality and how it harms our health
7 must be attacked. It's not hard to see that the
8 approach is to mislead people by wrapping these
9 attacks in rhetoric that's alternatively scary as
10 in secret science, and high-minded, as in
11 transparency.
12 We're told that the rationale for the new
13 proposed strengthening transparency standard is
14 that individual and medical records included in
15 research were secret. In fact, like all medical
16 records, they were confidential and they remain
17 so.
18 The record shows that the same argument
19 of secrecy against scientific studies has been
20 used by polluting industries going back many
21 years.
22 Health providers know that the facts may

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be scary when our health is threatened. But we also know that denying or ignoring facts blinds us to discovering and acting on the best ways to heal medical problems and protect our health. We can't let that happen. The EPA must live up to its charge and work to face facts and protect our environment and our health. With this proposed regulation, its leadership is pointing in the opposite direction. Thank you.

MR. ROBBINS: Thank you.

Okay. We're going to take a short recess now and we'll resume at noon.

[Morning session adjourned.] [On the record 12:00 p.m., Afternoon session.]

MS. RADZIKOWSKI: Good afternoon. If everyone will please take their seats? Hello, and thank you for coming. My name is Mary Ellen Radzikowski and I am in the EPA's Office of Research and Development and I'm one of the hearing officials. Joining me is Lynn Flowers, also from the Office of Research and Development and we have a number of folks: Nanishka Albaladejo, Lauren Hall and

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Lesley Stobert from SC&A Inc., helping with logistics.

The purpose of today's hearing is to accept public comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science". EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding and the testimonies will become part of the administrative record on which EPA will base its decision.

Public notice of this hearing was published in the Federal Register on April 30, 2018 (83 FR 18768). EPA is proposing this rule under the authority of 5 U.S.C. 301, in addition to the authorities listed in the proposed rule document dated April 30, 2018.

My role is to ensure that the EPA receives your comments in an orderly fashion. Although EPA panel members here may ask clarifying questions, the intent of the hearing is to listen to your comments, not to discuss or debate the proposal. Now I will go through a few housekeeping items and

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ground rules: Please refrain from interrupting speakers or asking questions. Shouting, noisemaking or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately and listeners on the phone hear the oral testimonies. For everyone's awareness, this hearing is open to the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio and photos. We ask that you not cause any disruption to those testifying or observing the hearing.

There is no formal lunch break scheduled. You may leave and return to the hearing. Please note that you will need to clear security again so please be aware of the time.

If you would like to make an oral comment at today's hearing and did not pre-register to speak, please see the hearing staff at the registration

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table located right outside the doors here. If you would like to provide a written comment for the official record, you may hand-submit it to EPA staff today, or mail, fax or email your comments. See the staff at the registration table for instructions on how to do that. There is a comment box at the registration table where you can leave hardcopies of your oral testimony or written comments. All comments received will be included in the official docket. If you submit written comments, it is not necessary for you to give the same comments orally; written comments and oral testimonies will receive equal consideration by EPA in preparing its final rulemaking decision.

EPA has extended the comment period. Written comments must now be received on or before August 16, 2018. EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science", so please refrain from making comments that are not related to this action.

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1 EPA will not be providing responses during the
2 hearing. Rather, EPA will prepare a written
3 summary of the comments received that includes
4 responses.
5 The summary of the Response to Comments, the
6 document, will be available at the time EPA issues
7 its final decision. EPA will not make a final
8 decision until all comments submitted during the
9 public comment period have been considered.
10 The hearing is being recorded by a court reporter,
11 who will be preparing a verbatim record of this
12 hearing.
13 Please speak clearly and slowly into the
14 microphone so that the court reporter can
15 accurately record your comments. A copy of the
16 transcript will be placed in the docket. This
17 hearing is also being audio streamed through Adobe
18 Connect via the telephones.
19 The hearing is scheduled -- started at 8 AM this
20 morning and is scheduled to go to 8 PM. We're in
21 the second session: 12pm-4pm.
22 Public restrooms are located down both sides of

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1 the hall. At the doors we have staff that can
2 escort you out and back. Please note the location
3 of the emergency exits. Please take a moment to
4 silence your cell phones.
5 Speakers should have been given a sticker upon
6 check-in that lists your assigned session. If you
7 plan to speak and have not received a sticker,
8 please be sure to check in at the registration
9 table. For this session, the speaker sticker
10 color is white, so if you have a white sticker
11 you're registered for this session.
12 Speakers will be called to the speakers' table
13 (located right over there) in pairs by their
14 speaker number.
15 When it is your turn to speak, please come to the
16 table, state and slowly spell your name for the
17 record, and if you are appearing on behalf of
18 someone or another organization. If you are not
19 in the room when it is your turn to speak, I will
20 recall you after all other speakers have made
21 their oral comments. Each speaker will be
22 allotted 5 minutes for remarks. Elected and

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1 appointed government officials may be provided
2 additional time, since they represent large groups
3 of constituents. Speakers will be notified when
4 their time has ended. Our timekeeping system
5 consists of green, yellow, and red lights. When
6 you begin to speak, the green light will come on
7 to indicate you have your 5 minutes. The yellow
8 light indicates that you have 1-minute left and
9 when the red appears, your 5 minutes are over. At
10 that moment, if needed, I will politely interrupt
11 you and ask you to wrap-up your testimony to give
12 others an opportunity to speak.
13 At this time, we are going to begin.
14 MS. STOBERT: If Speakers Numbers 1, Pamela
15 Miller, and 2, Elizabeth Geltman, will come to the
16 speakers table and Speakers 3 and 4, Patricia
17 Koman and Alexis Adiman would go to the on-deck
18 seating located near the stage.
19 MS. MILLER: Good afternoon, my name is Pamela
20 Miller, P-A-M-E-L-A, M-I-L-L-E-R. I serve as
21 Executive Director and provide these comments on
22 behalf of Alaska Community Action on Toxics.

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1 We're a nonprofit, public interest environmental
2 health, research and advocacy organization,
3 dedicated to protecting public health. I also
4 serve as principle investigator of multiyear
5 research studies involving several universities
6 that investigate exposures and health outcomes
7 concerning endocrine-disrupting chemicals in
8 collaboration with Arctic indigenous communities
9 in Alaska. I traveled the distance to Washington,
10 D.C., from St. Lawrence Island, Alaska, in the
11 Northern Bering Sea, two full days of travel,
12 where we are conducting summer field research and
13 interrupted this because EPA did not make it
14 possible to provide remote testimony.
15 Through a process known as global distillation,
16 the Arctic has become a hemispheric sink for
17 contaminants that are carried on atmospheric and
18 oceanic currents into the north where they
19 concentrate in the bodies of fish, wildlife and
20 people. Indigenous peoples of the Arctic are
21 among the most highly exposed populations on Earth
22 to persistent bio-cumulative and toxic chemicals

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because of their reliance on traditional foods including fish and marine mammals that they use for their spiritual, cultural and physical sustenance. The communities that I work with on St. Lawrence Island also have higher exposures to chemical contaminants from military operations associated with formerly used defense sites. Our research elucidates exposure pathways, body burdens and health outcomes associated with chemicals including PCBs, PBDEs (or polybrominated diphenyl ethers) and other flame retardants and also perfluorinated substances in homes, in air, water, traditional foods and in the blood serum of the Yupik people of St. Lawrence Island. Our studies have shown elevated body burdens as well as disruption of thyroid function associated with these exposures to certain PBDEs and perfluorinated substances. We are now beginning a research study to investigate exposures to PCBs, PBDEs and currently used organophosphate flame retardants in young Yupik children, age 2 to 12, because elders and other community leaders are

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concerned about possible adverse effects on children's neurodevelopment. They're concerned that chemical exposures might harm the children's abilities to learn the languages, songs and stories that are so vital for the continuance of the culture of Yupik people. Participation is dependent on the trust of confidentiality that they give to us as researchers. Our research team submits each proposal to rigorous review to the National Institute of Environmental Health Sciences. In the process of the research, we submit also to several institutional review boards for approval to collect sensitive and detailed information on health and behavior as well as spatial and demographic data in an ethical manner that protects human subjects. We have published results of our research in 11 peer-reviewed journal articles after receiving approval from the tribal leadership. These findings help inform interventions and policies to reduce burdens of toxic exposures and prevent further harm to public health. These studies are possible only because

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we guarantee to protect the medical privacy of participants, again dependent on trust of the researchers. We gather detailed information about peoples' health and occupational histories, practices in their homes and communities that might relate to chemical exposures. If the proposed rule were to go into effect, studies such as these would not be considered by EPA when it makes decisions about chemicals and pollutants that are poisoning the people of the Arctic such as decisions to limit the production and use of persistent biocumulative toxics and other chemicals including those regulated under TSCA and FIFRA and in regulations that hold military and industrial polluters responsible for contamination of air, waters and lands under CERCLA, the Clean Air Act and the Clean Water Act. EPA indicates that the proposed rule is intended to strengthen transparency of EPA regulatory science; however, we find this a duplicitous claim. It would favor industry data protected as confidential business information over public peer-reviewed research.

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We support the best scientific evidence to inform regulatory decisions. However, this rule would have a dangerous counter effect by limiting the science that should be used to inform decisions about public health. Furthermore, we disagree with the agency's conclusions as stated in the proposed rule document that this action does not have tribal implication as specified in the executive order and requiring government to consult with tribes. This rule would disproportionately affect vulnerable populations including American Indian and Alaska Native People and, therefore, is relevant and requires consultation.

MS. RADZIKOWSKI: Excuse me, your time is up. We need to be fair to others.

MS. MILLER: I'll wrap up to say that we urge EPA to end this rulemaking promptly and we strongly oppose the proposal. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. GELTMAN: Good afternoon. Thank you for the opportunity to comment on EPA's proposal entitled,

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1 "Strengthening Transparency in Regulatory
2 Science." My name is Elizabeth Glass Geltman, G-
3 E-L-T-M-A-N. I am a Professor of Environmental
4 Health Policy at the City University of New York -
5 - the CUNY School of Public Health, located in
6 Harlem. I am the author of 17 books on
7 environmental and natural resources policy, a
8 peer-reviewer of numerous journals and have worked
9 on EPA-regulated matters for over 30 years. I am
10 also the Chair Elect of the Law Section of the
11 American Public Health Association. As a
12 professor, I aim to advance public health by
13 preventing people from getting sick. My efforts
14 address reducing health impacts, and hence
15 controlling health costs, by evaluating chemical
16 and environmental determinants of health.
17 Although EPA's rule aims to establish a clear
18 policy concerning the use of dose-response data
19 and models that underlie pivotal regulatory
20 policy, the rule is, in fact, a continuation of
21 the Trump administration's two for one regulatory
22 reform policy announced in Executive Orders 13771,

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1 13777, and 13783. The rule promises, "to change
2 agency culture and practices regarding data access
3 so that scientific justification for regulatory
4 actions is truly available for validation and
5 analysis." However, the new rule, in fact,
6 creates new regulatory hurdles by discounting and
7 precluding consideration of long-standing,
8 established scientific practice. Rather than
9 promoting the transparency of scientific
10 information used to create environmental
11 regulations, the rule will obscure the democratic
12 process, slow the pace of science and progress,
13 and potentially prevent important health data from
14 being considered by U.S. EPA in outlying important
15 environmental policy. Administrative procedure
16 requires the EPA consider data submitted by the
17 public in evaluating regulations. Let's be clear,
18 scientific studies have always been of uneven
19 quality. EPA has a process in place, including
20 use of Scientific Advisory Board testimony and
21 written and oral public notice and comment, using
22 internal and external peer review to evaluate

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1 data. Depending on context some studies are given
2 greater weight than others. Some studies are
3 disregarded entirely. It is inappropriate,
4 however, and unlikely unlawful -- and likely to be
5 unlawful -- under the Administrative Procedure
6 Act. For EPA to categorically eliminate certain
7 types of studies, and hence certain types of data,
8 without considering context. But, even more
9 important, eliminating studies, unless all
10 underlying data is made public, is hazardous to
11 human health and the environment. Longitudinal
12 medical and epidemiological studies are often
13 conducted over years, if not decades. Many
14 studies require people who are study subjects to
15 share very, very personal information, often on
16 the legal or ethical condition that private
17 medical information provided will be protected
18 from public view. EPA is not, and has never been,
19 in the regular business of replicating studies.
20 Timing and the cuts in EPA funding make
21 replicating studies as a condition of promulgating
22 regulations an impossibility. EPA has presented

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1 no scientific reason to prevent use of human
2 health studies simply because the underlining
3 medical records are not available for public
4 inspection and review. One size fits all rarely
5 works in fashion and it is even more unworkable in
6 science and regulation. It is imperative the EPA
7 allow consideration of all available scientific
8 data pertinent to a proposed environmental rule or
9 regulation including random, controlled human
10 health trials and other epidemiological studies.
11 Eliminating certain classes of human health
12 studies would be like picking NFL players in the
13 draft without allowing any scouting reports or
14 eliminating the minor league in baseball. It
15 doesn't make sense in sports; it makes even less
16 sense when we're safeguarding our nation's air,
17 water and land. For the reasons stated, I
18 respectfully request the EPA withdraw the
19 misleadingly-named rule entitled, "Strengthening
20 Transparency in Regulatory Science." Thank you
21 very much for allowing me to speak. My comments
22 are my own. I'm happy to answer questions and I

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1 will submit more detailed comments for the record.
2 MS. RADZIKOWSKI: Thank you.
3 MS. STOBERT: Speaker Number 5 is Alexis Andiman.
4 Also, if Speaker Number 6 could take a seat on the
5 on-deck seating: Sarah Kogel-Smucker. Speaker
6 Number 3, Patricia Koman, and Speaker Number 4,
7 Alexis Andiman.
8 MS. PATRICIA KOMAN: Thank you. My name is
9 Patricia Koman, K-O-M-A-N. I'm an environmental
10 epidemiologist at The University of Michigan
11 School of Public Health. I'm a member of the
12 American Public Health Association, and in my
13 comments I'm representing myself and my colleagues
14 at the University of California at San Francisco
15 Program for Reproductive Health and the
16 Environment. As a scientist who has formerly
17 served at the U.S. EPA and has been significantly
18 involved in analyzing science to create regulation
19 and programs that protect the public's health from
20 diesel and air pollution, I value the importance
21 of open science which includes appropriate data
22 sharing and full reporting of methods. However,

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1 U.S. EPA's proposed rule is not consistent with
2 the principles of open science, inappropriately
3 codifies how science should be conducted, and
4 codifies science policy decision in direct
5 conflict with consensus reports from the National
6 Academies of Sciences 2009 and often the enabling
7 environmental statutes such as the Clean Air Act
8 and the amended Toxic Substances Control Act.
9 Therefore, EPA should withdraw this proposed rule
10 immediately. Instead, EPA should focus on
11 implementing existing initiatives and guidelines
12 for improving data sharing and transparency at
13 federal agencies. The proposed rule is
14 inconsistent with medical ethics and existing
15 legal requirements to ensure the privacy and/or
16 confidentiality of human subject data. The rule's
17 requirements for specific types of test methods,
18 defaults, dose response models and/or other
19 analyses are not supported by current science and
20 these provisions should be removed. The rule is
21 counter to mandates in the amended Toxic
22 Substances Control Act, to use the best available

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1 science and systematic reviews for chemical
2 evaluations. Specifically, the proposed rule
3 inappropriately codifies particular data analysis
4 approach such as dose response modeling that
5 should be made based on empirical considerations.
6 This proposed rule will lead EPA to utilize
7 inadequate science resulting in inaccurate
8 analysis and, consequently, inadequate public
9 health protections. The proposed rule does not
10 expressly address the issue of how the new
11 procedures will be protective of public health.
12 Alternatively, existing open science guidelines
13 can and should be used to protect public health
14 such as the 2013 memo from the Office of Science
15 and Technology Policy. In addition, protocols and
16 guidelines such as CONSORT, ARRIVE and STROBE do
17 not require public access to all study data and
18 will still improve the scientific basis of
19 evaluating studies and thus promote public health
20 goals.
21 I want to call your attention to especially
22 troublesome provisions of the proposed rule which

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1 is not consistent with current scientific practice
2 and why this proposal should be withdrawn. For
3 example, it is not appropriate to require the use
4 of standardized test methods, guideline studies or
5 so-called good laboratory practice studies. These
6 types of studies are not designed to address
7 health effects from low-dose exposures, complex
8 and systematic endocrine effects, behavioral or
9 learning effects, or metabolic changes. In
10 addition, the so-called good laboratory practice
11 and guideline studies are not consistently
12 associated with higher quality research, proper
13 study design or correct statistical analysis.
14 Further, by dictating the model choices without
15 empirical basis the proposed rule sets a dangerous
16 precedent of prescribing how science should be
17 conducted without regard to the data, or
18 hypothesis or peer review. This is especially
19 troublesome for dose response models. Simply
20 using a greater number of models as the proposal
21 preference is unlikely to improve results without
22 considering the models' assumptions and whether

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1 they fit the data set, the goals of the analysis,
2 and many other issues. Therefore, giving priority
3 to studies based on the number or range of models
4 used is scientifically inappropriate.
5 Contrary to the proposed rule's statement about
6 growing evidence of nonlinearity in concentration
7 response functions, the body of empirical evidence
8 points to the opposite, that for most chemicals
9 and pollutants there is likely no safe threshold
10 on a population level because of ongoing exposures
11 and preexisting vulnerabilities. The rule
12 mandates reconsidering using a linear no-threshold
13 dose response but the National Academy of Sciences
14 recommends exactly the opposite in considering
15 low-dose effects. "The committee recommends that
16 cancer and non-cancer responses be assumed to be
17 linear as a default." Regarding other defaults, I
18 oppose provisions that mandate reconsideration of
19 established science-based defaults on a case by
20 case basis. This is in direct contradiction to
21 the National Academy of Sciences recommendations.
22 The rule is counter to the mandates in the amended

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1 Toxic Substances Control Act to use the best
2 available science and systematic reviews for
3 chemical evaluations. In contrast, this proposed
4 rule will have EPA ignore well-conducted, relevant
5 studies simply because all the data are not
6 publically available and/or may not conform to the
7 rule's invalid assumptions about good laboratory
8 practices and guidelines, studies, and dose
9 response modeling. This is inconsistent with
10 modern science and the TSCA statutory mandates.
11 Further, EPA's risk evaluation framework rules
12 under TSCA mandate the use of systematic review
13 methods. Well conducted systematic reviews
14 consider the entire body of scientific evidence
15 and the quality and strength of all relevant
16 individual studies are considered to reach the
17 overall conclusion.
18 Therefore, for these reasons, and those outlined
19 in my full written comments, I strongly oppose
20 this proposed regulation and recommend that EPA
21 withdraw it immediately. Thank you.
22 MS. RADZIKOWSKI: Thank you.

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1 MS. ANDIMAN: Good afternoon, my name is Alexis
2 Andiman, A-N-D-I-M-A-N. I am an Associate
3 Attorney at Earthjustice, the nation's original
4 and largest nonprofit environmental law
5 organization. Earthjustice strongly opposes the
6 proposed rule entitled, "Strengthening
7 Transparency in Regulatory Science." If
8 finalized, this rule would drastically undermine
9 the U.S. Environmental Protection Agency's ability
10 to protect public health and the environment
11 through science-based regulations restricting the
12 presence of chemicals and pollutants in our air,
13 drinking water, food and consumer products. Under
14 the guise of increasing transparency, the proposed
15 rule would authorize EPA to ignore scientific
16 studies that incorporate personal data and other
17 information that researchers cannot practically,
18 legally or ethically disclose. Indeed, EPA admits
19 that the rule would preclude it from considering
20 landmark studies assessing the health consequences
21 including risks to children associated with
22 exposure to particulate matter and lead. This is

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1 unnecessary and unacceptable.
2 The proposed rule raises more issues than I can
3 address during five minutes of testimony. In
4 partnership with other environmental and public
5 health organizations, Earthjustice plans to submit
6 extensive written comments detailing our serious
7 concerns about the rule's procedural and
8 substantive defects. Today, I will focus on three
9 key points.
10 First, EPA lacks authority to adopt the proposed
11 rule. Second, the rule would directly conflict
12 with laws that EPA is charged with implementing
13 and enforcing. And finally, the proposed rule
14 would harm the communities of color and low-income
15 communities that are most in need of strong,
16 science-based protections.
17 First, EPA lacks authority to issue the proposed
18 rule: It is axiomatic that administrative
19 agencies may act only pursuant to authority
20 delegated to them by Congress. The Administrative
21 Procedure Act requires that each notice of
22 proposed rulemaking reference the legal authority

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1 under which the rule is proposed. EPA failed to
2 identify any meaningful authority for the proposed
3 rule at issue today. In announcing the rule, EPA
4 cited provisions of numerous environmental laws
5 but virtually every provision cited authorizes or
6 directs EPA to undertake research, not to impose
7 unfounded limitations on the research it will take
8 into account. EPA also cited provisions that
9 authorize it to promulgate rules necessary to
10 achieve the goals of these environmental statutes,
11 but ignoring credible scientific evidence is
12 neither necessary nor consistent with the statutes
13 enacted to protect public health and the
14 environment.
15 Second, the proposed rule directly conflicts with
16 numerous laws. Multiple statutes require EPA to
17 ground its decisions in credible science. For
18 instance, the Safe Drinking Water Act directs EPA
19 to rely on the best available, peer-reviewed
20 science and the best available public health
21 information. The Toxic Substances Control Act
22 similarly mandates that EPA consider all

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1 reasonably available information and act in a
2 manner consistent with the best available science.
3 At no point do these statutes suggest that the
4 quality of a scientific study depends on the
5 public's ability to access the underlying data.
6 Indeed, as the EPA previously determined, and as
7 the U.S. Court of Appeals for the D.C. Circuit
8 agreed requiring agencies to obtain and publicize
9 the data underlying all studies on which they rely
10 would be impractical and unnecessary.
11 Finally, the proposed rule would harm the
12 communities that are most in need of strong,
13 science-based protections. Decades of scientific
14 research have established that communities of
15 color and low-income communities are
16 disproportionately likely to experience exposure
17 to chemicals and pollutants. This research is
18 also critical to establishing regulatory
19 safeguards that will protect these communities and
20 their environment. Nonetheless, the proposed rule
21 would preclude EPA from considering this research
22 simply because it incorporates personal health

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1 information and other non-public data. As a
2 result, the rule would eliminate an important
3 means of understanding and beginning to resolve
4 the harms suffered by over-burdened communities
5 and that's what perpetuates the environmental
6 injustices these communities already face.
7 Earthjustice urges EPA to withdraw the proposed
8 rule without delay. Thank you.
9 MS. RADZIKOWSKI: Thank you.
10 MS. STOBERT: Speaker Number 5, Alexis Andiman, is
11 already seated at the table. She's speaking on
12 behalf of Devon Hall. If speaker Number 6, Sarah
13 Kogel-Smucker would come to the speaking table.
14 If we could have Speaker Number 7, John Doherty
15 and Speaker Number 8, Tricia Sheehan, come to the
16 on-deck seating. Speaker 5.
17 MS. ANDIMAN: Good afternoon. I am reading
18 testimony on behalf of Devon Hall. D-E-V-O-N, H-
19 A-L-L, who was unable to make it today. My name
20 is Devon Hall. I am the Cofounder and Program
21 Manager at the Rural Empowerment Association for
22 Community Health, also known as REACH. On behalf

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1 of REACH and the community we serve, I urge the
2 U.S. Environmental Protection Agency to withdraw
3 its proposed rule entitled, "Strengthening
4 Transparency in Regulatory Science." I cofounded
5 REACH in 2002 to address social, economic and
6 environmental inequities in and around Duplin
7 County, North Carolina. Our primary focus is
8 protecting our community from pollution caused by
9 industrial animal operations. North Carolina is a
10 leading producer of swine and poultry. There are
11 nearly 2-1/2 million hogs and pigs and more than
12 16 million chickens and turkeys in Duplin County
13 alone. Together, these animals generate well over
14 2 billion gallons of wet waste and more than
15 190,000 pounds of dirty litter each year. This
16 waste produces an overpowering odor and pollutes
17 our well water, rivers and streams. REACH uses
18 scientific research as a tool to educate and
19 empower our community. Common sense tells you
20 that it's not healthy to breathe air that smells
21 bad enough to make you gag and that makes your
22 nose run and your eyes water. I began to work as

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1 a citizen scientist in 2004 because I wanted to
2 understand exactly what I was breathing and how it
3 was likely to affect my body so that I could
4 better protect myself and help my neighbors
5 protect themselves. So far, I have coauthored
6 nine published studies documenting the threats
7 that under-regulated industrial animal operations
8 pose to community health. For example, I
9 contributed to a study showing that kids who
10 attend school downwind of industrial hog
11 operations are exposed to relatively high levels
12 of hydrogen sulfide, putting them at greater risk
13 of symptoms like difficulty breathing and impaired
14 lung function. I also worked on a study finding
15 that children of people who work in industrial hog
16 operations are more likely to carry dangerous,
17 antibiotic-resistant bacteria on their bodies,
18 even though those children likely never set foot
19 in industrial hog operations themselves.
20 REACH has no interest in putting anybody out of
21 business, but we believe it is possible for
22 industrial animal operations to be more

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1 environmentally friendly and more community
2 friendly. It is not enough for us to talk about
3 our symptoms and our diminished quality of life.
4 No matter what we say there will always be some
5 people who think we are just complaining or making
6 things up. My neighbors and I want to be part of
7 the science so that we can gather proof about what
8 we're living with on a daily basis. We hope that
9 policy makers will listen to that science which
10 reflects the experiences of real people and begin
11 to make some changes. If adopted the proposed
12 rule would prevent EPA from considering the
13 scientific studies that REACH helps to conduct.
14 We cannot make all of our data publically
15 available because we cannot risk compromising the
16 confidentiality of the people who contribute to
17 our work. Because we live in a rural community it
18 would be relatively easy to identify study
19 participants based on de-identified information
20 like age, sex, occupation and number in
21 households, even if the participants' names were
22 redacted. Simply put, people would not

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1 participate in our studies if they knew that the
2 identifying information they shared could become
3 publically available. Even if EPA were to expand
4 on its vague promise to protect confidentiality, I
5 would not trust the government to deliver. Once,
6 I called the North Carolina Department of
7 Environmental Quality to report a permit violation
8 at an industrial animal operation and, even though
9 I asked to remain anonymous, I received a call
10 back directly from the operator I had complained
11 about. The government apologized to me later, but
12 the damage was done. My anonymity had been
13 violated and I felt violated as a result.
14 On another occasion, the North Carolina Pork
15 Council tried to obtain the identities of study
16 participants from Dr. Steve Wing, a researcher who
17 worked closely with our community. Dr. Wing
18 worked hard to protect our trust, but I know that
19 the legal problems he experienced deterred other
20 researchers from studying the health effects of
21 industrial animal operations. EPA's proposed rule
22 might also deter researchers from partnering with

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1 communities like ours to study public health
2 impacts because it would dramatically reduce the
3 influence of those studies in agency rulemaking.
4 Contributing to research about a polluting
5 industry is a lot like acting as a police
6 informant. You're providing information that
7 could help to make everyone more safe, but you are
8 putting yourself at risk, too. People who work at
9 industrial animal operations would lose their jobs
10 if their employers knew they were participating in
11 a scientific study. And losing your job is not
12 the only risk. I have been spoken to hard by
13 powerful people who do not like the work I do.
14 And I know people who have been physically and
15 verbally threatened by industry representatives.
16 EPA has investigated this issue and in January
17 2017, it expressed grave concerns about the
18 intimidation we have experienced.
19 I'll wrap up quickly. My first priority is to the
20 people I serve. I will never do anything to
21 violate their trust or put them in danger. If EPA
22 cares about keeping people safe, it should

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1 withdraw the proposed rule immediately and instead
2 take steps to support community-based research.
3 Thank you.
4 MS. KOGEL-SMUCKER: Good afternoon, my name is
5 Sarah Kogel-Smucker, Special Assistant Attorney
6 General at the Office of the Attorney General for
7 the District of Columbia. I am commenting on
8 behalf of Karl A. Racine, the Attorney General for
9 the District of Columbia. EPA's proposed rule,
10 "Strengthening Transparency in Regulatory
11 Science," is a solution in search of a problem.
12 Instead of strengthening ways in which EPA can
13 benefit from advances in scientific studies, the
14 proposed rule limits EPA's access to important
15 studies and hampers the development of regulations
16 needed to protect the public health and welfare of
17 the residents of the District of Columbia and the
18 nation. The proposed rule should be withdrawn.
19 In these comments, I will briefly address why the
20 proposed rule limits the use of valid, peer-
21 reviewed scientific studies, violates several
22 environmental statutes and lacks sufficient

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1 details to be appropriately evaluated and
2 implemented.
3 First, the proposed rule impedes EPA's decision-
4 making by creating burdensome, and potentially
5 impossible, barriers to the use of certain
6 scientific studies needed to determine the impacts
7 of pollutants and toxic materials on air quality,
8 water quality and human health. The proposed rule
9 requires that EPA's significant regulatory
10 decisions be justified only by studies based on
11 dose response data and models that area available
12 to the public. This requirement limits EPA's
13 ability to rely on otherwise peer-reviewed
14 scientifically valid studies that do not or cannot
15 make their data publically available because of
16 confidentiality concerns. For example, EPA used
17 the landmark Harvard Six Cities study
18 demonstrating a dramatic link between premature
19 mortality and air pollution as part of its
20 justification for key clean air regulation. The
21 study has been rigorously independently peer
22 reviewed but the subjects were promised

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1 confidentiality and the data is not public.
2 Studies with confidential data can still be
3 appropriately peer reviewed through the use of
4 confidentiality agreements and subject to rigorous
5 scientific scrutiny over their methods and
6 conclusions. Where cost-effective and appropriate
7 use of open or publically available data should be
8 encouraged. EPA, however, should not provide
9 blanket limits on the use of studies that cannot
10 be made public because they contain confidential
11 health or business information. Scrubbing studies
12 of such information may be impossible while still
13 keeping the study reproducible. The proposed rule
14 may also have important implications for rules
15 subject to periodic update like the Clean Air Act,
16 NAAQS, if EPA can no longer use the same or
17 similar methods that were used to support the
18 existing rules.
19 Second, the proposed rule violates several
20 environmental statutes because it hinders EPA's
21 ability to rely on best available science or most
22 up to date information as they require. The Clean

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1 Air Act, Clean Water Act, Safe Drinking Water Act,
2 Toxic Substances Control Act, and Emergency
3 Planning and Community Right-to-Know Act all
4 require certain decisions or regulatory criteria
5 be based on the most up-to-date science. These
6 criteria are described as best available science,
7 latest scientific knowledge and best available
8 public health information. The proposed rule
9 would illegally limit EPA's ability to rely on
10 best available science in violation of these
11 statutes.
12 The nearly 700,000 residents of the District of
13 Columbia rely on EPA to protect their health and
14 environment. While air quality in the District
15 has improved over the last several decades, many
16 residents who face disproportionate exposure risks
17 because of where they live or work still face
18 risks to their health from air pollution. For
19 example, the American Lung Association's "2018
20 State of the Air (sic)" report gave the District a
21 failing grade for the period from 2014 to 2016
22 because of the number of days that the air was

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1 unhealthy for vulnerable populations due to high
2 levels of ozone. The District's vulnerable
3 populations, including the estimated 10,415
4 children in the District with asthma, are entitled
5 to protection from unhealthy air. Because people
6 of color and children living in poverty
7 disproportionately suffer from childhood asthma,
8 environmental justice demands that EPA continue to
9 use advances in scientific research to improve air
10 quality through appropriate regulation. EPA
11 should not be artificially hampered in this duty
12 just because the data or models from a high-
13 quality, peer-reviewed study are not publically
14 available.
15 Lastly, the proposed regulations are too vague to
16 be meaningfully evaluated and successfully
17 implemented. For example, it is unclear whether
18 Section 30.7 requires EPA to conduct its own peer
19 review of all pivotal regulatory science and, if
20 so, whether EPA has the capacity or capability to
21 perform those reviews. Likewise, the exemption
22 process does not provide sufficient standards to

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1 ensure that the administrator made consistent
2 determinations. For these reasons, the proposed
3 rule should be withdrawn. Subsequent EPA
4 transparency initiatives, if any, should be based
5 on consultation with the National Academy of
6 Sciences and should not restrict EPA's ability to
7 rely on the universe of best available science
8 when promulgating regulations. Thank you for the
9 opportunity to comment today.
10 MS. RADZIKOWSKI: Thank you.
11 MS. STOBERT: If Speaker Number 7, John Doherty,
12 and Speaker Number 8, Trisha Sheehan, would come
13 to the speaker's table. Speaker Number 9, James
14 Duffy, and Speaker Number 10, Erika Rosen, if
15 you'd go to the on-deck seating.
16 MR. DOHERTY: As a retired EPA toxicologist I know
17 the firsthand frustrations of having to deal with
18 epidemiological reports. However, I believe that
19 epidemiological reports are valuable but more,
20 critical, initial review is needed. Today, I hope
21 to present a path forward. The animal studies
22 that I've reviewed are required to support the

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1 registration of pesticides follow very strict
2 quality assurance, good laboratory practices and
3 ethics and reporting standards. Multiple layers
4 of primary and secondary reviewers are identified
5 and assigned to review documents to assure quality
6 assurance and transparency. Every force, however,
7 has a mixed bag of standards to my experience for
8 QLT, quality assurance ethics in reporting. They
9 are often accepted at their face value without
10 documentation of independent review. There is no
11 way to verify the procedures or results presented
12 and the EPA reviewers are not identified. This is
13 very unfair to the public. Historically, I would
14 like to mention two situations where more critical
15 initial evaluation would have prevented social and
16 medical problems. The first is the report on the
17 Kallikak family published in 1912 by Henry
18 Goddard. The book was the foundation of eugenics
19 and was well received at first, but very serious
20 social consequences resulted. However, closer
21 examination revealed that much of the interviewing
22 reflected the biases of the interviewers. Goddard

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1 later regretted publication of this book. The
2 other is associated with vaccinations and autism
3 that could not be verified. The publisher
4 retracted the original publication; however,
5 within the past two years there is an increase in
6 measles in Minnesota because people feared autism
7 from vaccinations. When the concept of disparity
8 in the views of animal versus epidemiological
9 studies, and the need to provide a more critical
10 initial review the EPA posed, I am proposing an
11 epidemiology peer review consult with the goal of
12 creating a transparent document reflecting a
13 thorough review be established at EPA. The
14 Council will consist of six independent
15 subcommittee and relevant experts as follows:
16 First would be an ethics subcommittee. All
17 aspects of assuring the personal safety and
18 identities of the individuals on the study would
19 be protected. Second is an end-point evaluation.
20 The relevant experts knowledgeable in cancer and
21 rural behavioral, or whatever the condition is,
22 they would discuss the factors like how many

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1 people are really needed in a cohort to make a
2 decision. Identify what is known about that
3 particular condition environmental factors or
4 chemicals are known to cause it. The other -- is
5 self-explanatory. Exposure evaluation, statistic
6 evaluation, analytical chemistry and animal
7 toxicity and structure activity correlations.
8 Each subcommittee will articulate why additional
9 data are or are not needed. The Council will
10 consist of qualified individuals from the EPA, FDA
11 or other agencies' consultants as needed. The
12 Council will have considered the reports of the
13 six independent subcommittees and make their
14 recommendations especially with regard to
15 additional data needed to support a transparent
16 regulatory decision.
17 The report of the Council -- the final report of
18 the Council, will append each of the six
19 subcommittee reports as well as any dissenting
20 opinions. The Council owns the decisions and
21 since all responsible individuals will be
22 identified, the report is thus transparent. Thus

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1 AP may further review the Council report.
2 In conclusion, controversies associated with
3 epidemiologic reports may not be eliminated by the
4 Council, but the Council should contribute to
5 minimizing these controversies. Thank you.
6 MS. RADZIKOWSKI: Thank you.
7 MS. SHEEHAN: Good afternoon, my name is Trisha
8 Sheehan, S-H-E-E-H-A-N, and I'm representing Moms
9 Clean Air Force. I traveled here today from my
10 home in New Jersey. I'm the National Field
11 Manager for Moms Clean Air Force. We are an
12 organization of over 1 million members from across
13 the country who are fighting every day to protect
14 the health and safety of their children from toxic
15 chemicals, air pollution and dangerous climate
16 change. I am also a mom to three young boys and
17 last week my family and I joined Democratic House
18 Leader, Nancy Pelosi, to share our own story of
19 how my family was impacted from a toxic chemical
20 accident and today I'm here to speak out in
21 opposition to Acting Administrator Andrew
22 Wheeler's attempts to censor science in the name

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1 of transparency. Limiting the scientific
2 information the EPA can use to identify public
3 health threats and protect us from pollution is
4 reckless and dangerous. Not only does this
5 proposal compel EPA to subject high-quality
6 research to extreme unnecessary and untenable
7 levels of disclosure, but it also includes
8 loopholes that would allow the administration to
9 exempt industry from having to disclose details of
10 their own studies. American families depend on
11 the EPA and high-quality science to protect
12 families like mine from the impacts of air
13 pollution and toxic chemicals. This proposal puts
14 that protection in jeopardy, placing the health of
15 our children at risk. This proposal is
16 misleading. It would require the EPA to only
17 consider those studies that use public data. This
18 would prevent the EPA from using studies that are
19 based on personal medical data, eliminating some
20 of the most important long-term epidemiological
21 studies that investigate the impacts of pollution
22 on public health. This proposal would

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1 significantly limit the research and data the EPA
2 can use to make informed policy decisions under
3 major public health and environmental laws
4 including the Clean Air Act, the Safe Drinking
5 Water Act and the Toxic Substances Control Act.
6 This proposal means that many studies on
7 populations such as the elderly, children and
8 people of color, groups who often suffer
9 disproportionately from pollution, would be
10 excluded from EPA consideration because making the
11 data public could identify the participating
12 individuals. Excluding this important data from
13 consideration means that implementing the proposal
14 could even further exacerbate negative
15 environmental impacts on these and other
16 vulnerable communities. As a mom who has
17 witnessed her children's health deteriorate due to
18 polluted air they were breathing, I know
19 personally what it's like to rely on scientific
20 studies whose data informed us during that
21 horrifying time. On behalf of my family and Moms
22 Clean Air Force's one million members, I strongly

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1 urge the EPA to withdraw this dangerous proposal
2 for the health and safety of our children. Thank
3 you.
4 MS. STOBERT: Speaker 9, James Duffy, and Speaker
5 10, Erika Rosen, if you would come to the
6 speaker's table. Speaker 11, Gretchman Goldman,
7 and Speaker 12, Maggie Flaherty, if you would come
8 to the on-deck seating.
9 MR. DUFFY: Good afternoon, my name is J. Duffy.
10 I am an Associate Attorney with Clean Air Task
11 Force. CATF seeks to help safeguard against the
12 worst impacts of climate change by working to
13 categorize the rapid global development and
14 deployment of low carbon energy and other climate-
15 protecting technologies through research and
16 analysis and public advocacy leadership. EPA's
17 proposal at best is a solution in search of a
18 problem. The Agency has failed to identify a need
19 for further review of the already extensively
20 peer-reviewed public health and environmental
21 science it uses in its decision-making, nor has it
22 made the case the underlying health data must be

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1 made more public than current statutes and
2 practices allow. The only thing transparent about
3 the proposal is that is an attempt to undermine
4 EPA's ability to use the best available science by
5 placing arbitrary limits on the ability to
6 consider these studies.
7 As a professor who has cited multiple times the
8 proposal recently stated, if this proposal is
9 finalized, science will be practically eliminated
10 from all decision-making processes so that public
11 health and environmental regulation would then
12 depend on opinion and whim. Banning the use of
13 fully peer-reviewed studies because their
14 underlying data must be kept confidential would
15 eliminate the consideration of vital information
16 in critical public health-making decisions. This
17 is not only unnecessary, it also represents a
18 significant shift in decades-long policy without
19 any justification. As the D.C. Circuit has held
20 when considering this exact question, requiring
21 agencies to obtain and publicize the data
22 underlying the studies on which they rely would be

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1 impractical and it would be unnecessary. Congress
2 has clearly spoken, moreover, mandating that the
3 agencies must consider all relevant science. It
4 is well understood, and it has been for decades,
5 that many of the most important public health
6 studies are those based on actual patient
7 information. Because that information must be
8 kept highly confidential and because making even
9 some of the patients' details public would allow
10 them to be identified, the information must be
11 kept private. But that does not mean that these
12 studies can't be, or haven't been, verified. For
13 example, the Harvard Six Cities Study linking fine
14 particulate matter and mortality has been
15 exhaustively reanalyzed by independent
16 institutions, including by the researchers under
17 the auspices of the Health Effects Institute.
18 This reanalysis confirmed the study's essential
19 findings while keeping confidential the underlying
20 data. There are already several ways in which the
21 public can access the studies that EPA uses and in
22 some cases their underlying data without the

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1 release of confidential information, including
2 through the Freedom of Information Act which
3 provides an avenue to request raw data, including
4 a process to ensure that sensitive data is
5 protected. The proposal puts the EPA in the
6 untenable position of either violating its mandate
7 to consider all relevant science or violating
8 confidentiality laws. Additionally, the proposal
9 is impermissibly scatter-shot, it's vague, it's
10 confusing, it's insufficiently formed to allow for
11 meaningful comment. It seems more like a request
12 for ideas about how to discredit the best
13 available science than for how to make it more
14 accessible. For example, the proposal claims that
15 it is consistent with the Data Quality Act and
16 HIPAA as well as various executive orders, but
17 each of these contain checks on the release of
18 confidential information. In fact, the
19 longstanding OMB guidelines stemming from the Data
20 Quality Act recognizes peer review as the per se
21 marker of objectivity and the Harvard Six Cities
22 Study reanalysis set the gold standard for

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1 reproducibility.
2 Finally, in violation of Executive Order 12866,
3 the proposal fails to perform any analysis
4 regarding the impact this rulemaking could have on
5 the environment, public health or science
6 generally -- or even on what it would cost to
7 implement. Because the Agency does not have
8 authority to undertake this effort, and because it
9 would undermine the consideration of relevant
10 science in its public health and environmental
11 rulemaking, it should be abandoned. Thank you.
12 MS. RADZIKOWSKI: Thank you. I'd like to remind
13 speakers to please speak into the microphone.
14 MS. ROSEN: Good afternoon, this testimony is on
15 behalf of Lynn Goldman. She is a pediatrician and
16 an epidemiologist and has been Dean of the Milken
17 Institute School of Public Health at the George
18 Washington University since 2010 and former
19 Assistant Administrator for Toxic Substances at
20 the US Environmental Protection Agency. My name
21 is Erika Rosen and I am delivering this oral
22 testimony on her behalf. Her full written

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1 comments will be submitted for the record. This
2 proposal suffers from lack of involvement of the
3 scientific community, either within or outside of
4 the EPA. No clear justification is given for why
5 it is needed. The proposed rule is a dramatic
6 departure from how the EPA and other US regulatory
7 agencies, as well as similar agencies
8 internationally, use science for the development
9 of dose response assessments. It ignores a number
10 of adverse downstream consequences including:
11 risking disclosure of personal information of
12 people volunteering for human subjects' research;
13 delaying EPA decision. making; exacting unknown but
14 probably considerable costs to the research
15 community and to the EPA; and making best
16 available science unavailable to the EPA. It
17 creates no regulatory authority or any other
18 mechanism for the EPA to compel submission of data
19 from academic scientists and industry, other than
20 those that already are accessible under the
21 Information Quality Act of 2001, nor a mechanism
22 for access to industry data claimed as

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1 Confidential Business Information. It creates an
2 unfortunate precedent for EPA in the creation of
3 science policy by rulemaking. The proposal
4 ignores the "systematic review" methods for review
5 of evidence that have been developed, refined and
6 improved over a number of years in the context of
7 IRIS, pesticides, toxics, and priority air
8 pollutants. The application of such methods has
9 been reviewed and improved upon by the National
10 Academy of Sciences and the National Toxicology
11 Program. Of note is no authoritative body of
12 experts has ever recommended requiring "raw data"
13 in order to perform or review dose response
14 assessments.
15 Risk assessment activities at EPA are extensive
16 and its programs are performing more than 1,000
17 risk assessments per year. The proposal does not
18 consider the costs, the significant time and
19 paperwork burdens, and major regulatory delays
20 that will occur when EPA is waiting for data to be
21 made publically available, which may not ever
22 happen.

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1 For years, both Congress and successive
2 administrations have required the EPA to use the
3 best science for its decisions. Directing EPA
4 scientists to exclude key studies is not
5 consistent with good scientific practice and is
6 contrary to years of effort to improve the base
7 underpinning EPA's decisions.
8 The proposal misrepresents the recommendations of
9 prior expert reviews such as the
10 so.called NAS "Silver Book" and the Bi.Partisan
11 Commission review. It is oblivious to NAS
12 conclusions that thresholds of chemical exposure
13 for chemical effects are the exception rather than
14 the rule. Single studies are used to inform risk
15 assessors of the possible shape of dose response
16 curves. Instead, EPA evaluates all of the
17 scientific information to gain a biological
18 understanding of the "mode of action". When data
19 do not prove mode of action, EPA often applies
20 default assumptions such as low dose linearity for
21 carcinogens, and certain noncancer effects that
22 have no practically identifiable thresholds.

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1 This proposed rule for the first time opens the
2 door to EPA's scientific practices being
3 determined by regulators, and not scientists. This
4 is a rush down a slippery slope that would replace
5 a scientific process with a political one and
6 would freeze the science in procedures that
7 certainly will not be scientifically defensible in
8 the future. This is a breach of the fundamental
9 notion of separating risk assessment from risk
10 management.
11 I strongly urge the EPA administrator: (1) not to
12 use the Agency's regulatory authority to prescribe
13 specific risk assessment processes; and (2) not
14 undertake changes in EPA's science policies
15 without leadership from EPA scientists and full
16 engagement of the science community. What is at
17 stake is no less than the credibility of the
18 Agency with the American public and public
19 confidence in the integrity of EPA's science and
20 decisions.
21 MS. RADZIKOWSKI: Thank you.
22 MS. STOBERT: Speaker 11, Gretchen Goldman, and

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1 Speaker 12, Maggie Flaherty, if you would come to
2 the stage. Speaker 13, Adam Finkel, and Speaker
3 14, Augusta Wilson, if you'll come to the on-deck
4 seating.
5 MS. GOLDMAN: my name is Gretchen Goldman, G-R-E-
6 T-C-H-E-N, G-O-L-D-M-A-N. I'm the Research
7 Director at the Center for Science and Democracy
8 at the Union of Concerned Scientists, and I'm also
9 a mom. As a scientist, I'm deeply troubled by
10 this proposal. As a mom, I'm alarmed by it, and
11 the risks that it poses to my children and others.
12 The EPA's mission is to protect public health but
13 this proposal does the opposite. This proposal
14 needlessly restricts the science that EPA can use
15 to make decisions about all of our families'
16 health. Many crucial scientific studies that rely
17 on public health data, intellectual property,
18 confidential business information and other
19 scientific information that may not be publically
20 acceptable would be unavailable to EPA experts
21 under this proposal. As a result, the EPA will be
22 prevented from making rules that protect people

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1 using the best available science. There is no
2 reason for such a rule. The EPA already follows a
3 rigorous, science-based process for determining
4 when and how studies are used in its decisions.
5 I've seen this first-hand when the EPA contacted
6 me about my own scientific research. The Agency
7 needed to obtain results data from my peer-
8 reviewed studies looking at ambient air pollution
9 exposure in time series' epidemiologic studies. I
10 can attest to the fact that the EPA already
11 ensures it is using reliable and robust scientific
12 information to make decisions. When my son was
13 born he spent five days in the neonatal intensive
14 care unit because of a respiratory problem and
15 when I took him home I knew it would be important
16 for me to make sure that he could breathe clean
17 air. I can't protect him from the air outside
18 always but the EPA can. When my children breathe
19 outside I need to know that the air is healthy.
20 When my children play in the grass I need to know
21 that there aren't harmful pesticides in it. When
22 my children drink from their sippy cups, they need

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1 to know -- I need to know that the water is safe.
2 How can EPA scientists protect my family and
3 others if they can't use the best available
4 science?
5 I urge you to withdraw this proposal and instead
6 focus on EPA's mission of ensuring safe water, air
7 and land for people across the country. Thank
8 you.
9 MS. RADZIKOWSKI: Thank you.
10 MS. FLAHERTY: Good afternoon and thank you for
11 the opportunity to speak today. My name is Maggie
12 Flaherty, F-L-A-H-E-R-T-Y, and I would like to
13 express my strong opposition to the proposed,
14 "Strengthening Transparency in Regulatory Science"
15 rule. I would first like to emphasize that this
16 rule proposed during Scott Pruitt's time as
17 administrator of the EPA is a purely political
18 decision. It is modeled after past efforts from
19 the tobacco and fossil fuel industries for similar
20 policies that prevent the use of science that
21 reveals the harmful human health impacts of such
22 industries. This proposed rule is not about

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1 legitimate transparency; it is about making it
2 harder for the EPA to make decisions based on the
3 best available science. Under this rule studies
4 that rely on personal health data, confidential
5 business information, intellectual property, or
6 studies whose data is no longer available would be
7 excluded from the EPA's consideration when making
8 decisions regarding regulations. When it comes to
9 regulating things such as air pollution, water
10 pollution and toxic substances, some of the most
11 vital scientific information comes from studies of
12 respiratory illnesses, cardiovascular diseases,
13 and premature deaths, all of which rely on
14 personal health data. If such vital studies are
15 excluded because of this arbitrary rule, the EPA
16 would be lacking critical public health
17 information when making decisions that directly
18 impact our health and environment.
19 If EPA is truly worried about transparency in
20 science they would listen to the voices of the
21 numerous scientists who have come out in
22 opposition to this proposed rule and who have,

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1 additionally, suggested other ways of introducing
2 transparency. Instead of focusing on disclosure
3 of data that can contain confidential and private
4 information, a rule that truly increased
5 transparency in science would focus on funding
6 disclosure. Despite how strict the peer review
7 process is, people should be able to know who is
8 funding a study. This rule proposed by the EPA
9 does not address the issue of funding transparency
10 at all. According to an article in the Journal of
11 the American Medical Association if all of the
12 EPA's proposed changes to environmental policies
13 since the election of President Trump go into
14 effect, the result would be at least 80,000
15 unnecessary deaths per decade. This assessment is
16 based on numerous scientific studies that would
17 most likely be excluded by this rule. The EPA
18 should not exclude studies that demonstrate the
19 true health costs of their actions and remember
20 their true mission of protecting our public health
21 and the environment. I therefore urge the EPA to
22 withdraw this proposed rule. Thank you.

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1 MS. RADZIKOWSKI: Thank you.
2 MS. STOBERT: If Speaker 13, Adam Finkel, and
3 Speaker 14, Augusta Wilson, will come to the
4 speakers' table. Speaker 15, David Coursen, and
5 Speaker 16, Abigail Omojola would come to the on-
6 deck seating.
7 MR. FINKEL: Thank you. I appreciate the
8 opportunity to comment as a former chief
9 regulatory official at OSHA and a former member of
10 the EPA Science Advisory Board and Board of
11 Scientific Counselors. I support a wide spectrum
12 of efforts to improve the transparency of the
13 inputs to and the outputs of risk assessment and
14 cost-benefit analysis, especially if they involve
15 a more honest disclosure of uncertainty and
16 variability. I will submit a recent paper I wrote
17 with George Gray in this regard. But this
18 proposal decreases transparency and reliability in
19 three ways: It fails to identify a legitimate
20 problem; it ignores closely related and glaring
21 actual problems with regulatory analysis; and it
22 promotes remedies that add noise while decreasing

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1 signal.
2 First, the central dogma of regulatory policy
3 since 1993, and most enthusiastically touted by
4 this administration, holds that no regulation can
5 be proposed absent a real problem to be solved,
6 like market failure. Here, there is no failure of
7 the scientific market and hence no need for a
8 disruptive set of hurdles. By its own policies it
9 developed to constrain its own regulatory excess,
10 EPA should demonstrate, and not just with an
11 anecdote or two, the crisis justifying the need
12 for this proposal, or else should scrap it. I
13 note that of the five URLs the EPA provides in
14 Footnote 12 to document its claim that there is a
15 "replication crisis," two of the links are broken
16 and the other three discuss psychology and
17 clinical trials. The end points in epidemiology,
18 toxicology and exposure studies are simply not as
19 subjective as psychology experiments are. There
20 have been some problems found with clinical trials
21 but the unmeasured variability is likely much more
22 important with respect to whether a drug will cure

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1 and weather a pollutant will harm.
2 Most importantly, the EPA has cited no studies
3 giving even guesstimate of what percentage of
4 environmental science studies might be in need of
5 replication or reanalysis and, of course, some of
6 the shrill prior claims of error others have noted
7 in the Six Cities Study have turned out to be
8 fallacious. Surely EPA does not intend that most
9 epi studies or bio-assays need to actually be
10 replicated. Some epi studies can be redone but
11 surely not natural experiments we never want to
12 repeat such as the atomic bomb survivors study or
13 the changes in air pollution during groundings
14 right after 911. Lifetime animal bio-assays
15 already use multiple doses, species and sexes and
16 they are expensive and take years to complete.
17 Why would we waste time and money duplicating
18 them? And so, what if someone did try another
19 species and got a lower potency estimate or didn't
20 get positive results? Would we allow a rat or
21 mouse carcinogen in unlimited quantities because
22 it might not also be an aardvark carcinogen? I

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1 don't think so. So, EPA probably means reanalyze,
2 not replicate, and it should say so. But then EPA
3 presents no evidence that anyone is hindering
4 anyone else from reanalyzing anything. Any bio-
5 acid that the EPA would use would already have
6 individual tumor data and exposures and could be
7 reanalyzed with any model that anyone wanted.
8 Ditto for epi studies. But what would a
9 reanalysis program actually do other than be
10 costly and invite delay? What if someone
11 reanalyzed a health study and got a different
12 answer? One that suggests the first study had
13 exaggerated the harm. In such a case the second
14 study would be right and the first wrong only if
15 both of these conditions were true. First, the
16 difference in the results was not already
17 acknowledged or contained within the uncertainties
18 in each answer. If somebody claimed that banning
19 a chemical would save between 500 and 1000 lives
20 across the country, EPA chose to estimate it at an
21 expected value of 750; another study that said 550
22 would not be different from the first study at

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1 all. And secondly, the first study would have to
2 be not just different, but wrong. Anybody can
3 take the same data and botch the risk analysis of
4 it making seem like they have a better answer.
5 Just like there are potential problems with an
6 analysis that doesn't control for some variable,
7 it can be a mistake to control for a variable that
8 shouldn't be included.
9 In short, EPA should never refuse to look at a
10 study just because someone could reanalyze it but
11 hasn't, has done so and gotten a different but not
12 a better answer, or has done so, didn't like what
13 it saw, and suppressed the results while claiming
14 the original study still needs to be reanalyzed.
15 Secondly, there is a crisis in regulatory analysis
16 and EPA is completely ignoring it for reasons that
17 are obvious to me. It's the economists' analysis
18 of the costs of regulation and the values of
19 benefits that are flawed, opaque and in need of
20 reanalysis. Every criticism leveled at this
21 proposal ought to first be applied to regulatory
22 economics. They are obviously as pivotal as

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1 estimates of risk. Regulatory cost estimates are
2 notoriously biased high and they are surrounded by
3 more uncertainty than surrounding risk estimates,
4 but unlike risk estimates, cost estimates are
5 rarely, if ever, presented with uncertainties and
6 are sometimes even of the wrong side. In my
7 written comments I'll give two examples. I have a
8 paper newly published with Brandon Johnson. We
9 looked at more than 1000 estimates, the value of a
10 statistical life, certainly the most pivotal
11 quantity in all of risk regulation derived from
12 hundreds of studies. Only 40% of those studies
13 gave any information about the ranges or standard
14 deviations of the individual VSL values. So, no
15 one can reanalyze that work to see what higher or
16 lower values of the VSL are also compatible with
17 the data. And perhaps the most well-known so-
18 called study of the costs of regulation is the
19 series of reports from Mark and Nichole Crane
20 suggesting that regulations "cost the U.S. nearly
21 two trillion dollars a year."
22 MS. RADZIKOWSKI: Excuse me, sir, we are out of

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1 time.
2 MR. FINKEL: I'm sorry?
3 MS. FLOWERS: We are out of time, in fairness to
4 others.
5 MR. FINKEL: I'm sorry, I didn't realize. The
6 third one is about defaults and I will submit
7 those, but EPA is a protection Agency, not a
8 prediction Agency. Thank you.
9 MS. RADZIKOWSKI: Thank you.
10 MS. WILSON: Good afternoon, my name is Augusta
11 Wilson, and I am here representing the Climate
12 Science Legal Defense Fund. The first name is
13 spelled A-U-G-U-S-T-A. I appreciate the
14 opportunity to speak to you today and the Climate
15 Science Legal Defense Fund will file more detailed
16 written comments in the online docket for this
17 proposed rulemaking. CSLDF is a nonprofit
18 organization whose mission is to protect the
19 scientific endeavor. In this capacity, we work
20 closely with scientists at government agencies and
21 at research institutions, so we have particular
22 insight into how attempts to silence science

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1 negatively impact both researchers on an
2 individual level and the conduct of scientific
3 research as a whole. There are numerous reasons
4 why EPA should not proceed with this rule. In the
5 time I have today I will focus on a few of the
6 most important from the perspective of protecting
7 the integrity of the scientific endeavor. First,
8 studies that involve human subjects, particularly
9 those investigating the human health impacts of
10 exposure to environmental pollutants, are among
11 the most relevant to EPA's core mission. In order
12 to conduct such studies, scientists need
13 participants willing to allow researchers access
14 to their confidential health information. If
15 enacted as currently proposed, this rule would
16 make it much more difficult for scientists to
17 credibly promise study subjects that their patient
18 information will remain confidential. This could
19 have deeply concerning, chilling effects on the
20 conduct of important human health studies.
21 Privacy concerns could influence what science gets
22 done and what science does not get done. Lines of

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1 scientific inquiry that would have been pursued
2 may not be. The quality of data may be poorer
3 than it otherwise would have been. Furthermore,
4 the justification for this rule to the extent it
5 exists seems to be based on the false premise that
6 scientific studies cannot be adequately evaluated
7 or reproduced unless all of their underlying data
8 are made public. This is simply not the case. On
9 the contrary, the reviewers can evaluate the
10 merits of studies even when they rely on data that
11 cannot be made publically available. This is
12 because part of a scientist's core, fundamental
13 training is the ability to assess research based
14 on the strength of the experimental design and the
15 precision with which experimental methods and
16 analyses are described. In addition, when
17 necessary and appropriate, reviewers, as well as
18 other researchers seeking to reproduce or extend
19 scientific analysis, can have confidential access
20 to key data in conformity with privacy
21 requirements.
22 That said, the scientific community has certainly

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1 recognized that recent technological developments
2 allow for significant improvements in data sharing
3 and reproducibility and that such improvements can
4 benefit science. There are numerous scientific
5 societies, journals, and other organizations, as
6 well as individual researchers, who are actively
7 engaged in a dialogue about how to improve
8 transparency while protecting scientists and
9 taking into account issues like patient
10 confidentiality and proprietary business
11 information. If EPA is genuinely concerned about
12 these issues, it should engage deeply in this
13 discussion and with the scientists who are having
14 it and should move forward only in concert with
15 them. As written, this rule which EPA professes
16 is intended to strengthen science will ultimately
17 do significant damage to it and to the United
18 States' ability to lead the world in research.
19 EPA should not promulgate such a rule. Thank you.
20 MS. RADZIKOWSKI: Thank you.
21 MS. STOBERT: If Speaker 15, David Coursen, and
22 Speaker 16, Abigail Omojola, would come to the

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speakers' table. Speaker 17, Alan Lockwood, and Speaker 18, Elizabeth Woolford, if you would come to the on-deck seating.

MR. COURSEN: Good afternoon. My name is David Coursen, C-O-U-R-S-E-N, and I'm here on behalf of the Environmental Protection Network, a nonprofit organization of EPA alums working to protect the Agency's progress toward clean air, water, land and climate protection. There are so many things wrong with this proposal that it's easy to downplay the most important one: The harm it will do to peoples' health and the environment. The proposal hides this in a fog of ambiguous language, meaningless generalities and vague platitudes about the value of transparency. It requires EPA to wear a blindfold when it is developing major rules by ignoring what relevant and reliable science tells us about health risks any time the raw supporting data is not publically available. Transparency is important, but it is not part of the Environmental Protection Agency's mission and certainly cannot be the basis for a

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one-size-fits-all litmus test for when the Agency must ignore what science tells us about the risks of pollution.

The laws governing EPA programs require it to consider all of the available scientific information in deciding how to protect peoples' health and the environment. Ignoring such information would be both arbitrary and unlawful. EPA rulemaking has always relied on the best available science, a principal the proposal gives lip service even as it outlines a scheme to prevent the EPA from using even the best available science if it is not "transparent." The proposal would put even the most persuasive and useful science off limits subject only to a vague and standardless exemption process. The proposal does not show that the EPA's existing practices have produced bad environmental outcomes or that increasing so-called transparency will lead to better outcomes. Those are not things the proposal seems to care about. There is no legal or environmental basis for the proposed

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restriction and, not surprisingly, the proposal fails to mention that EPA's statutes do not allow the Agency to ignore available information about the risks of pollution. Inevitably, restricting the science EPA considers in rulemaking will produce less informed and less protective decisions. In effect, the proposal sacrifices relevant and reliable scientific information, a cornerstone of effective environmental protection on the altar of so-called transparency. A proposal to ignore science when all of the supporting data is not public would preclude using even recent studies that are subject to confidentiality agreements or legal restrictions on disclosure. It also will certainly and deliberately exclude older studies where the data is no longer available, even if their findings are widely accepted as authoritative and form the basis for EPA regulations that have proven effective in protecting peoples' health for many years.

The proposal is evasive about its targets using

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footnote language only a lawyer could understand to identify two seminal air pollution studies that it excludes and says nothing at all about what other important studies it would ban. Written comments via the Environmental Protection network will spell out the policies that proposes many legal and policy defects in detail. The proposal is brief and cursory and provides far too little information to meet the legal requirement to alert the public to its substance and basis. It would prohibit EPA from considering important science in rulemaking even though the laws governing EPA's use of science require it casting a wide net. It sheds little light on how the proposal would work and no light at all on its environmental consequences. Instead of explaining how EPA will implement and interpret the rule, it largely throws these questions to the public. It doesn't show a need for any rule much less an absolute rule that sweeps across eight statutes. It claims its approach is consistent with a host of policies and studies but what Environmental Protection

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Agency looked at them it found almost no support for the proposal and in some cases the authors have objected to the use of their studies and it posed the proposal. In sum, there is neither a legal basis nor a need for this rule. It would require the EPA violate explicit statutory provisions and unlawfully shifts the basis for deciding what science to use in rulemaking away from the statutory goals of reliability and environmental protection to so-called transparency, a term not found in the relevant EPA statutory provisions. It is too full of undefined or ambiguous terms to create a workable legal frame work. In other words, the proposal is unintelligible, unlawful and unworkable. EPA, I respectfully request that EPA withdraw it.

MS. RADZIKOWSKI: Thank you.

MS. OMOJOLA: Good afternoon, my name is Abigail Omojola, O-M-O-J-O-L-A, and I am here on behalf of Breast Cancer Prevention Partners to speak in strong opposition to the proposed rule and to urge the EPA to withdraw it immediately.

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Breast Cancer Prevention Partners is a national organization committed to preventing breast cancer by eliminating exposures to chemicals and radiation that have been linked to an increased risk of the disease. We take great care and pride in ensuring that all of our public education, programs and policy advocacy are based on a strong foundation of peer-reviewed science.

Contrary to its stated intent, the proposed rule under consideration today would not serve to provide the public with greater "confidence in and understanding of" EPA's regulatory decisions. Rather, it would deeply undermine the ability of the EPA to use all the best available science in its regulatory decisions, which, in turn, will negatively impact public health. In fact, it is hard not to come to the conclusion that the proposed rule is a strategy to disregard many studies that have shown negative impacts of chemical exposures on public health.

Breast cancer is a disease with complex causation and often a long latency period. Only about 10% of

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breast cancer diagnoses can be attributed solely to genetics. Breast cancer risk is a web of interactions between environmental exposures, genetics and lifestyle characteristics. Much of the data showing the connection between unsafe chemical exposures and breast cancer risk comes from laboratory studies. However, epidemiological studies, and in particular longitudinal studies, provide unique insights and important corroboration of these findings.

The proposed rule's requirement that underlying data must be made public before the EPA can consider a study in agency decision-making will have the practical impact of eliminating many of these critical studies from the regulatory process. Epidemiological studies involve the collection of extensive and detailed individual health data and researchers have an ethical obligation to protect the confidentiality of that data. The elimination of these studies will result in less scientifically sound conclusions and, most importantly, the public health benefits they would

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provide.

An example of the kind of study this proposed rule could eliminate from the EPA's regulatory process is the National Institute of Environmental Health Sciences' Sister Study. From 2003 to 2009, the Sister Study enrolled 50,000 women whose sisters had breast cancer. Those women will be followed for a minimum of 10 years to study how genes and the environment interact to impact the risk of developing breast cancer, leading to a greater understanding of ways to prevent both breast cancer and other diseases. It does not serve the public interest to hinder the EPA's ability to use this type of research in their regulatory decisions.

This proposed rule will not only undermine the use of previously conducted epidemiological studies; it will also damage the ability of researchers to conduct future studies. Recruitment of study participants will be severely undermined if people fear their personal information may be made publically available. This is particularly true

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for vulnerable marginalized communities that are both disproportionately exposed to toxic chemicals and have historical reasons to distrust researchers. Yet, it is the exposures experienced by these communities, and the resulting health effects, that we most need to understand and address.

The integrity of scientific methodology is thoroughly reviewed at many points in the processes of designing, conducting and publishing scientific research already. There is the competitive grant process; Institutional Review Board requirements; peer-review prior to publication; the expertise and judgment of career EPA scientists when considering the strength and relevance of studies included in EPA decisions; and finally review of those decisions and the underlying science by EPA's Science Advisory Board; all provide more than sufficient opportunities to assess the soundness of scientific studies. This proposed rule is not only damaging, it is unnecessary.

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On behalf of the 1 in 8 women who will be diagnosed in their lifetime and the 40,000 lives that are lost each year in the U.S. to breast cancer, the EPA has an obligation to take action to prevent this devastating disease. This proposal takes a hard step away from that goal.

Thank you for the opportunity to provide this public comment urging the EPA to withdraw this misguided and damaging proposed rule.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Speaker 17, Alan Lockwood, and Speaker 18, Elizabeth Woolford will take seats at the speaking table. If Number 19, Paul Allwood, and Speaker 20, John Stine, would take seats at the on-deck seating.

Mr. LOCKWOOD: Good afternoon, my name is Alan Lockwood, A-L-A-N, L-O-C-K-W-O-O-D. Thank you for this opportunity to speak on behalf of Physicians for Social Responsibility. I am a board-certified neurologist and an elected fellow of the American Neurological Association and the American Academy of Neurology, and Professor Emeritus of Neurology

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at the University at Buffalo. PSR is a 501(c)(3) scientific and educational organization headquartered in Washington DC with over 30,000 physicians, medical students, and others across the country. Our mission is to protect human life from the gravest threats to health and survival.

We submit this testimony in strong opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." The proposed rule would change the standards for the inclusion of studies used by the Agency and lead to the abolition or weakening of virtually all protections under the purview of the Agency.

Under the misleading veil of "transparency," the proposed rule could force investigators to invade the confidentiality of research participants and make confidential and private data open to all. A similar concern was voiced by the current Scientific Advisory Board, writing, "there are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests ..." The rule could replace evidence-

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based decision-making with arbitrary determinations based on political considerations.

Peer-reviewed research has led to important gains in health. The Clean Air Act protects us from air pollution and is arguably the most health-protective law in effect. I have written extensively about this in The Silent Epidemic.

Peer-reviewed studies link air pollutants with leading causes of death in the United States including heart disease, stroke, and respiratory diseases. Additional studies link particulates to Alzheimer's disease and Type II Diabetes. Seminal studies include the Harvard Six Cities Study that involved 8,111 adults followed for between 14 and 16 years showing a clear link between pollution and mortality. The Women's Health Initiative study involving 65,893 post-menopausal women that demonstrated a link between particulates, and cardiovascular disease and stroke mortality. I attended closely to the study of 1,705 neurologist-confirmed strokes showing that a transient increase in small particles was

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1 associated with a statistically significant
2 increase in strokes even though levels were within
3 limits "generally considered safe" by the EPA. A
4 congressionally mandated report prepared by the
5 EPA projected that by 2020 Clean Air Act
6 provisions would save two trillion dollars per
7 year in adverse health impacts. Many savings will
8 positively impact the budgets of state and federal
9 agencies at a time of ballooning deficits.
10 EPA rules provide significant protection for the
11 developing brains of children by establishing
12 limits on lead. Lead impairs brain development
13 and has adverse effects on behavior and cognition.
14 Other data link arsenic levels in drinking water
15 to Type II diabetes and cancer.
16 Natural gas production, particularly "fracking"
17 harms health due to human proximity to wells,
18 pumping stations, and contamination of water
19 supplies and contributes to climate change.
20 Protecting the privacy of research participants is
21 a keystone of biomedical research and one with
22 which I have had years of personal experience as a

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1 member then chairman of the Buffalo VA
2 Institutional Review Board. Peer-reviewed
3 journals require authors to affirm their adherence
4 to federal privacy protections as a pre-condition
5 for publication. This standard should not be
6 abolished. PSR's mission is to "to protect human
7 life from the gravest threats to health and
8 survival." To protect the scientific integrity of
9 the EPA and protect health, we oppose the
10 deceptively named proposal, "Strengthening
11 Transparency in Regulatory Science." Thank you.
12 MS. RADZIKOWSKI: Thank you.
13 MS. WOOLFORD: My name is Elizabeth Woolford and I
14 am an undergraduate student at Wesley University
15 and an intern with the National Parks Conservation
16 Association. My comments are my own. Today, I
17 would like to express my strong opposition for the
18 proposed rule titled, “Strengthening Transparency
19 in Regulatory Science.” This rule would have
20 sweeping impacts on the ability for the EPA to
21 consult public health studies, as almost all
22 utilized data from medical records that are

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1 protected from public scrutiny. Their proposal
2 would force the Agency to disregard such studies
3 unless scientists reveal their participants’
4 private medical information. Scientists
5 conducting public health research would then be
6 left with two unacceptable options: To break
7 confidentiality agreements in order to disclose
8 the personal health records of their subjects; or
9 not to have their studies consulted by policy
10 makers at all. As a result, some of the most
11 significant research from the past decade, for
12 example studies linking air pollution to premature
13 deaths and measuring human exposure to pesticides
14 would be left completely unavailable to the
15 Agency. I would like to emphasize that data of a
16 sensitive nature does not imply inherent
17 unreliability, rather this kind of information is
18 essential to achieve an accurate understanding
19 about how human health is impacted by chemicals,
20 chemical compounds and other substances. Such an
21 understanding is necessary for the EPA to fulfill
22 its mission to protect public health and protect

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1 the environment with the creation of effective
2 regulations under the Clean Air Act, Clean Water
3 Act, CERCLA, and other cornerstone environmental
4 laws.
5 This proposal is based on a false premise about
6 data quality and acceptability. There is no
7 reason why one cannot protect the confidentiality
8 of subjects and at the same time use information
9 about them. This rule questions the integrity of
10 the scientists and doctors conducting public
11 health studies by implying that these
12 professionals may have biased their subjects to
13 achieve a particular outcome. However, it is
14 evident that peer review already protects against
15 for such bias.
16 For these reasons, one must consider how this
17 proposal fails to achieve the requirements of
18 OMB’s Information Quality Act. It is clear that
19 this proposal is overkill and would unnecessarily
20 exclude scientific studies simply because they do
21 not meet an unrealistic transparency standard.
22 This would all be to the detriment of public and

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1 environmental health.
2 In addition, this rule would create a blatantly
3 political and dangerous double standard by
4 eliminating the use of studies that follow
5 confidential health guidelines while allowing
6 polluting industries to keep their data under
7 wraps. That alarming imbalance would skew
8 regulation inherently favoring polluters over
9 those impacted by their pollution.
10 Furthermore, this proposed rule would cross Agency
11 lines and interfering with informed policy making
12 and undermining the safeguards that protect
13 millions of people, our public lands, and the
14 space and places we call home. EPA's scientific
15 research and related policies influences the
16 decisions of other agencies charged with
17 protecting our health and environment. For
18 example, the National Parks Service needs access
19 to the best available science to inform decisions
20 that protect parks' air, land, water, wildlife and
21 people. If EPA goes forward in placing
22 unreasonable limits on the scientific record, the

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1 National Parks Service and similar agencies will
2 be unable to protect public health and the
3 environment to the extent they otherwise could.
4 As a young person, this proposal leaves me
5 frightened. Within a decade I will be part of the
6 generation that inherits the responsibility for
7 this nation. If adopted, the negative
8 implications of this rule will not be short-lived
9 and could forever change the safeguards that EPA
10 is supposed to develop to protect public health
11 and our environment. In the many more decades of
12 life I have in front of me, I intend to finish my
13 education in this country, I intend to raise a
14 family in this country, I intend to enjoy public
15 lands and outdoor spaces in this country, and I
16 intend to breathe this country's air and drink
17 this country's water and eat this country's food.
18 I hope to do so knowing that the regulatory body
19 charged with keeping my body and environment safe
20 has made decisions based on nothing less than the
21 best scientific information there is. For these
22 reasons, I urge the EPA to abandon this dangerous

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1 and misguided proposal. Thank you.
2 MS. RADZIKOWSKI: Thank you.
3 MS. STOBERT: Speaker Numbers 19 and 20, Paul
4 Allwood and John Stine, if you would take seats up
5 here. And Speaker Number 21, Virginia Ruiz, and
6 Speaker 22, Karen Mongoven, if you would take
7 seats the on-deck seating.
8 MR. ALLWOOD: Good afternoon, my name is Paul
9 Allwood. I am Assistant Commissioner of Health
10 Protection at the Minnesota Department of Public
11 Health. Commissioner Stine is with me and we're
12 going to do this joint testimony. Commissioner
13 Stine will go first.
14 MR. STINE: Thank you. As Commissioner of the
15 Minnesota Department of Health, Mr. Allwood is the
16 Assistant Commissioner there, and as Commissioner
17 of the Minnesota Pollution Control Agency, my name
18 is John Link Stine, S-T-I-N-E. We are appointees
19 of Minnesota's Governor, Mark Dayton. We are
20 deeply disappointed in and troubled by this
21 proposed rule, "Strengthening Transparency in
22 Regulatory Science." We have traveled 1100 miles

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1 from our home in Minnesota to be here today to
2 speak against this rule. On May 15, 2018, our two
3 state agencies commented against this rule in a
4 letter from Commissioner Malcolm of the Health
5 Department and myself. Our testimony today
6 expands upon those comments and provides specific
7 examples from Minnesota that show why this
8 arbitrary and non-ethical rule must not be
9 adopted.
10 MR. ALLWOOD: The first example is that the State
11 of Minnesota is dealing with a massive area of
12 contamination with PFAS chemicals, otherwise known
13 as PFCs. The contamination came from 3M
14 Manufacturing and disposal sites that contaminated
15 groundwater on a very massive scale impacting over
16 150,000 residents. Minnesota's Department of
17 Health conducted bio-monitoring studies of over
18 200 people living in those impacted communities to
19 be able to understand their exposure and their
20 potential health implications. Those studies help
21 Minnesota derive health protected values under
22 state law and furthermore also help the state of

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1 Minnesota reach a settlement with 3M Company of
2 over 890 million dollars. Now, without these
3 studies and without these data we would not have
4 been able to be successful in our litigation with
5 3M Company and residents of the communities that
6 were impacted by this pollution would have had to
7 foot this bill.
8 Now, these studies are only possible because we
9 provided absolute guarantees to the participants
10 that their data would be protected and that we
11 would assure its confidentiality. The proposed
12 rule will make it unlikely that public health data
13 such as this -- and you heard it from other
14 testifiers -- would be available for states to
15 use, but even more so for the EPA to use in its
16 decision-making. This is to be avoided.
17 MR. STINE: Our second example is the 2015 study
18 and report that our agencies jointly released
19 "Life and Breath". We released that report
20 regarding the health impacts of air pollution in
21 the Twin Cities Metropolitan Area of Minneapolis
22 and St. Paul. The study used public health data

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1 and mathematical modeling software developed by
2 the U.S. EPA. EPA's modeling software is based on
3 published, peer-reviewed scientific studies of the
4 relationship between human health and air
5 pollution. The study confirmed air pollution
6 leads to increased disease and death in our
7 population. Every year about 2000 premature
8 deaths, 400 hospitalizations and 600 emergency
9 room visits occur in the Twin Cities Metropolitan
10 Area that are caused by fine particle or ground-
11 level ozone exposure. In fact, the study found
12 that fine particle air pollution and ground-level
13 ozone was a causal factor for some deaths and
14 hospital visits for lung and heart conditions.
15 The implications of the proposed rule are that
16 under this rule's requirement for the use of
17 public data, future public health data on which
18 studies like our "Life and Breath" were based
19 would not be available. Public health data and
20 research relies on citizen confidence in
21 confidentiality of their personal information.
22 We believe the rule would lead to an over-reliance

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1 on animal studies and toxicological data which
2 cannot estimate disease burden as well as
3 population health data and studies. The proposed
4 rule would lead to weaker environmental
5 regulations, more air pollution, greater levels of
6 heart and lung disease and death. As a result,
7 health care costs will increase. Asthma already
8 costs the United States 56 billion dollars
9 annually and the incidence of asthma is
10 increasing. The rule language under Part 30.8
11 requires that EPA implement the rule in a manner
12 that minimizes cost. Ironically, the rule will
13 lower the cost to EPA and environmental polluters.
14 A fundamental principal of our environmental
15 protection law is that polluters pay. The plain
16 truth is that your rule does not address the
17 increased costs that come with relaxed
18 regulations. In fact, the polluters will pay less
19 and costs will shift onto the public in health
20 insurance. With that I'll kick it to Mr. Allwood.
21 MR. ALLWOOD: So, to conclude, to say that state
22 as public officials we are responsible for

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1 protecting the health of our state population,
2 it's really important for us to be assured that
3 EPA is going to use the best science in its
4 regulatory decision-making. This rule severely
5 brings that into question and we would like you to
6 know that we are looking at this as an urgent
7 matter that requires the EPA's attention and would
8 urge that time be taken to suspend and slow the
9 process of adopting this rule so that a full and
10 complete review can be done. Thank you.
11 MR. STINE: Thank you.
12 MS. RADZIKOWSKI: Thank you both.
13 MS. STOBERT: Speaker 21, Virginia Ruiz, and
14 Speaker 22, Karen Mongoven, if you would come to
15 the speakers' table. Speaker 23, Steve Milloy,
16 and Speaker 24, Steve Milloy for John Dunn, if you
17 would have seats at the on-deck seating?
18 MS. RUIZ: Good afternoon, my name is Virginia
19 Ruiz. I am the Director of Occupational and
20 Environmental Health at Farmworker Justice, an
21 organization devoted to working with migrant and
22 seasonal farmworkers to improve their living and

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1 working conditions. On behalf of my colleagues at
2 Farmworker Justice and the farmworkers that we
3 represent, I strongly urge the U.S. EPA to
4 withdraw its proposed rule, "Strengthening
5 Transparency in Regulatory Science." If
6 finalized, this rule would endanger farmworkers
7 and other vulnerable people across the country.
8 We oppose EPA's proposed rule for three reasons:
9 First the rule would prohibit EPA from considering
10 credible scientific evidence about the dangers
11 farmworkers face including exposure to pesticides
12 and other chemicals. Second, the rule would deter
13 farmworkers themselves from participating in
14 future scientific studies. Third, the rule would
15 make it more difficult for Farmworker Justice to
16 obtain the research we need to advance our
17 mission. With respect to the first point, the
18 proposed rule would prohibit EPA from considering
19 credible scientific evidence about the dangers
20 that farmworkers face. As EPA's own Science
21 Advisory Board acknowledged, there are many
22 reasons why researchers and study participants

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1 might choose to keep data confidential, and many
2 of these reasons have no bearing on the
3 credibility of a scientific study. For instance,
4 because farmworkers are often migratory, moving
5 for work across domestic and international
6 borders, researchers may be unable to locate
7 farmworkers they last encountered as study
8 participants years ago, and thus unable to
9 renegotiate privacy agreements struck at the time
10 the research was conducted. Farmworkers
11 themselves may also have legitimate reasons for
12 wanting to preserve their privacy. For example,
13 some research shows that farmworkers face an
14 increased risk of exposure to chemicals that
15 impair fetal development resulting in lower IQ
16 scores, an outcome associated with significant
17 social stigma. We already suffer from the dearth
18 of scientific evidence and information about
19 occupational and environmental health risks that
20 farmworkers face. EPA should base its regulatory
21 decisions on the credibility of scientific
22 evidence and not on arbitrary factors like the

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1 public availability of research data.
2 With respect to the second point, the proposed
3 rule would deter farmworkers from participating in
4 future scientific studies. Farmworkers are
5 extremely vulnerable members of our society and
6 it's unlikely they would agree to participate in
7 scientific research without an iron clad guarantee
8 that their identities would be kept confidential.
9 Farmworkers value their privacy for a number of
10 reasons including an undocumented or other tenuous
11 immigration status and insecure employment.
12 Farmworkers whose identities are exposed would
13 risk retaliation from their employers ranging from
14 termination to deportation. As a result the
15 proposed rule would present farmworkers with a
16 false dilemma. They could choose to participate
17 in research studies that might eventually yield
18 better regulatory protections at great personal
19 risk, or they could choose to protect their
20 privacy by refusing to participate in research
21 studies, thus forgoing badly needed protections,
22 also at great personal cost. EPA should not

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1 present farmworkers with such a choice.
2 Finally, the rule would frustrate Farmworker
3 Justice's ability to achieve our mission. We rely
4 on credible scientific evidence to educate
5 farmworkers, policy makers and the public at large
6 about the risks farmworkers face. Much of this
7 evidence comes in the form of epidemiological
8 studies that the proposed rule would categorically
9 exclude from consideration unless the underlying
10 data were made publically available. If EPA's
11 proposed rule were to result in fewer scientific
12 studies focusing on farmworkers, as seems
13 inevitable, we would lack information we need to
14 carry out this important aspect of our mission.
15 It would severely undercut our ability to
16 effectively advocate for farmworker health and
17 safety.
18 Accordingly, we urge EPA to protect farmworkers
19 and other vulnerable communities by withdrawing
20 the proposed rule without delay.
21 MS. RADZIKOWSKI: Thank you.
22 MS. MONGOVEN: Good afternoon, I'm Karen Mongoven;

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1 K-A-R-E-N, M-O-N-G-O-V-E-N, Senior Staff Assistant
2 at NACAA, National Association of Clean Air
3 Agencies, and I appreciate the opportunity to
4 testify today on behalf of NACAA. NACAA
5 recommends that EPA withdraw this proposed rule.
6 In our view the proposal would likely undermine
7 the very objectives that it's supposed to promote.
8 In particular, we believe it would hinder EPA's
9 use of best available science and environmental
10 regulations and it would likely diminish, rather
11 than improve, public confidence in the integrity
12 of EPA's scientific decision-making. Reliance on
13 best available science is a fundamental
14 requirement of the Clean Air Act and other
15 environmental statutes the EPA administers.
16 Indeed, science-based decision-making is at the
17 very core of our shared mission as air regulators
18 to protect public health and the environment from
19 the harmful effects of air pollution.
20 There is a long-term trend toward increased
21 transparency in science including toward providing
22 greater public access to underlying data and

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1 analytical techniques after scientific studies are
2 published. We think this trend is a laudable one,
3 but complete public access to underlying data is
4 not always possible, especially in the case of the
5 epidemiological studies based on private health
6 data that must remain confidential. Transparency
7 concerns must not override EPA's obligation to
8 consider the full range of peer-reviewed, sound,
9 scientific research that is available and relevant
10 to its regulatory decisions.
11 Full public access to underlying data and models
12 is not necessary to assure the validity of
13 scientific studies. Rather, the most effective
14 assurance is the process of peer review itself, a
15 process to which the vast majority of scientific
16 information on which EPA relies has already been
17 subject. When the results of a scientific study
18 are submitted for publication, the uncertainties,
19 assumptions, parameters and theories utilized by
20 the scientists are laid out in the publication.
21 Peer review analyzes all of these components to
22 establish validity. The process of peer review

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1 has been rigorously developed over centuries. If
2 EPA believes the peer review process is flawed, it
3 should explain exactly why it believes the process
4 is inadequate and how this proposal specifically
5 addresses those inadequacies. If adopted, the
6 proposed rule could serve to bar EPA's
7 consideration of relevant scientific literature
8 and the establishment of air regulations to
9 protect public health and the environment
10 resulting in serious adverse effects on the
11 nation's air program.
12 In a footnote in the proposal, EPA cites two D.C.
13 Circuit cases that upheld the Agency's reliance on
14 confidential data in setting health-based air
15 quality standards for lead and fine particulate
16 matter. In that footnote, EPA states that it is
17 "proposing to exercise its discretionary authority
18 to establish a policy that would preclude it from
19 using such data in future regulatory actions."
20 The clear implication is that EPA will discard
21 rigorously vetted scientific literature in the
22 service of greater transparency. This would be an

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1 abdication of EPA's legal obligations and stated
2 intention to rely on the best available science.
3 NACAA is also concerned with a provision that
4 would require EPA to conduct its own "independent
5 peer review of scientific studies underlying
6 significant regulatory decisions." The EPA
7 included no details about how this provision would
8 be implemented and moreover the proposal failed to
9 acknowledge the EPA already has institutional
10 mechanisms to review and vet scientific
11 information through panels of scientific experts
12 including a Science Advisory Board and its Clean
13 Air Scientific Advisory Committee. EPA does not
14 explain why scientific literature that has already
15 undergone peer review and been vetted by EPA's
16 science advisory panel should be subjected to an
17 additional layer of peer review. We do recognize
18 that the proposal would allow the EPA
19 administrator to grant exemptions to the rule's
20 requirements on a case by case basis if he or she
21 determines that "it is not feasible to make
22 underlying data publically available or to conduct

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1 an independent peer review of scientific studies."
2 However, the rule does not include any criteria
3 for how the administrator would make such a
4 determination. We believe this provision would
5 have the effect of interjecting the appearance of
6 politics into what should be a fair and unbiased
7 assessment. It's an opportunity for arbitrary
8 decision-making and it is insufficient to protect
9 against the exclusion of relevant valid scientific
10 studies.
11 EPA requested comments on whether the proposal
12 should be applied retroactively or retrospectively
13 should they decide to adopt it. We believe the
14 rule should not be applied retrospectively. To do
15 otherwise would create significant regulatory
16 uncertainty by calling into question existing
17 standards as well as prevent state implementation
18 plans and other decisions that are based on those
19 standards.
20 In conclusion, NACAA respectfully requests that
21 EPA withdraw the proposed rule. If the Agency
22 does intend to update its approach to transparency

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1 and reproducibility it should do so in
2 consultation with the National Academy of Sciences
3 and in the spirit of cooperative federalism EPA
4 should also consult from the earliest stages with
5 the state and local agencies that are responsible
6 for implementing our nation's environmental laws.
7 NACAA appreciates the opportunity to provide the
8 testimony I offered today and we also intent to
9 submit written comments to further elaborate on
10 the concerns I discussed here. Thank you.
11 MS. RADZIKOWSKI: Thank you.
12 MS. STOBERT: If Steve Malloy, Speakers 23 and 24
13 would come to the speaker's table. Speaker 25,
14 Meredith McCormick, and Speaker 26, Olivia
15 Bartlett if you would go to the on-deck seating.
16 MR. MILLOY: Good afternoon, my name is Steve
17 Milloy. I publish JunkScience.com.. I am making
18 my comments here on behalf of myself and also Dr.
19 John Dale Dunn, who is an emergency room physician
20 in Texas. We are here to support the proposed
21 transparency initiative. Science transparency in
22 EPA is long past overdue. When I first started

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1 working on EPA issues in 1990, the main
2 controversy with EPA science was the use of
3 science policy and default assumptions, like
4 linear no-threshold model of carcinogenesis. The
5 problem wasn't necessarily the use of science
6 policy default assumptions, the problem was,
7 rather, the EPA's failure to disclose the nature
8 of those default assumptions in regulatory
9 actions. In other words, what part of the
10 regulatory actions was science, what part was
11 guesswork and what was politics? When I first
12 reported on this problem from the Department of
13 Energy in 1994, the Clinton administration tried
14 to censor my report but they failed. But I didn't
15 and many others didn't. So here we are, many
16 years later, making progress on this important
17 issue.
18 More recently, the major problem with EPA science
19 has been what has become known as secret science.
20 Since the 1990's EPA grantees like Harvard's Doug
21 Dockery and Brigham Young University's Arden Pope,
22 have refused to make available to the public the

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1 raw data used in their epidemiologic studies, and
2 this is true despite the fact that these studies
3 were cited by EPA as the principle scientific
4 basis for major air quality rules like those that
5 constituted the Obama administration's war on
6 coal.
7 Worse, prior EPA administrations actually aided
8 and abetted Dockery and Pope hiding their data
9 from public review. In 1996 and 1997 the Clinton
10 administration refused a request of Congress. In
11 the 2000's things got so bad Congress actually had
12 to subpoena the Obama EPA for the data and they
13 refused to provide it.
14 I can only conclude that this is because
15 independent review of the Harvard Six Cities and
16 the American Cancer Society line of studies would
17 prove them to be highly problematic, embarrassing
18 and even fraudulent. Desperate to defend the
19 indefensible, supporters of Dockery and Pope have
20 wrongly maintained that making the data in
21 question public would violate medical and personal
22 privacy rights. Nothing could be further from the

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1 truth. For the most part, data is electronic.
2 Scrubbed files with key data needed for
3 independent review can easily be made available.
4 No one -- no one -- is interested in any personal
5 or medical data. It has no value to anyone. The
6 State of California has made such data files
7 available for use for many years. I know. I have
8 obtained this data -- over 2 million death
9 certificates to be precise -- and with it enabled
10 research to be published that completely debunks
11 the secret science of Dockery and Pope. Fear of
12 exposure of their research as faulty, if not fake,
13 is why Dockery and Pope are so scared of producing
14 their data for independent review. To make these
15 comments current, up to date, efforts have been
16 made this month to obtain the Dockery and Pope
17 data but they continue to keep their data secret.
18 Given that the Dockery and Pope research and
19 related PM2.5 research has been funded by
20 taxpayers to the tune of more than 600 million
21 dollars and then this research is used to regulate
22 the public costing untold billions more dollars

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1 without providing any public health or
2 environmental benefits, the conspiratorial hiding
3 of this secret data is more akin to crime than
4 science.
5 If EPA wants to regulate, that is fine, but the
6 basis of the regulations and the reason for the
7 regulations must be clearly laid out so there
8 could be full and fair debate. Harvard's Doug
9 Dockery and Brigham Young's Arden Pope don't want
10 independent scientists to check their work for
11 some reason. Dockery and Pope supporters may
12 offer whatever excuses they like but we all know
13 what the reality is: Fear of exposure. Thanks to
14 the Trump administration the days of secret
15 science are coming to an end. Thank you.
16 MS. RADZIKOWSKI: Thank you.
17 MS. STOBERT: Speaker 25 and Speaker 26, Meredith
18 McCormack and Olivia Bartlett are now onstage. If
19 Speaker 27, Dan Byers, and Speaker 28, Antonia
20 Herzog, would come to the on-deck seating.
21 MS. McCORMACK: Meredith McCormack, M-E-R-E-D-I-T-
22 H, M-c-C-O-R-M-A-C-K. My name is Meredith

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1 McCormack and I'm a pulmonary critical care
2 physician at Johns Hopkins University where I care
3 for patients and I also investigate the effects of
4 air pollution on lung health in cohort studies of
5 children and adults. I serve on the American
6 Thoracic Society Environmental Health Policy
7 Committee and I'm speaking today on behalf of the
8 ATS, the American Thoracic Society.
9 The ATS is extremely concerned about the proposed
10 EPA policy. In short, we believe this policy is
11 not in the best interests of our profession, the
12 patients that we serve, or the public health. The
13 focus on transparency is highly reminiscent of the
14 rhetoric used by tobacco lawyers decades ago. As
15 revealed in tobacco industry documents, in 1996 a
16 tobacco industry lawyer drafted a plan for tobacco
17 giant, R.J. Reynolds, to combat research that
18 documented the health effects of second-hand
19 smoke. A tobacco industry lawyer described a plan
20 to construct explicit procedural hurdles the
21 Agency must follow. The memo used the same terms
22 of transparency, sound science and calls for

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1 reproducible science, the language that the EPA is
2 now using in its proposed policy. While the
3 guidance provided in that memo was intended to
4 undermine research studies that documented the
5 adverse effects of second-hand smoke, the
6 recommendations provide a road map for any
7 industry seeking to undermine science that could
8 lead to greater regulation. While concerning, it
9 is no accident that EPA is proposing policy once
10 touted by tobacco industry lawyers. By proposing
11 this policy, EPA is literally taking a page out of
12 tobacco industry's playbook to undermine the
13 legitimate role that science plays in public
14 policy formation.
15 The ATS supports transparency in upholding
16 scientific rigor but the approach proposed in this
17 rule is flawed. The proposed policy would require
18 all science and biomedical research used by the
19 Agency in major regulatory actions to have its raw
20 data and health records made publically available
21 under the guise of allowing third party analysis
22 to confirm the results of the research. This

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1 artificial standard cannot be met without forcing
2 the release of confidential patient information
3 and is in direct conflict with the mandates of our
4 institutional review boards and updated privacy
5 laws.
6 As a physician, no doctor or medical society would
7 advocate ignoring large portions of the medical
8 literature because the underlying data were not in
9 the public domain. Medical guidelines are based
10 on the best available evidence: Evidence that
11 emerges from multiple peer reviewed publications,
12 not a single study. The medical field is rapidly
13 moving towards increasing transparency but this
14 cannot be applied retroactively. Is the best
15 available science only the subset of studies whose
16 data are available for analysis by the public?
17 That is not the case for medical research studies
18 and is certainly not the case for studies of
19 environmental health effects.
20 EPA's new transparency standard introduces a more
21 severe standard than the FDA uses to make
22 decisions about the approval of drugs or that

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1 Medicare uses to decide which treatments to cover.
2 As a doctor I would do my patients a disservice if
3 I ignore the best available evidence to guide my
4 clinical decision-making. The proposed rule will
5 allow the EPA to ignore the best scientific
6 evidence in future decision-making about health
7 effects of the air that we breathe and the water
8 that we drink. The Transparency Rule fails to
9 recognize the power of replication, a key criteria
10 for defining the strength of scientific evidence.
11 Replication refers to the fact that consistent
12 findings from studies in different populations in
13 different places strengthens the likelihood of an
14 effect. The proposed rule would create a context
15 for the EPA administrator to have the discretion
16 to disregard studies that have provided the
17 strongest scientific evidence underlying the
18 dramatic health effects and dramatic improvements
19 in air quality in the U.S. -- improvements that
20 have led to measurable health benefits to our
21 children, our patients and the general public.
22 For the EPA to use these studies will patients

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1 forego their confidential information? Or will
2 the EPA now ignore the evidence from dozens of
3 studies that have replicated findings that
4 pollution is associated with increased risks of
5 premature death. The Transparency Rule is
6 unnecessary as there are processes in place to
7 rigorously review the scientific integrity of the
8 studies that are used in regulatory science.
9 In short, we fully concur with the statement from
10 the editors of several leading scientific journals
11 that the merits of studies relying on data that
12 cannot be made publically available can still be
13 judged. It does not strengthen policies based on
14 scientific evidence to limit the scientific
15 evidence that can inform them.
16 In summary, this policy is issued in bad faith, is
17 bad for science and bad for patients and bad for
18 public health. The ATS strongly urges the Agency
19 to withdraw this ill-conceived policy proposal.
20 Thank you.
21 MS. RADZIKOWSKI:
22 MS. BARTLETT: I'm Olivia Bartlett. B-A-R-T-L-E-

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1 T-T. I'm from Bethesda, Maryland and I represent
2 the 1200 members of Do the Most Good, Montgomery
3 County. I am a retired PhD health scientist. For
4 15 years I conducted research involving human
5 subjects and also served as a peer reviewer for
6 both grant applications and research papers
7 submitted for publication. For the next 30 years
8 I oversaw the scientific peer review of thousands
9 of applications for funding of a wide variety of
10 health science studies including the women's
11 health study that was mentioned by a previous
12 speaker, so I'm very familiar with the scientific
13 research and publication process and the rules
14 regarding protection of human subjects. I also
15 have asthma, as do my son and my grandson, so I am
16 also very familiar with the impact of soot and
17 smog in the air on the ability to breathe.
18 EPA's mission is to protect health and the
19 environment. I strongly oppose EPA's so-called
20 Transparency Rule since it will restrict the
21 scientific studies that EPA can use to carry out
22 that mission and to set safety standards for toxic

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1 chemicals and pollutants in the air we all breathe
2 and the water we all drink. The proposed rule was
3 given an appealing title but it's just a
4 politically motivated attempt to undermine decades
5 of progress in protecting human health from
6 hazards, particularly small particulate pollutants
7 in the environment, while allowing soot-producing
8 industries off the hook. The proposed rule is
9 seriously flawed in several important ways.
10 First, it reflects former EPA Administrator
11 Pruitt's woefully inadequate understanding of
12 scientific research methods, the nature of the
13 long-term large-scale epidemiologic studies
14 necessary to gather the kinds of data needed to
15 determine toxicity of a pollutant and the rigor of
16 peer review of both research grant applications
17 and publications. Peer reviewers carefully
18 scrutinize the methods that will be used to
19 collect and analyze the data before a research
20 study is ever funded. Additional peer reviewers
21 and different ones scrutinize the data collection
22 and analysis methods and whether the data supports

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1 the conclusions, again prior to publication.
2 Studies with flaws in design, data collection or
3 data analysis don't make it into reputable
4 journals. The proposed rule also seriously
5 underestimates the burden and the consequences of
6 making all raw data publically available.
7 Most research funding agencies and journals now
8 have policies that require researchers to make
9 their data available to other scientists for
10 reanalysis, validation and meta-analyses after
11 publication and this has already been mentioned by
12 previous speakers. However, many studies involve
13 sensitive and personal data that could identify
14 individual subjects even if the subject's name and
15 address are redacted, so releasing these data sets
16 to the public would violate patient
17 confidentiality rules. The proposed rule may also
18 violate the requirements of the Clean Air Act and
19 Clean Water Act and other standard acts already
20 mentioned to use criteria that accurately reflect
21 the latest scientific knowledge, the best
22 available science and inclusive analysis of all

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1 available studies in assessing potential effects
2 on public health. Furthermore, the proposed rule
3 would create an unacceptable double standard for
4 industry-sponsored and academic research by
5 allowing companies to shield their confidential
6 business data, thus corporate secret science would
7 be okay but data sets that expose individual
8 subjects' identities would have to be made public
9 or would be excluded from consideration in
10 rulemaking. This ill-conceived proposed rule has
11 been condemned by hundreds of scientists, all but
12 one of the previous speakers today, and numerous
13 scientific societies across health and
14 environmental fields. Editors of prestigious
15 journals have denounced the proposed rule and
16 stated excluding relevant studies simply because
17 they do not meet rigid transparency standards will
18 adversely affect decision-making processes. The
19 bipartisan policy center, the bipartisan
20 environmental protection network represented
21 earlier by a speaker, the Attorney Generals of
22 seven states and D.C. who was here earlier and

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1 EPA's own Science Advisory Board have also
2 denounced the proposed rule. Rather than
3 increasing transparency, the proposed rule will
4 hamstring EPA, eliminate some of the best science
5 available to inform standards under the National
6 Ambient Air Quality Standards program and
7 jeopardize both the environment and public health
8 by making it more difficult to adopt rules that
9 protect public health and the environment in the
10 future. EPA's long-standing process using data
11 from peer-reviewed science, EPA in-house
12 scientists and the EPA Science Advisory Board
13 works well and mirrors the processes of other
14 science-based agencies. The system isn't broken
15 and doesn't need to be fixed. If EPA wants to
16 accomplish its mission, the proposed rule should
17 be withdrawn immediately and should not affect any
18 rulemaking going forward or any of the studies
19 used in periodic reanalysis of existing rules.
20 Thank you for allowing me to comment.
21 MS. RADZIKOWSKI: Thank you.
22 MS. STOBERT: Speaker 27, Dan Byers, and Speaker

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1 28, Antonia Herzog, if you would take seats on the
2 stage. Speaker 29, Tess Dermbach, and Speaker 30,
3 Mary Angly, if you would take seats in the on-deck
4 seating.
5 MR. BYERS: Good afternoon. My name is Dan Byers.
6 The U.S. Chamber of Commerce strongly supports the
7 intent of the proposed rule and applauds EPA for
8 addressing a long-standing problem inherent in
9 much of its regulatory decision-making processes.
10 While the Agency's proposed reforms are clearly
11 controversial they are grounded in a universally-
12 accepted democratic principle: Citizens have a
13 right to the data and information that are used in
14 the development of public policy. This spirit of
15 openness with respect to the regulatory process is
16 found throughout government. It is enshrined in
17 statute and countless federal directives and EPA
18 memos reinforce the principle and detailed
19 guidance for implementing it. It is also
20 supported by experts of all political stripes. In
21 2012, congressional testimony, President Obama's
22 Science Advisor, Dr. John Holdren, unequivocally

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1 endorsed this idea, stating that: "Absolutely the
2 data on which regulatory decisions and other
3 decisions are based should be made available to
4 the committee and should be made public. The
5 Chair of EPA's Science Advisory Board during the
6 Obama administration subsequently echoed this
7 sentiment. Unfortunately, while this principle is
8 generally accepted, EPA has not followed it
9 consistently in practice. In fact, for many years
10 EPA has relied upon non-public data to justify its
11 aggressive regulatory agenda. The most egregious,
12 but certainly not the only, example of this
13 involves two controversial studies undertaken in
14 the 1980s that suggest a linkage between certain
15 types of particulate matter and health outcomes.
16 The data associated with these decades-old studies
17 has never been made public but EPA nonetheless has
18 used them to monetize regulatory benefit claims
19 that dominate the communications and regulatory
20 marketing associated with nearly all of its major
21 rules. It's also worth pointing out here that,
22 separate from the studies themselves, EPA's

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1 benefit monetization is highly subjective and
2 controversial in and of itself. For example, in
3 2009 the Agency modified its assumptions in a
4 manner that resulted in a quadrupling of purported
5 benefits without any change to the underlying data
6 and information used to monetize it. We hope that
7 these sorts of subjective and questionable
8 practices will be addressed since the Agency
9 concurrently examines the development of
10 regulatory cost-benefit analyses. The scale of
11 EPA's practice in this respect is mind boggling.
12 Data compiled by the U.S. Chamber found that
13 between 2000 and 2016, EPA issued 62 rules
14 claiming a total of 923 billion dollars in
15 regulatory benefits. Incredibly 898 billion of
16 these benefits, or 97%, were monetized based on
17 the non-public data associated with PM2.5. In
18 fact, these benefits comprise nearly 80% of all
19 regulatory benefits across the entire federal
20 government. Even though the vast majority of
21 these rules were not intended to address PM2.5,
22 and even though the vast majority of their

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1 corresponding claim benefits came from areas of
2 the country already deemed safe and in compliance
3 with the standard, the Agency repeatedly touted
4 these figures to build public support for its
5 regulations. It's one thing to be cavalier about
6 transparency principles when their application has
7 little or no import to public policy. The federal
8 rules that impact millions of people and billions
9 of dollars should be held to a higher standard.
10 For these reasons, we applaud EPA's effort to
11 establish and meet a higher standard and we
12 commend the Agency for doing so through the formal
13 public comment and rulemaking process rather than
14 simply instituting a new policy. As EPA makes
15 clear throughout the rule, these changes will
16 require considerable effort and cooperation, and
17 despite suggestions otherwise, the proposal
18 clearly states that its aim is not to exclude
19 science but rather to ensure: "That over time more
20 of the data and models underlying the science that
21 informs regulatory decisions is available to the
22 public for validation." And, to more broadly

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quote: “Change Agency culture and practices regarding data access.” The outcome will not just lead to better public policy, it will improve the integrity of the rulemaking process and in doing so increase public trust in, and support for, EPA itself. Whether you agree with the administration’s regulatory approach or not, that is a good thing. With that fundamental background in mind I will close by calling attention to six high-level areas that warrant emphasis and attention as the Agency works to finalize the rule. These are elaborated on in my written comments.

1) Protect sensitive information;

2) Formally coordinate with other agencies working to address similar regulatory transparency challenges;

3) Develop further guidance and processes for employing the administrator’s exemption authority under the rule;

4) Consider alternative approaches to balancing trade-offs between goals related to

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transparency and maximizing the quantity and quality of information relied upon. For example this could include assigning greater decision-making weight to publically available data while still allowing for the consideration of nontransparent data;

5) Where possible, work to protect and de-identify sensitive information to allow for its continued use in regulatory decision-making, and;

6) Ensure that relevant transparency information is incorporated into public communications and marketing materials associated with regulatory initiatives. Thank you for your time and consideration today.

[Substitution of panel members.]

MS. HUBBARD: Thank you.

MS. HERZOG: Hello, my name is Antonia Herzog, H-E-R-Z-O-G, and I am a scientist with a doctorate in Physics. I am particularly concerned about preserving the scientific integrity of the EPA. I work in the Environment and Health Program at Physicians for Social Responsibility, a nonprofit

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organization here in D.C. with chapters in multiple states across the country and over thirty thousand members and activists around the country. Our mission is to protect human life from the gravest threats to health and survival; we number environmental pollution among those key threats. PSR would like to express its strong opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." This proposed rule could arbitrarily exclude many important scientific studies-including thousands of public health and epidemiological studies that the Agency uses to make informed policy decisions regarding major public health and environmental laws. While it pretends to be about "transparency", the policy actually will limit the Agency's ability to use the best available science thereby weakening protections for public health and the environment. In essence it could censor and block much of the peer reviewed scientific research that has allowed us to address many serious environmental health threats over the decades.

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EPA's proposed rule would place crippling restrictions on the use of data the Agency would accept in the rulemaking process by ultimately requiring investigators to divulge personal information about the participants in research studies. Scientific studies that failed to meet this criterion would not be acceptable to the Agency. At present, this kind of information must be kept confidential according to the generally accepted rules that govern the conduct of research that must be adhered to by agencies of the federal government and institutions that receive federal funds. A particular example that is concerning to me and is particularly relevant today where it’s so hot outside and the air quality is questionable, is the Clean Air Act, a bedrock environmental law that protects us from dangerous air pollutants. It is such a critical health protection that would be endangered under this proposed rule because it relies on a longitudinal epidemiologic study of thousands of individuals. This includes the National Ambient Air Quality

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Standards (NAAQS) in the Clean Air Act. These standards address six major classes of common air pollutants, including standards for fine particles {PM2.5), and these are the backbone of the U.S. air quality management system.
The Clean Air Act specifies that new or revised NAAQS be based on scientific criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." EPA has relied largely on community epidemiology and controlled human studies in establishing the specific pollutant levels and averaging times for NAAQS. If these studies were excluded by the EPA restrictions it would greatly reduce the availability of information that has proved to be significant in assessing the consistency and coherence of the evidence upon which the standards are based and would certainly weaken the scientific basis for maintaining or strengthening

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those current standards. If the proposed rule is approved, we could lose the Clean Air Act's sweeping improvements to the air we breathe that we've benefited from over the last several decades thereby putting thousands of lives that are saved each year at risk, because EPA will no longer be able to use key scientific research.
PSR's mission is very similar to EPA's stated mission "to protect human health and the environment." To accomplish these objectives, we must protect the scientific integrity of the EPA. Physicians for Social Responsibility thus, strongly opposes the EPA's deceptively named proposal, "Strengthening Transparency in Regulatory Science." Thank you.

MS. HUBBARD: Thank you.
MS. STOBERT: Speaker 29, Tess Dernbach, and Speaker 30, Mary Angly. If you come to the speakers' table. Is Mary Angly in the room? Okay, we'll come back to her at the end.
MS. DERNBACH: My name is Tess Dernbach, T-E-S-S,

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D-E-R-N-B-A-C-H. I am a third-year law student at Columbia Law School and a legal intern at Earthjustice, speaking on behalf of Earthjustice. EPA's proposed rule, "Strengthening Transparency in Regulatory Science," requires a choice between breaching medical privacy or ignoring data for rulemaking decisions altogether. Breaching a patient's medical confidentiality can have severe and wide-ranging consequences for patients' lives and livelihoods. Various groups have often tried to access patient data for retaliatory purposes. For example, when pork industry associates tried to access the identities of individuals who had participated in a study by the University of North Carolina Professor Steve Wing, about the harmful health impacts of hog farming, or when the Department of Justice tried to access names of women who had late term abortions for use in litigation challenging the Partial Birth Abortion Ban Act. Employees' health information can be and is used against them by employers as an excuse for termination or other poor treatment. Moreover,

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when the medical confidentiality of research participants is breached, people are deterred from participating in research altogether. Medical confidentiality is a necessary element of modern medicine. Patients must feel safe telling their doctors the most intimate details of their lives. The expectation of confidentiality fosters openness and trust between doctors and patients and is crucial to the delivery of medicine and conducting clinical research. Courts recognize, too, the importance of medical confidentiality and privacy. In 1928, Justice Brandeis described the right of privacy as: "The most comprehensive of rights and the right most valued by civilized men." At least five circuit courts have recognized an individual's constitutional interest in or right to the privacy of their medical information. In Farnsworth v Procter and Gamble in the 11th Circuit, the court recognized that: "Even without an express guarantee of confidentiality, there is still an expectation, not unjustified, that when highly personal and

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1 potential embarrassing information is given for
2 the sake of medical information it will remain
3 private." This right to medical privacy can
4 extend to beyond publication of medical data to
5 situations where medical information is available
6 to those without a legitimate interest in it.
7 See, for example, Tucson Women's Clinic v Eden in
8 the 9th Circuit, where the court observed that
9 even if safeguards against public disclosure were
10 adequate, the lack of safeguards against release
11 of information to government employees who have no
12 need for the information could create a violation
13 of the right to privacy.
14 The EPA claims, vaguely, that confidential data
15 will be protected by redaction or de-
16 identification. However, these mechanisms are
17 entirely inadequate to maintain patient
18 confidentiality. Latanya Sweeney, a Harvard
19 Professor of Government and Technology, found in
20 her study simple demographics often identify
21 people uniquely that she was able to identify 87%
22 of people in the United States with only their

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1 gender, zip code and birth date. She has also
2 found particular problems in patient
3 confidentiality de-identification observing that
4 in many healthcare data sets there will be unique
5 data about people that can be used to identify
6 them even when they are not explicitly identified
7 in the data set. Sweeney found that even without
8 identifying data in health data sets: "The
9 remaining data can be used to re-identify
10 individuals by linking or matching the data to
11 other databases or by looking at unique
12 characteristics found in the fields and records of
13 the database itself."
14 Paul Ohm from the Georgetown Law School found in
15 his pivotal work: Broken Promises of Privacy:
16 Responding to the Surprising Failure of
17 Anonymization, that using traditional, personally
18 identifiable information focused anonymization
19 techniques, any data that is even minutely useful
20 can never be perfectly anonymous. These studies
21 seriously undermine government claims that de-
22 identifying data will provide adequate privacy for

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1 patient data contained within research studies.
2 Because of these reasons and those given before
3 me, I strongly urge EPA to revoke the proposed
4 rule immediately. Thank you.
5 MS. HUBBARD: Thank you.
6 MS. ANGLY: Hello, my name is Mary Angly and I'm
7 interning for the organization Physicians for
8 Social Responsibility and I've come to speak
9 against the proposed rule, "Strengthening
10 Transparency in Regulatory Science." Medical
11 studies, clinical reports, and real-world field
12 studies all include data and information that
13 cannot be made public without violating
14 confidentiality in patient protection laws. The
15 proposed rule implies that these studies are not
16 transparent because researchers necessarily
17 suppress names and other identifying information
18 about patients whose health information is
19 relevant to study findings. Releasing individual
20 participants' data to the public would violate
21 confidentiality requirements legally mandated by
22 the IRB and/or by HIPAA. By restricting these

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1 studies, the proposed rule would essentially force
2 the EPA to base many of its regulatory decisions
3 on industry-sponsored studies and this rule could
4 have huge environmental and public health
5 implications. Despite a supposed scientific
6 process, the funding source for a study can have
7 significant implications on study findings. For
8 example, in a review of research into the health
9 effects of EPA an evaluation of 115 relevant
10 studies was conducted in 2009. The review found
11 that 94% of the publically funded studies found
12 that chemicals have harmful effects whereas none
13 of the industry-backed studies found these same
14 findings. This is a huge disparity that cannot
15 have occurred due to chance alone. Successful
16 regulatory policies can have huge and quantifiable
17 effects on exposure levels in human health.
18 Biannually, the CDC collects data recording the
19 blood and urine levels of 265 chemicals in people
20 across the country. Longitudinal data can be used
21 to visualize falling exposure levels and thus not
22 measure the impact of a policy. For instance,

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1 following the 1970's era lead regulations, 2009
2 blood lead levels were 8% of 1980 levels, which is
3 a compelling example of a successful public
4 benefit that occurred as a result of regulatory
5 efforts. This is especially important when one
6 considers that the detrimental effects of lead
7 exposure are well known and well documented. Lead
8 exposures leading to a blood concentration of 1
9 mcg/dL are correlated with an IQ loss of about 0.2
10 points. Each IQ point is estimated to raise
11 worker productivity about 2%. Moral arguments
12 aside, when considered from a population
13 perspective, lead regulation has had huge economic
14 benefits. A review of the EPA's archives shows
15 that much of the original clinical research that
16 formed the EPA's decision to regulate lead would
17 have contained private health information. Under
18 the proposed rule many of these studies would not
19 have been able to be taken into consideration
20 which is why it's so important that these studies
21 are allowed to regulate future chemicals.
22 Although lead specifically, and its health effects

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1 are well known and well documented, my fear is
2 that the future regulation of dangerous chemicals
3 will be prevented due to the restrictive nature of
4 this rule. Barring the use of major health
5 studies under the veil of transparency will have
6 huge and detrimental effects on the breadth and
7 validity of the sources the EPA is able to
8 consider when making regulatory decisions.
9 Dangerous chemicals will not be able to be
10 adequately regulated if the scientific processes
11 are stymied.
12 I urge you to consider the health of this country
13 when deciding whether or not to implement this
14 rule. If the health implications are not enough
15 to prevent the enactment, please consider the
16 economic implications. The cornerstone of a
17 healthy and productive population is a healthy
18 environment. This rule would pose a serious
19 barrier to the EPA's ability to effectively
20 regulate. The power of landmark laws defined to
21 protect human health such as the Clean Air Act,
22 Safe Drinking Water Act, and Toxic Substances

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1 Control Act, could be significantly undermined if
2 this rule comes to fruition. Thank you for your
3 time.
4 MS. HUBBARD: Thank you.
5 MS. STOBERT: Speaker 31, Brenda Munive, and
6 Speaker 32, George Thurston, if you would come to
7 the speakers' table. Speaker 33, Brittany Meyer,
8 and Speaker 34, Adam Spanier, if you would come to
9 the on-deck seating.
10 MS. MUNIVE: Good afternoon. My name is Brenda
11 Munive and I am currently interning with the
12 nonprofit organization called Physicians for
13 Social Responsibility. I am a recent graduate of
14 the University of California, Santa Barbara, with
15 degrees in Environmental Studies and
16 Communication. I am testifying today to voice my
17 opposition to the EPA's proposed rule,
18 "Strengthening Transparency in Regulatory
19 Science." I believe that scientific transparency
20 is critical. Scientists, policy makers, and the
21 public alike must all be able to trust and rely
22 upon the scientific evidence that shapes our

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1 society and the extent of human knowledge.
2 However, I believe the EPA's proposed rule instead
3 represents a serious misunderstanding of the
4 institution of science. Furthermore, I believe
5 that the proposed rule risks unnecessarily
6 excluding valid scientific evidence from informing
7 EPA policy, and therefore harms our fellow
8 Americans through the creation of ineffective
9 policies. The nature of the scientific field is
10 unique. While most professions are motivated by
11 political, economic or societal interests,
12 scientists are motivated by seeking truth.
13 Scientists perform research with the sole
14 objective of uncovering the reality of how our
15 world operates and gain status and recognition by
16 succeeding in that goal. Top scientists are
17 granted tenure or the assurance they cannot be
18 fired from their position for whatever reason.
19 Tenure guarantees scientists that they will not
20 lose their position even if their research points
21 to facts that are controversial or at odds with
22 the current political societal climate. For these

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1 reasons, ideally, they are not suspect to the same
2 biases as most of the public. To prove this point
3 it is helpful to look at the four norms of
4 scientists as explained by renowned sociologist,
5 Robert Merton. These are: Universalism, or the
6 idea that truth applies to all regardless of
7 belief; communalism -- the fact that all
8 scientific knowledge belongs to the public;
9 disinterestedness -- the fact that scientists are
10 not concerned with the outcome of the research,
11 only that it is factual; and organized skepticism
12 or the tendency to be doubtful of any research to
13 ensuring the deep truth. These norms describe the
14 ideal foundation on which scientists and their
15 research operate. Because of communalism, we can
16 be confident that scientific research is as open
17 as possible. Being intentionally secretive
18 violates this ideal, so critical data must be
19 accurately presented. This norm does not mean
20 that all data is presented, however. Minute
21 details, such as the identities of the subjects,
22 are usually withheld in research studies of all

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1 types to protect privacy and ensure participation
2 -- or, encourage participation. It is important
3 to emphasize that these omissions do not diminish
4 the quality or the outcome of the research, but
5 are made in the interest of the well-being of the
6 participants. Because of this intrusiveness, the
7 public can be confident that scientific research
8 is virtually free of any bias favoring one agenda,
9 and because of organized skepticism, scientific
10 research is subjected to heavy review and fact
11 checking before it is published in a scientific
12 journal, so the public can be confident that
13 published research is factually sound. Of course,
14 there are exceptions to these ideals. For
15 example, the norm of disinterestedness could be
16 jeopardized if a scientist is hired by an outside
17 party such as a company or noted member of the
18 industry. The outside party introduces a monetary
19 benefit and a desired outcome for the research,
20 putting unconventional pressure on the scientist
21 to fulfill the desires of whoever hires them. If
22 the EPA's proposed rule is enacted, industry

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1 funded research could comprise a disproportionate
2 amount of what informs EPA policies, giving the
3 industry, and not the scientific community, a
4 large degree of input in shaping environmental
5 protections.
6 Based on this knowledge, the proposed EPA rule is
7 unnecessary. Mandating that underlying data be
8 made public in order for scientific research to be
9 utilized in informing EPA policies, attempts to
10 increase transparency but fails to recognize that
11 scientists already take thorough and exhaustive
12 steps to assure their published research is
13 unbiased, truthful and as transparent as possible.
14 Research that does not meet these standards is
15 rejected by the scientific community. The rule
16 would restrict valid scientific data, particularly
17 within health research where patient
18 confidentiality mandates that identifying
19 information remain anonymous. The result would be
20 ineffective and harmful policies that could allow
21 for practices and chemicals that genuinely harm
22 our nation to remain rampant and unregulated.

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1 This outcome would benefit no one and runs
2 contrary to the EPA's mission of protecting public
3 health and the environment. Furthermore, a
4 healthy economy depends on healthy communities.
5 For these reasons, I implore the EPA to reconsider
6 enacting this rule. Thank you for this
7 opportunity to present my testimony.
8 MS. HUBBARD: Thank you.
9 MR. THURSTON: Good afternoon, I'm George
10 Thurston. I'm a professor at the New York
11 University School of Medicine. Today I'm here
12 representing the International Society for
13 Environmental Epidemiology, the ISEE, which
14 includes researchers who study environmental
15 causes of ill health including ambient air
16 pollution subject to the National Ambient Air
17 Quality Standards, or NAAQS, promulgated by the
18 EPA, as well as its standards for heavy metals,
19 pesticides, drinking water and other environmental
20 contaminants. As such, our members have supplied
21 a substantial part of the research that is the
22 basis of those standards. We strongly oppose the

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1 implementation of EPA's proposed changes to the
2 way that studies are considered in setting such
3 standards. Based on an incorrect interpretation
4 of transparency and replication in science, the
5 proposed rule would deprive policy makers of the
6 real-world epidemiological evidence based on real
7 exposures of real people that have been, and will
8 continue to be, vital for future considerations of
9 EPA's health-based standards. I especially want
10 to highlight for you the manuscript that I wrote
11 20 years ago entitled, "Band-Aiding the Release of
12 Health Research Data: Issues and Implications,"
13 and the article is already posted on EPA's SAB web
14 page. This article considered a similar proposal
15 that was made in July of 1997 as an amendment to
16 the U.S. House Appropriations Bill without any
17 hearings. The problems I raised at that time are
18 directly relevant to today's transparency
19 proposal.
20 First, the increased potential for compromise of
21 medical record confidentiality. As you've heard
22 before today in a time of big data it's all too

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1 easy to crack any de-identification process,
2 especially when lots of publically available
3 spatial and environmental data are matched to
4 people in the study as they are in the studies
5 that EPA considers. The solving of the Golden
6 State Killer case, for example, is one example
7 where a combination of two separate databases
8 allowed de-identification of an individual.
9 Second a loss of researchers' intellectual
10 property. This can involve lost publications and
11 academic career derailment. Third, the imposition
12 of a government unfunded mandate. The USOMB has
13 estimated that a similar law considered in the
14 Congress, but that was never passed by the Senate,
15 could cost the government up to 250 million
16 dollars per year. There would also be the data
17 prep costs to the scientists and their
18 institutions.
19 Fourth, damage to future scientific research.
20 When people no longer wish to enroll for fear that
21 their medical data will be released, new
22 scientific studies could be inhibited. Fifth, the

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1 proposed rule will allow the EPA to ignore large
2 portions of the scientific literature in decisions
3 that are supposed to protect public health. In
4 cases where key studies are excluded from the
5 evaluation of environmental issue because of an
6 inability to release study participants' private
7 health records, the EPA may then ignore key
8 scientific studies. This would diminish the
9 evidence supporting protective health studies,
10 potentially allowing the EPA to conclude that
11 there's insufficient evidence to support proper
12 health protective standards.
13 Sixth, the abuse of research data to undermine
14 science credibility. This problem is likely the
15 most dangerous aspect of this proposal. Past
16 documented examples of abuse by consultants to a
17 vested interest resulted when the state of Georgia
18 set up an open records law and the R.J. Reynolds
19 Company used it to obtain research data to attack
20 study findings that the use of cartoon characters,
21 such as Joe Camel, in tobacco advertising
22 influenced children's product recognition. That

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1 research was later validated in other studies but
2 the damage was done and the physician involved
3 left research for private practice. Thus, this
4 data release approach has already been tried in
5 the past and shown to be too easily abused by
6 vested interests. There is also a tobacco
7 connection to today's proposal. Just before the
8 1997 open data amendment was presented to the
9 House, there was a December 1996 memo from the
10 consultant of the tobacco industry, from
11 Christopher Horner, laying out a similar strategy
12 to address federal agency science with respect to
13 second-hand smoke including a now familiar call
14 for science transparency.
15 Finally, there's no need for this rule.
16 Independent validation has already been conducted
17 by groups such as the Health Effects Institute for
18 air pollution studies, such as for the ACS and the
19 Six Cities studies. Indeed, these are the studies
20 mentioned by an earlier speaker, I believe it was
21 Steven (sic) Milloy, and he incorrectly said that
22 they were never released, they would never release

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their data, and in fact they did release it. So, his testimony was incorrect. And whoever it was, I think it was Steven (sic) Milloy, but anyway, earlier speaker who said that Pope and Dockery had not released their data. They have done so and, in fact, it’s an excellent example of how the system works. So, finally just to say such independent evaluations could easily be applied again to any new cases of concern for data validation without the above-noted risks. Thus, this dangerous rule seeks to needlessly solve a purported problem that just doesn’t exist. Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 33, Brittany Meyer, and Speaker 34, Adam Spanier, if you would come to the speakers’ table. Speaker 35, Sean Moulton, and Speaker 36, Andrew Bergman, if you would come to the on-deck seating.

MS. MEYER: Hi. My name is Brittany Meyer and I am the Associate Director of Public Policy at the Michael J. Fox Foundation for Parkinson's

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Research. I am here on behalf of the nearly one million people with Parkinson's disease in the United States who rely on the Environmental Protection Agency to safeguard their health and inform them about potential hazards in the environment.

For over the past ten years, we've learned a lot about the mechanisms of Parkinson's disease and now know that the condition is caused by both genetic and environmental factors. It is now very clear that when coupled with a genetic risk factor, exposure to several chemicals, most notably solvents and certain pesticides, can trigger the disease. Just eight weeks ago, a study out of Canada suggested that low-level exposure to pesticides disrupts cells in a way that mimics the effects of mutations known to cause Parkinson's. More research is needed to fully understand the mechanisms at work and how to prevent them.

Many of the studies used to identify risk factors for Parkinson's disease are investigated via large population-based epidemiology studies and will be

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impacted by EPA's proposal. I am going to highlight one clear example- though along with my health and science colleagues here today, we can provide hundreds of examples of studies that could be impacted.

A 2009 study used GPS to estimate participants' well-water contamination exposure from agricultural pesticides. The results showed that consuming well water from a private well located in an area with historical pesticide use resulted in an increased risk of Parkinson's disease. Due to the nature of wells - typically serving a relatively limited number of people within a very small radius - the detail needed to perform the study renders proper de-identification impossible. All one needs to know is that a certain person lives near a particular well along with a demographic detail such as their age, gender, race, etc., and privacy is at great risk.

Data from studies like this cannot be de-identified to the degree needed to protect patient's identification while still providing the

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amount of specificity needed to help a scientist trying to replicate the results. Obtaining consent is not a solution. Some people make the choice to not disclose their Parkinson's diagnosis for a variety of reasons including privacy concerns, fear of prejudice or retaliation at work, and others. It is simply unreasonable to put people in the position of outing their diagnosis or to decline to participate in a study that could someday find a cure for their condition.

Additionally, people who are willing to sign away their privacy and those who are not are different in ways we cannot predict or control for in study analysis.

The Michael J. Fox Foundation believes in open, reliable, and replicable science. We fund approximately 90 million dollars in research per year and hold our funded scientists to the highest standards. Our contracts require science studies to be peer reviewed and most require data to be as available as possible while protecting precious health data. We echo the call of our fellow public

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1 health groups here today and the nearly seventy
2 public health, science, academic, and medical
3 groups who signed on to a joint statement calling
4 for the rule to be abandoned for the sake of
5 science and for our health. Thank you.
6 MS. HUBBARD: Thank you.
7 MR. SPANIER: Good afternoon, my name is Adam
8 Spanier, S-P-A-N-I-E-R. I am a pediatrician and
9 Associate Professor in the Department of
10 Pediatrics at the University of Maryland School of
11 Medicine. I'm also a member of the American
12 Academy of Pediatrics, Council on Environmental
13 Health Executive Committee. I'm here today on
14 behalf of the American Academy of Pediatrics. The
15 AAP strongly objects to EPA's proposed rule,
16 "Strengthening Transparency in Regulatory
17 Science." The proposal will require EPA to ignore
18 the best available, peer-reviewed scientific
19 evidence on pediatric and reproductive
20 environmental health, may violate patient
21 confidentiality, and could dampen scientific
22 processes by creating barriers to the use of

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1 quality research in EPA science. Children and
2 pregnant women are disproportionately affected by
3 environmental pollutants and changes. Between
4 1990 and 2010, the Clean Air Act prevented over
5 160,000 premature deaths, 54,000 cases of chronic
6 bronchitis, 130,000 acute myocardial infarctions,
7 1.7 million asthma exacerbations, 3.2 million lost
8 school days and 13 million lost work days.
9 Landmark academic studies guided EPA to implement
10 policies leading to these dramatically positive
11 outcomes. However, EPA's proposed rule will no
12 longer allow EPA scientists to use much of the
13 scientific evidence that's brought on these life-
14 saving regulatory changes.
15 Scientific studies used by EPA to make regulatory
16 changes are already rigorously examined prior to
17 being published in peer-reviewed scientific
18 journals. Scientists not associated with the
19 research study must review the study design to
20 ensure that it is scientifically sound before the
21 study can be published. Many of the studies that
22 inform EPA policy to protect the health of

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1 children and pregnant women are based on IRB
2 approved studies of the health of human subjects
3 that require data confidentiality. Such studies
4 involve observing the longitudinal effects on
5 reproductive and child health from exposures to
6 lead, particulate matter and other toxic
7 substances. Replicating such investigations for
8 the purpose of providing open access data for EPA
9 to use would be morally unacceptable as it would
10 require exposing children to lead, ozone and other
11 damaging pollution. It would also not be ethical
12 to exempt the study participants from data
13 confidentiality protections. By requiring
14 reproducibility the rule may also exclude many
15 landmark public health studies that were so
16 scientifically rigorous and resource-intensive
17 that they could not be reproduced, such as the
18 Framingham Heart Study, a 70-year-long
19 cardiovascular epidemiologic study. Requiring
20 reproducibility may also exclude studies done
21 after landmark ecologic events such as oil spills
22 and natural disasters. This rule does not improve

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1 the scientific merit of the studies used for EPA
2 policies, and, instead, creates significant
3 barriers to EPA's assessment of past, current and
4 future scientific work. This proposed rule
5 contravenes EPA's mission to ensure that American
6 pregnant women, children and families have clean
7 air, land and water, and the AAP strongly urges
8 you to not move forward with it. Thank you.
9 MS. HUBBARD: Thank you.
10 MS. STOBERT: Speaker 35, Sean Moulton, and
11 Speaker 36, Andrew Bergman, if you'll come to the
12 speakers table. Before they speak I wanted to
13 note that the time is now 2:39 and Speakers 35 and
14 36 are the last two speakers here to speak during
15 the afternoon session. So, at this time if
16 there's any speakers currently registered for the
17 evening session but would like to speak now, if
18 you would go to the registration desk we can get
19 you a speaker number. Go ahead.
20 MR. MOULTON: Good afternoon, my name is Sean
21 Moulton, Senior Policy Analyst at the Project On
22 Government Oversight, a national nonprofit,

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1 nonpartisan, government accountability
2 organization. Thank you for the opportunity to
3 speak this afternoon. I'm here to express my
4 organization's strong objections to the proposed
5 rule, "Strengthening Transparency in Regulatory
6 Science," and urge the Agency to withdraw it. In
7 the proposed rule the Agency notes that the best
8 available science must serve as the foundation for
9 EPA's regulatory actions. It is hard to argue
10 with that fundamental principle, but this policy
11 won't make scientific information better, nor more
12 available. Instead, the new rule will often mean
13 the best available science is off limits to the
14 Agency, create delays in rulemaking and result in
15 greater litigation.
16 I'd like to focus primarily on the rulemaking
17 process and first raise serious concerns about the
18 insufficient development process that produced
19 this rule, a rule that fundamentally changes what
20 information can and cannot be used in future
21 rulemakings is a major undertaking and requires a
22 great deal of certainty and evidence, yet this

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1 proposal offers no clear explanation of the
2 precise problem, no supporting evidence, no
3 studies establishing that EPA has an information
4 problem, nor citations that the proposed standard
5 has been successfully used before or that EPA
6 understands what its impact will be on the
7 regulatory process when implemented. Even if the
8 Agency truly believes there is some deficiency in
9 its information policies and procedures, this
10 proposed rule is premature. The starting point
11 should be conducting studies of the issue to
12 better understand the scope of the problem, if
13 there is one, and the best way to improve
14 transparency of regulatory science. The Agency
15 should allow the Science Advisory Board to fully
16 investigate and offer specific recommendations
17 before moving forward with any proposed rule.
18 There are any number of steps that the EPA should
19 be completing before rushing into a formal
20 rulemaking. The incomplete foundations for this
21 rule reveal themselves in the vague language and
22 unclear standards. The rule does not specify how

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1 the new standards will be implemented, what
2 mechanisms will be made available to allow
3 publishing of more detailed data. More
4 importantly the rule doesn't address how it will
5 fit into the legal requirements the Agency has
6 under the Administrative Procedure Act or other
7 environmental laws.
8 The proposed rule is being done at EPA's
9 discretion with no statutory authority backing it
10 up. So, should this policy come into conflict
11 with statutory requirements under existing law,
12 those laws take precedent, and laws governing
13 rulemaking have a number of requirements that this
14 proposed rule would be in conflict with. The
15 Administrative Procedure Act makes clear that an
16 Agency cannot engage in arbitrary, capricious
17 actions or decisions in its rulemaking; while the
18 Agency has authority in its given area, that
19 authority is not absolute. The Agency must have
20 clear and strong justifications for its actions.
21 Given the lack of supporting evidence for this
22 policy or a statutory requirement from Congress,

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1 EPA will be hard pressed to prove that this
2 untested standard is not arbitrary. Even if the
3 rule isn't immediately dismissed under the APA,
4 the EPA's requirements under other laws, such as
5 the Clean Air Act, that it consider all available,
6 or best available, science in rulemaking and this
7 policy would be in direct conflict with those. If
8 the Agency seeks to apply this new standard in
9 areas ungoverned by such statutory requirements,
10 it will result in a confusing patchwork of
11 standards where a study may be available for
12 consideration under a Clean Air Act rule or a TSCA
13 rule, but that same study would not be
14 considerable in another rule.
15 I wanted to note in a case before the U.S. Court
16 of Appeals for D.C. around the availability of air
17 quality data study information, the court
18 addressed this very issue, stating that, "If the
19 EPA and other governmental agencies could not rely
20 on published studies without conducting an
21 independent analysis of the enormous volume of raw
22 data underlying them, then much plainly relevant

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1 scientific information would become unavailable to
2 EPA for use in setting standards to protect public
3 health and the environment." Placing large
4 portions of scientific research off limits simply
5 goes against common sense. EPA should be able to
6 use any and all available information to produce
7 the best, most up-to-date rules. If a study is
8 unreliable or flawed in some way, then the Agency
9 can decide that based solely on that study's
10 merits, and sometimes even flawed or partial
11 studies can offer important insights that the EPA
12 should benefit from.
13 We strongly urge EPA to withdraw this rule. Thank
14 you very much for your time.
15 MS. HUBBARD: Thank you.
16 MR. BERGMAN: I'm Andrew Bergman, and I'm speaking
17 today as the Special Environmental Advisor at the
18 Project On Government Oversight, but I'm also
19 currently a Ph.D. student in applied physics at
20 Harvard University.
21 While the proposed "Strengthening Transparency in
22 Regulatory Science" rule uses the words

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1 "transparency" and "reproducibility" to project
2 lofty goals, it's real effect will be to undermine
3 the way that the EPA is able to rely on and even-
4 handedly assess scientific studies for use in the
5 rulemaking process. I'm here today to urge EPA to
6 withdraw this rule. My colleague, Sean Moulton,
7 has just addressed how the proposed rule conflicts
8 with the EPA's regulatory process, and the
9 statutory requirements underlying that process,
10 but the rule will also have a direct impact on how
11 the EPA approaches science.
12 The rule fails to properly address its two key
13 considerations that will have a major impact on
14 how it is implemented. First, the rule states that
15 data relied on in making regulations must be made
16 publically available, but it doesn't suggest a
17 mechanism for how personally identifiable
18 information or confidential business information
19 would be handled.
20 This is an incredibly important issue, as so many
21 studies that EPA uses rely on this type of
22 confidential data. Yet it's reasonable to conclude

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1 from the rule that, if it goes into effect, the
2 EPA will no longer be able to use most
3 longitudinal human health studies to craft public
4 safeguards, even though those studies have been
5 conducted by reputable researchers at academic
6 institutions, and peer reviewed to ensure
7 validity. Instead, they will be left with
8 industry studies that more often use animal test
9 subjects, which don't have any personal privacy
10 concerns.
11 Second, while the rule refers to replicability of
12 scientific findings, the background information
13 supporting the rule focuses on scientific studies'
14 reproducibility, which has a wholly different
15 meaning in a scientific context. But because the
16 rule itself says it must be possible to
17 "replicate" studies' findings, we should assume
18 that the rule intends the strongest possible
19 meaning: that it must genuinely be possible to
20 conduct all studies used in rulemaking again, from
21 scratch, and obtain the same findings.
22 The Agency uses many studies, however, such as

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1 those that link leaded gasoline to brain damage in
2 children or a study that found a link between fine
3 particulate air pollution and premature deaths,
4 that examine dangerous real-world exposures and
5 cannot, of course, be safely repeated. Just
6 because they can't, or shouldn't, be repeated,
7 however, doesn't mean we should ignore the vital
8 insights they provide. The knowledge we have
9 gained from these tragedies can and should be used
10 to help safeguard the public in the future.
11 Without knowing the details of how these two
12 provisions, central to the rule, will be
13 implemented, commenters can't even begin to assess
14 the wide-ranging outcomes of this rule. We can
15 conclude that the result will be that large swaths
16 of studies will be arbitrarily ruled out for use
17 in future rulemakings.
18 The rule's constraints on the use of scientific
19 studies mean that even the use of studies that
20 don't end up being haphazardly tossed out by this
21 rule will be hindered substantially. The CBO found
22 that a policy very similar to the proposed rule,

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when it was proposed as legislation, would significantly reduce the number of studies that EPA is able to rely on when issuing and proposing rules without a substantial input of funding--a major loss when Agency scientists already have the tools to conduct thorough assessments of studies they rely on.

The rule also puts the Agency in a position where it's forced to serve as an independent reviewer of all scientific data underlying studies it uses, which will again hamstring Agency scientists who have limited resources. When the EPA was sued over air quality standards for particulate matter and ozone during the George W. Bush administration, the U.S. Court of Appeals for the District of Columbia Circuit said a requirement to make public underlying data for the key studies used in rulemaking would be "impractical and unnecessary." The three-judge panel said: "If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying

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them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment ..." Essentially, the judges concluded that a policy like the proposed rule wouldn't serve the Agency's purposes at all.

Instead of arbitrarily slicing out broad types of studies from being cited in rulemaking, why not continue to give Agency scientists the ability, as they have had for decades, to comprehensively assess and compare the scientific evidence presented in a study and give weight to each study as a result of careful deliberation?

If the EPA wants to address the accessibility of scientific studies and data, an important issue to scientists as well as members of the public, it should acknowledge that those efforts, which might include building a new public-facing platform or carefully considering certain types of standards, will amount to a years-long process and will require an enormous investment of Agency time and funding. That type of proposal shouldn't be made

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in a brief proposed rule and should only be made if extensive studies demonstrate that there is a real need for an update to how scientific studies are used in Agency rulemaking.

The proposed, "Strengthening Transparency in Regulatory Science" rule, instead, gestures toward an unsubstantiated set of concerns. It's hard to conclude that its purpose is to do anything other than undermine Agency scientists' ability to use scientific studies and data to craft regulations, under EPA's statutory mandates, that protect public health. For this reason, I urge you again to withdraw the rule. Thank you for your time and for the opportunity to comment on this important proposal.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 37a, Emma Glidesgame, and Speaker 38a, Jyotsna Pandey if you would come to the speakers' table. Speaker 39a, Patricia Cohen speaking on behalf of Tracy Woodruff, if you would come to the on-deck seating.

MS. GLIDESGAME: Good afternoon. My name is Emma

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Gildesgame, G-I-L-D-E-S-G-A-M-E. I'm a Master of Environmental Management student at the Yale School of Forestry and Environmental Studies, and an intern with the National Parks Conservation Association. My comments today are my own. I'm here to express my strong opposition to the proposed, "Strengthening Transparency in Regulatory Science" rule, that would censor science and threaten the health of all Americans.

Last week, many of us in D.C. awoke to alerts warning of potential contamination in our water system. We were told to boil water before drinking or brushing our teeth or to avoid tap water altogether. For those few days, stores sold out of bottle water, Starbucks stopped selling coffee, and public pool splash pads and water fountains went dry. In the face of an urgent public health risk we did not censor the science that told us that contamination in our water is a threat. To know that clean water is important we didn't need the health records of every person who participated in landmark studies that helped us

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1 understand the effects of contaminated water on
2 our bodies and brains. The science is real. It's
3 not secret, it's been repeated. It's been peer
4 reviewed, analyzed and reaffirmed by generations
5 of experts.
6 Just as the residents of D.C. took precautionary
7 actions to protect ourselves and our loved ones in
8 the face of a potential public health threat, the
9 EPA must be allowed to use the best available
10 scientific data to accurately assess environmental
11 and public health threats to protect all
12 Americans. The Clean Air Act, Clean Water Act,
13 Safe Drinking Water Act and other historic laws
14 that helped the United States become a leader in
15 environmental protection recognized something that
16 we forget far too often: Human health is
17 environmental health. They are one in the same.
18 Pollutants in the air travel hundreds of miles to
19 become pollutants in our lungs. Contaminated
20 soils grow contaminated food. Toxic river water
21 becomes toxic drinking water. At the same time,
22 clean air builds stronger kids. Healthy rivers,

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1 lakes and watersheds build healthy communities.
2 Good environmental and public health policies rely
3 on a strong backbone of good science. The
4 proposed rule would eliminate many credible,
5 respected, long-standing, peer-reviewed,
6 scientific studies from EPA consideration because
7 they rely on confidential health information which
8 cannot be made public. This proposal allows
9 politically appointed regulators to pick and
10 choose which studies they want to consider and
11 would force scientists to choose between their
12 ethical obligation to protect their subjects'
13 privacy and the obligation to contribute knowledge
14 to apply to regulatory science. Using good
15 science to make strong policy has made America
16 great for decades. The EPA and other agencies
17 have kept countless Americans healthier, safer and
18 more prosperous by using science to inform
19 conservative, proactive protections for human
20 health and the environment. We have protected
21 historic and cultural monuments like the Jefferson
22 Memorial, Statue of Liberty and even the Capitol

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1 Building from the corrosive power of acid rain.
2 We have reduced smog and air pollution in national
3 parks like Great Smoky Mountains, Joshua Tree and
4 Yosemite. We have improved water quality from the
5 Great Lakes to the Everglades. Thanks to the EPA,
6 my peers and I were born into an era of healthier
7 air, cleaner rivers, and safer drinking water than
8 our parents. I hope that someday my children can
9 say the same, and that is why today I am joining
10 thousands of scientists and public health
11 professionals all over the country in speaking out
12 against this rule and asking you to stop it in its
13 tracks. We are all counting on you to listen to
14 the sound and transparent science the EPA has used
15 for decades and we are counting on our medical
16 records remaining private. I strongly urge the
17 EPA to stop this radical proposal for the health
18 and safety of all Americans. Thank you.
19 MS. HUBBARD: Thank you.
20 MS. PANDEY: Good afternoon, my name is Jyotsna
21 Pandey, and I'm the Quality Manager for the
22 American Institute of Biological Sciences. My

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1 organization appreciates the opportunity to
2 comment on the EPA proposed rule, "Strengthening
3 Transparency in Regulatory Science." We thank EPA
4 for extending the initial 30-day public comment
5 period and scheduling this public hearing on the
6 proposed rule. We support the objective of
7 increased transparency in the rulemaking process.
8 But, the proposed rule is inadequately defined and
9 thus itself lacks transparency and appropriate
10 public protections. We request the EPA rescind
11 the proposed rule and initiate an open process for
12 gathering the information required to more
13 thoroughly articulate the proposed rule. Any
14 proposal to increase transparency in the
15 regulatory process must not arbitrarily exclude
16 important scientific information from the
17 decision-making process, nor can personal
18 information about individuals, such as genetic
19 information or health status be sacrificed. A
20 failure to protect these data will hinder future
21 scientific investigations of people who refuse to
22 participate in recent studies if they are not

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1 confident that their most personal information is
2 protected. Importantly, scientific journals take
3 steps to protect personal information. They are
4 not aware of any secure way to mask or protect
5 personally identifiable information in the public
6 domain and therefore think that any rule requiring
7 this information be made public is needlessly
8 risky. These data are important, however, to
9 informing the decision-making process and should
10 not be excluded for rulemaking processes because
11 they are not publically disclosed.
12 As far as this request for comment, EPA has
13 solicited input and measures to "provide protected
14 access to identifiable and sensitive data." This
15 is a significant issue and one that EPA should
16 fully understand prior to moving forward with any
17 new rule. Time and expertise are required to
18 identify and properly evaluate the feasibility,
19 cost and effectiveness of potential actions. It
20 is unlikely that EPA can effectively gather and
21 evaluate this information in the time prescribed
22 by the proposed rule. We recommend that EPA

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1 initiate a formal request for public comment on
2 this issue alone and use what it learns to help
3 inform and guide any potential future rule on
4 transparency.
5 High-quality, curated and vetted mega data are
6 generally required for someone else to
7 appropriately reanalyze or use data such as those
8 that could be made available by the proposed rule.
9 The proposal is silent on meta data standards and
10 practices. This is a significant challenge and
11 another major problem with the proposed rule. We
12 support EPA's goal of conducting independent peer
13 reviews of the science and data used to inform
14 regulatory decisions but thinks the section lacks
15 adequate specificity. Who will conduct and manage
16 the peer review process? Will these reviews be
17 managed by the Office of Research and Development
18 or by the various regulatory offices within EPA?
19 Does EPA have appropriate staffing, expertise and
20 resources to manage these peer reviews? We
21 recommend that EPA partner with scientific
22 organizations and professional communities to

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1 administer and manage these reviews. Such
2 outsourcing and partnerships will help to ensure
3 that EPA gains access to independent and highly
4 qualified experts and to promote greater public
5 confidence in the independence of these peer
6 reviews. This kind of process for managing peer
7 review will also allow EPA to more cost
8 effectively, nimbly and rapidly conduct reviews as
9 it will not require EPA to substantially increase
10 staffing for the remaining reviews. Such a
11 process would also provide EPA with greater
12 capacity to conduct reviews on time skills that do
13 not needlessly delay regulatory and rulemaking
14 schedules. After reviewing this proposed rule the
15 AIBS respectfully urges EPA to rescind the current
16 proposal. We ask that EPA initiate a new
17 transparent and interactive process with the
18 scientific, public health and environmental
19 management communities, as well as other
20 appropriate stakeholders, to identify responsible
21 and viable approaches for promoting greater
22 understanding of the science and data used to

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1 inform EPA decision-making. Thank you for your
2 consideration of our request.
3 MS. HUBBARD: Thank you.
4 MS. STOBERT: Patricia Koman, if you'd come to the
5 speakers' table.
6 MS. KOMAN: Good afternoon. My name is Patricia
7 Koman, spelled K-O-M-A-N. I am speaking on behalf
8 of Dr. Tracy Woodruff, W-O-O-D-R-U-F-F. Dr.
9 Woodruff is a professor in the Department of
10 OB/GYN and the Director of the Program on
11 Reproductive Health and the Environment at the
12 University of California, San Francisco. Dr.
13 Woodruff is a PI, or Principle Investigator, for a
14 Children's Environmental Health Center and she,
15 along with 15 other principle investigators of
16 other Children's Centers, have submitted comments
17 to the EPA about this proposed rule in writing.
18 They are concerned that the proposed rule will
19 adversely affect EPA's ability to use science in
20 decision-making and ultimately negatively
21 influence protections for children's health.
22 Research from Children's Centers contribute

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1 significantly to the foundation of science that
2 informs and supports the Agency's ability to
3 protect the public health. The National Academy
4 of Sciences highlighted that Children's Centers
5 have led to an improved understanding of the
6 environmental impacts on child health and
7 development. Children's Centers research
8 identified the critical contributions of
9 environmental exposures to asthma, obesity, ADHD,
10 cancer, autism and other childhood illnesses.
11 This research has led to new direction, treatment
12 and prevention strategies for these diseases
13 including informing EPA standards for cleaner air
14 which has improved the quality of life for
15 children. Collectively, we have research data
16 from thousands of participants across the country,
17 including some of our most vulnerable populations,
18 children and women in communities of color. To
19 not use or consider studies that do not comply
20 with the proposed rule is inconsistent with
21 scientific principles and evidence-based policy
22 and this would put the public's health at risk

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1 from toxic chemicals. Institutional review boards
2 require that we protect the privacy and
3 confidentiality of our participants, but
4 institutional review boards' requirements conflict
5 with this rule's mandate to publically reveal
6 individual level data. Data masking, coding and
7 de-identification techniques have limitations,
8 because re-identification of participants is still
9 possible. We are especially concerned that the
10 rule inappropriately codifies specific data
11 analysis approaches such as dose response modeling
12 and other scientific decisions that should be made
13 on the basis of scientific judgment and empirical
14 considerations. This will hinder scientific
15 inquiry and lead to inaccurate results. As
16 scientists, we value open science but the mandates
17 laid out in this rule will not improve data
18 sharing, replicability or transparency. Instead,
19 implementation of this rule, especially
20 retroactively, could lead to EPA excluding
21 numerous relevant studies from policy decisions to
22 the ultimate detriment of children's health. We

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1 urge EPA not to move forward with this proposed
2 rule.
3 Finally, I want to comment about this public
4 hearing and its lack of access to all
5 stakeholders. By not providing the ability to
6 make comments remotely or virtually, EPA limits
7 the public comments to those that have the
8 financial resources to travel to Washington D.C.
9 and limits the participation of populations that
10 are going to be most affected by this rulemaking.
11 This undermines civic engagement and conflicts
12 with the principles of a fair democracy. This is
13 not a technical issue, as U.S. EPA has made
14 virtual public comment in the past.
15 Finally, we urge EPA not to move forward with this
16 proposed rule. Thank you.
17 MS. HUBBARD: Thank you.
18 MS. STOBERT: It's now 3:02 p.m. This was our
19 last speaker for this session that we know of. We
20 are going to repeat the request that if there is
21 any speaker that has registered but is registered
22 for the evening session, if you'd like to speak

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1 now go to the registration desk and you will
2 receive a speaker number for this session. We're
3 going to wait a few minutes and see if there's
4 anybody that decides to speak now. Otherwise, we
5 will break until the 4:00 session starts.
6 MS. HUBBARD: And if I could just make a quick
7 announcement, we do have a member of Congress who
8 is on his way to speak who should be here shortly,
9 so we won't go into recess quite yet, so if
10 everyone could just remain in their seats if
11 you're interested in hearing him speak, otherwise
12 feel free to go on and head on out and then we'll
13 go into recess after that.
14 MS. STOBERT: Sorry, Peter Ferrara, speaker 40a,
15 if you would come to the speakers' table?
16 MR. FERRARA: Good afternoon. My name is Peter
17 Ferrara, that's F-as in Frank, E-R-R-A-R-A. I'm
18 the Senior Fellow for Legal Affairs at the
19 Heartland Institute. We submitted our comments
20 during the comment period online in response to
21 the notice for public comment in rulemaking posted
22 on April 30, 2018. EPA proposes the rule I am

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1 commenting on intending the strengthen the
2 transparency and integrity of EPA regulatory
3 science. The proposed rule provides that EPA
4 should ensure that the data and models underlying
5 scientific studies pivotal to EPA regulations are
6 publically available in a manner sufficient for
7 independent validation, especially concerning
8 regulations for which the public is likely to bear
9 the cost of compliance. We applaud this proposed
10 rule and find that governing statutes and
11 executive orders, not to mention the basics of the
12 scientific method, authorize the proposed rule and
13 indeed have long required it. In not following
14 the proposed rule in the past, EPA has been
15 flouting the governing statutes and executive
16 orders, departing from the scientific method and
17 abusing its authority. The proposed rule provides
18 that for science pivotal to significant regulatory
19 action, EPA will ensure that the data and models
20 underlying the science are publically available in
21 a manner sufficient for validation and analysis.
22 This new policy is needed because EPA admits to

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1 having not previously implemented these policies
2 and guidance in a world-best, robust and
3 consistent manner.
4 Examples where EPA previously has fallen short
5 include the public health research used to
6 implement and defend the PM2.5 particulate matter
7 standards, the corporate average fuel economy
8 standards, the ozone standards and carbon dioxide
9 standards. EPA's admitted reliance on secret
10 science occurs at a time when the publications
11 Nature, PLoS, Science, The Economist and other
12 report half or more of published research on
13 public health issues cannot be replicated. This
14 replication crisis is genuine and even more broad
15 and critical than the sources cited by the EPA for
16 this proposed rule are willing to admit. A
17 scientific publishing industry has been created by
18 lavish government funding of politically directed
19 research. Examples of this include supposedly
20 scientific studies finding human impact on the
21 climate or an association between ozone and
22 climate. It may take generations before the

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1 effects of this corruption can be overcome. The
2 root cause of EPA science malfunction has been
3 corruption of EPA's peer review process. Peer
4 review for the EPA has become power review with
5 insiders typically armed with millions of dollars
6 in government funding acting to censor and exclude
7 scientists who disagree with the reigning
8 political agenda. That perverts the whole point
9 of peer review, turning it into a tool used to
10 shut out anyone who disagrees, instead of a
11 process forcing scientists to defend their work
12 against critics. The more widespread replication
13 crisis is proof that this disease has affected
14 most of the world's leading science journals and
15 even its National Academies of Sciences. One
16 scientific finding that has been suppressed by the
17 corruption of peer review was just singled out by
18 EPA in its call for comments, is evidence of non-
19 linearity in the concentration response function
20 for many pollutants. The entire regulatory model
21 is precariously perched on an invalid assumption
22 of linearity and the resulting scientific crisis

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1 continuing to build must now be openly faced,
2 removed and regulations based on such science
3 malfunction, or even outright corruption, must be
4 revised and repealed entirely. EPA's new policy
5 of scientific integrity and transparency should be
6 applied to computer climate models that currently
7 prevail in EPA's funded published and cited
8 climate science. The continued use of default
9 models, not consideration of alternatives or model
10 uncertainty create a false scientific
11 justification for EPA actions, policies and
12 regulatory burdens.
13 So, we applaud this new proposed rule and
14 encourage the EPA to implement it rapidly.
15 MS. HUBBARD: Thank you.
16 MS. STOBERT: Speaker 41a, Liz Hitchcock, and
17 Speaker 42a, Benjamin Kirby, if you would come to
18 the speakers' table.
19 MS. HITCHCOCK: Good afternoon, my name is Liz
20 Hitchcock, and I direct Safer Chemicals Healthy
21 Families. We lead a coalition of hundreds of
22 local, state and national groups. This variety of

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1 groups of labor, consumer, parents, educators,
2 scientists, health care providers, health-affected
3 and others shares the concern about the growing
4 recognition of the links between our exposures to
5 toxic chemicals and the increases in cancers and
6 other chronic illnesses and in learning and
7 developmental disabilities, and we share a
8 commitment to reducing and eliminating exposures
9 to toxic chemicals in our homes, our places of
10 work, and the products that we use every day. I
11 thank the Agency for responding to the large
12 number of public comments that objected to the
13 length of the initial comment period by extending
14 it and for scheduling this hearing.
15 Safer Chemicals Healthy Families joins a long day
16 of voices in opposition to this proposal. Many of
17 our coalition partners and a number of respected
18 scientists have offered strong cases for
19 withdrawing the proposal already today and I thank
20 those speakers for their comments and will try to
21 keep my own comments brief.
22 The proposed rule is irreparably flawed and

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1 misconceived. In the name of transparency it will
2 prove needlessly burdensome, requiring unnecessary
3 and costly procedures of EPA scientists that are
4 counter to the Agency's longstanding application
5 to base public health decisions on the best
6 available science. Under this proposal without a
7 guarantee of full public access, the study will be
8 considered unreliable and will play no role in
9 assessing a chemical's health effects on human
10 health. This ignores the many ways in which the
11 scientific community, regulators and the public
12 have traditionally determined the quality and
13 relevance of study results. It also disregards
14 the way that hard-working EPA science
15 professionals have taken seriously their charge to
16 use the best available science in their decision-
17 making. Safer Chemicals Healthy Families played a
18 key role in the reform of the Toxic Substances
19 Control Act which requires that EPA use the best
20 available science in the review and management of
21 toxic chemicals. As EPA begins to review the tens
22 of thousands of chemicals already on the market we

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1 are concerned that they be able to take into
2 consideration all information that is reasonably
3 available. For the fence line communities that
4 have been harmed by their exposures to chemicals,
5 for the families who have lost loved ones to
6 asbestos-related diseases, for the firefighters
7 exposed to a soup of toxics as they protect our
8 communities, and to children who are born pre-
9 polluted by a range of industrial chemicals, the
10 stakes are high for these evaluations. EPA
11 scientists working on risk and hazard assessments
12 collect and review thousands of studies.
13 Published reports of these studies typically do
14 not include all the underlying data. This
15 proposal would add the burdensome requirement in
16 such cases that EPA contact the researcher,
17 determine the nature and extent of the underlying
18 data, and put in place a mechanism for the public
19 to access the data. Many before me have called
20 this proposal a solution in search of a problem,
21 but it bears repeating. In proposing this rule
22 EPA leaders have painted a stark picture of EPA

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1 reliance on so-called secret science developed
2 behind closed doors, but is this really so? EPA
3 science assessments generally include an
4 exhaustive and critical review of relevant studies
5 and a full explanation of how they are being
6 interpreted. Extensive information about each
7 study is typically part of the public record, even
8 if all underlying data may not be included. EPA
9 assessments are normally subject to public comment
10 and independent peer review and members of the
11 regulatory community are free at any time to
12 replicate studies they deem flawed or to
13 independently seek access to underlying data and
14 reanalyze them. In short, the so-called problem
15 that the proposed rule seeks to fix is largely
16 fiction.
17 In conclusion, EPA should withdraw this proposed
18 rule. The public health stakes are just too high.
19 Thank you.
20 MS. HUBBARD: Thank you.
21 MR. KIRBY: My name is Ben Kirby. I'm an
22 environmental engineer with a doctorate and

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1 master's degree in environmental engineering from
2 Virginia Tech and George Mason University
3 respectively. I'm representing Hall and
4 Associates, and environmental consulting firm in
5 Washington D.C. We support the application of
6 this rule to EPA's environmental impact analyses,
7 particularly TMDLs, or Total Maximum Daily Loads,
8 and NPDES or National Pollutant and Discharge
9 Elimination permits under the Clean Water Act.
10 These legally binding permits include ethylene
11 limits for wastewater treatment facilities for
12 pollutants such as lead, mercury or phosphorus.
13 Slight alterations in these permit limits can cost
14 a single wastewater facility tens of millions of
15 dollars, the cost of which is passed on to
16 individual local rate bearers. These permit
17 limits are supposed to be derived in a manner
18 similar to dose-response relationships as
19 mentioned in the rule where, for example, a lower
20 level of the pollutant in the discharge will
21 result in a measurable increase in receiving water
22 quality working with health. However, we have

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1 dealt with instances throughout the country where
2 environmental agencies have based regulations on
3 publically unavailable data, outdated science or
4 faulty science, even in the face of data or
5 studies which indicate stringent permit limits
6 imposed by these agencies are not anticipated to
7 result in any quantifiable environmental or human
8 health benefit despite the cost. We hope that
9 this rule would remedy these shortcomings.
10 We also strongly support the use of independent
11 expert peer reviews as an additional level of
12 review for fiscal regulatory science. Our firm
13 has been involved in independent peer reviews of
14 various Clean Water Act related EPA regulations
15 which have concluded that the technical basis for
16 EPA's regulations and permit limits were
17 scientifically indefensible. Had no peer reviews
18 occurred, these regulations would have imposed
19 hundreds of millions of dollars of wastewater
20 treatment costs to rate bearers with no
21 anticipated benefit. As a science-based Agency
22 applying science-based statutes it is critical to

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1 both receiving water quality and rate payers
2 throughout the country that these permits and
3 regulations are based on sound science and not
4 speculation.
5 In this regard, we support application of EPA's
6 proposed rule to Clean Water Act regulations.
7 Thank you for the opportunity to come.
8 MS. HUBBARD: Thank you.
9 MS. STOBERT: Speaker A, Dan Lipinski, you are now
10 invited to speak at either the table or the
11 podium.
12 MR. LIPINSKI: Good afternoon, I'm Congressman Dan
13 Lipinski of the Third District of Illinois. I'm
14 here to ask the EPA to rescind the proposed rule.
15 The origins of the rule are in the 2014 House Bill
16 called, the Secret Science Reform Act, which I
17 voted against in that year and again in 2015, and
18 when it was reintroduced as the Honest Act in
19 2017. The goal of these bills and of the proposed
20 rule, contrary to its name, is to limit
21 availability of science to inform regulatory
22 decision-making. I'm disappointed to see the

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1 Trump administration circumventing the will of
2 Congress, attempting to administratively implement
3 policies that cannot pass through the Legislature.
4 On June 7th of this year, I joined 102 of my
5 colleagues from both political parties in sending
6 a letter to then Administrator Pruitt urging him
7 to withdraw the proposed rule. My comments today
8 build on that earlier commentary and expand on my
9 opposition to this misguided policy.
10 EPA's admission, as it appears on the Agency
11 website, is to protect public health and the
12 environment and to ensure that national efforts to
13 reduce environmental risks are based on the best
14 available scientific information. The proposed
15 rule works in direct opposition to that mission by
16 requiring that the data underlying the scientific
17 studies used in informed regulatory actions are
18 available to the public. The proposed rule will
19 exclude vast quantities of valuable research
20 including that based on personal health data,
21 confidential business information, and even older
22 studies whose authors or data sets are no longer

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1 available. In some cases, the rule will require
2 the exclusion of the best available scientific
3 information. To make matters worse, this rule
4 would grant the administrator wide latitude to
5 exclude studies from its provisions, enabling him
6 or her to cherry pick studies in order to affect
7 the outcome on the rulemaking process. There is
8 no basis in any of the statutes under which EPA
9 operates for giving an administrator such broad
10 authority to choose which science is used in
11 rulemaking.
12 Let me give an example of how the proposed rule
13 could affect a future EPA rulemaking. EPA is
14 planning to update its lead and copper rule in the
15 near future the rule that limits the levels of
16 these metals in drinking water. This update
17 cannot come soon enough. We all know about the
18 drinking water crisis in Flint, Michigan. Chicago
19 and Washington D.C., as well as many other cities
20 around the country, are finding troubling levels
21 of lead in drinking water right now. Most of what
22 we know about the health effects of lead exposure

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1 comes from older studies of children with high
2 levels of lead in their blood. Yet these studies
3 may be excluded from consideration, both because
4 their data are not publically available and
5 because it would be unethical to replicate them.
6 As a result, it is possible that an Agency could
7 conclude that there is no evidence that lead is
8 bad for you and, therefore, does not need to be
9 updated. This would be a tremendous mistake. I
10 have spent my career in Congress working to enable
11 science-based decision-making in government. The
12 proposed rule represents a significant step
13 backward and I urge the Agency, in the strongest
14 terms possible, to rescind it. Thank you.
15 MS. STOBERT: Speaker 43a, Mahealani Daniels. If
16 you'd come to the speakers table.
17 MS. DANIELS: Good afternoon. My name is
18 Mahealani Daniels and I'll spell that M-A-H-E-A-
19 L-A-N-I, D-A-N-I-E-L-S. I would just like to
20 thank you for allowing me the opportunity to share
21 my comments in opposition to the EPA's new policy
22 on so-called transparency. The EPA must utilize

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1 the best available science to inform its actions
2 in the creation of environmental and public health
3 laws. Judicial precedents establish that the best
4 available science is all existing scientist
5 evidence relevant to the decision. In further
6 supporting these precedents, the EPA's own
7 regulations state that the best available science
8 would be information that the EPA possesses or
9 could reasonably generate, obtain or synthesize,
10 whether or not that be information that is
11 confidential business information that is
12 protected from public discourse. While increasing
13 transparency and ending an era of secrete science
14 are two statements that publically resonate as
15 appealing advances, when digging deeper it is
16 clear that the EPA's implementation of these
17 standards would do just the opposite and would
18 actually violate judicial precedent as well as the
19 Agency's own regulations. A majority of
20 confidential health data can't be used with the
21 EPA's new standards of transparency, thus limiting
22 the scientific evidence they could use to inform

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1 studies and standards. Since personal health data
2 informs the production of environmental laws that
3 protect public health, it's exceptionally
4 important that the EPA continues to use it.
5 For example, a recent study released by MIT
6 demonstrates that 200,000 early deaths occur every
7 year in the United States as a result of air
8 pollution. Utilizing data on patients' health is
9 not only necessary to establish the aforementioned
10 research, but is also necessary when the EPA goes
11 to set standards on environmental and pollution
12 regulations that affect the lives and health of
13 millions of Americans. I am hopeful that just as
14 a majority of Americans are guided by their own
15 personal values to abide by the laws established
16 by our government, the EPA will too decide to
17 function under judicial precedents and be guided
18 by its principle to utilize the best available
19 science. And with that, I thank you so much for
20 your time.
21 MS. STOBERT: Thank you. I believe that was the
22 last speaker for this session, so we will recess

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now and resume the hearing at 4:00 p.m. Thank you.
[Off the record 3:26 p.m.]
[On the record 4:00 p.m., Evening session. Substitution of panel members.]
MR. RODAN: Okay, so welcome back at 4:00. Let us commence session three of this public hearing. Hello and thank you for coming. This public hearing is now in session. My name is Bruce Rodan and I am in EPA's Office of Research and Development. I will be one of the hearing officials of this two-hour period. Lou D'Amico, also from the Office of Research and Development will be joining me. We also have Nanishka, Lauren and Lesley from SC&A Incorporated helping with logistics.
The purpose of today's hearing is to accept public comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science." EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding and the testimonies will become part of

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the administrative record on which EPA will base its decision. Public notice of this hearing was published in the Federal Register on April 30, 2018 (83 FR 18768). EPA is proposing this rule under authority of 5 U.S. Code 301 in addition to the authorities listed in the proposed rule document dated April 30, 2018.
My role is to ensure that the EPA received your comments in an orderly fashion. Although EPA panel members may ask clarifying questions the intent of this hearing is to listen to your comments, not to discuss or debate the proposal.
Now for a few housekeeping items and ground rules. Please refrain from interrupting speakers or asking questions. Shouting and noisemaking or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately and listeners on the phone hear the oral testimonies.
For everyone's awareness, this hearing is open to

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the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio and photos. We ask that you not cause any disruption to those testifying or observing the hearing. There was no formal lunch break scheduled. You may leave and return to the hearing. Please note that you will need to clear security again, so please be aware of time and the rain outside. If you'd like to make an oral comment in today's hearing and did not pre-register to speak, please see the hearing staff at the registration table positioned at the entrance of the room. If you would like to provide a written comment to the official record, you may hand submit it to the EPA staff today or mail, fax or email your comment. See staff at the registration table for instructions on how to submit written comments. There is a comment box at the registration table where you can leave hard copies of your oral testimony or written comments. All comments received will be included in the official docket. If you submit written comments

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it is not necessary for you to give the same comments orally. Written comments and oral testimonies will receive equal consideration by EPA in preparing the final rulemaking decision. EPA has extended the comment period. Written comments must have been received on or before August 16, 2018. EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science," so please refrain from making comments that are not related to this action. EPA will not provide responses during the hearing, rather EPA will prepare a written summary of the comments received that includes responses. The Response to Comments, RTC, document will be available at the time EPA issues its final decision. EPA will not make a final decision until all comments submitted during the public comment period have been considered.
The hearing is being recorded by a court reporter who will be preparing a verbatim record of the hearing. Please speak clearly and slowly into the microphone so that the court reporter can record

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your comments accurately. A copy of the transcript will be placed in the docket. The hearing is also being audio streamed through Adobe Connect and via phone lines.

The hearing is scheduled from 8:00 a.m. to 8:00 p.m., or one hour after the last registered speaker has spoken, whichever is earlier, and is divided into three sessions: 8:00 a.m. to 12:00 p.m., 12:00 p.m. to 4:00 p.m., and this session 4:00 p.m. to 8:00 p.m. Public restrooms are located down both sides of the hall and we have staff to escort you. Please note the location of the emergency exits.

Please take a moment to silence your cell phone (I've done that). Speakers should have been given a sticker upon check-in that lists your assigned session. If you plan to speak and have not received a sticker, please be sure to check in at the registration table. For the current 4:00 p.m. to 8:00 p.m. session, the speaker sticker collar is blue. Speakers will be called to the speakers' table located directly across from the EPA panel

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members' table in pairs by their speaker number. When it is your turn to speak, please come up to the table and watch your step. State and slowly spell your name for the record, and if you are appearing on behalf of someone or an organization. If you are not in the room when it is your turn to speak I will recall you after all other speakers have made their oral comments. Each speaker will be allotted five minutes for remarks. Elected and appointed government officials may be provided additional time since they represent large groups of constituents. Speakers will be notified when their time has ended. Our timekeeping system or speaker timer consists of green, yellow and red lights. When you begin to speak, the green light will come on to indicate you have five minutes to speak. The yellow light indicates that you have one-minute left to speak. When the red light appears your five minutes are over. At that moment, if needed, I will politely interrupt you and ask you to wrap up your testimony. So, let's begin.

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Speakers Numbers 1 and 2 in the afternoon session, please come forward and take a seat at the speakers' table. We will start with Speaker Number 1. Again, please speak directly into the microphone and state and spell your name for the record.

MR. SHIPPS: Thank you for this opportunity to provide public comments on EPA's proposed rule, "Strengthening Transparency in Regulatory Science." My name is Karl Shipps. That's spelled K-A-R-L, S-H-I-P-P-S. I live in New Carleton, Maryland, and I'm speaking as an individual. I am not employed by EPA or an EPA contractor, I am simply a very concerned person. I am a Navy submarine veteran, a grandfather, and have a master's degree in applied physics from the Johns Hopkins University. Because my time is limited I will confine my remarks today to three observations about the proposed rule and two recommendations.

My first observation is this: The proposed rule is based on a faulty premise, namely that only

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studies whose underlying data are publically available sufficient to support replication should be considered by EPA as it develops regulations governing clean air, clean water and exposure to toxic substances and pesticides. The rule's premise, which was also the premise of the Secret Science Reform Act and the Honest Act, cannot stand. There are valid peer-reviewed studies that should be included in EPA's regulatory work even though their underlying data sets cannot be released to the public. Two of the most widely known are the Harvard School of Health's Six Cities Study, and the American Cancer Society's Cancer Prevention Study II. Those studies were revalidated by the Health Effects Institute in July of 2000 using an independent oversight board and a competitively selected analysis team. They remain valuable today. Since the proposed rule is based on a faulty premise, I recommend that it be withdrawn. A new rule addressing concerns about reproducibility and replicability should be developed in public with participation by the

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1 scientific community, the environmental community
2 and industry. The rule developers should avail
3 themselves of the results of the ongoing
4 reproducibility and replicability study being
5 conducted by the National Academies of Sciences.
6 That study will report in December 2018.
7 Perhaps the EPA will not take my recommendation to
8 withdraw the proposed rule. In that event, my
9 second observation is germane. My second
10 observation is that the EPA administrator is given
11 extraordinary powers under Section 30.9 of the
12 proposed rule for new EPA regulations or for
13 regulations undergoing periodic update, the
14 administrator could waive or not waive the
15 provisions of the rule. This puts potentially
16 thousands of studies underpinning EPA's
17 regulations at risk of being discarded out of hand
18 at the administrator's whim. The result would not
19 be the best science and it would reduce public
20 confidence in EPA rulemaking, not increase it.
21 Based on that prospect, I recommend what the Texas
22 Commission on Environmental Quality recommended,

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1 namely to give governing authority for granting
2 exceptions to the proposed data Transparency Rule,
3 as well as the oversight of raw data collection,
4 storage and access, to an external entity or
5 entities to ensure independence and objectivity.
6 You can see Docket comment EPA-HQ-OA-2018-0259-
7 2426.
8 My final observation is that the scientific
9 community was not consulted as the proposed rule
10 was prepared. Even EPA's own Science Advisory
11 Board was not consulted, learning about the rule
12 only through press accounts and publication in the
13 Federal Register. The joint statement on the EPA
14 proposed rule and public availability of data in
15 the 30 April edition of Science disagrees with the
16 proposed rule. EPA should heed the concerns being
17 voiced by the scientific community. Thank you for
18 your attention.
19 MS. WHITE: Good afternoon. My name is Dr. White,
20 W-H-I-T-E, on behalf of the American Chemistry
21 Council's Formaldehyde Panel. I appreciate the
22 opportunity to provide feedback on EPA's proposed

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1 rulemaking. Utilization of transparent, objective
2 and modern scientific approaches to draw
3 conclusions regarding human health risks is
4 critical to developing sound regulatory decisions.
5 Throughout the EPA the application of scientific
6 information to underpin regulatory activities has
7 often been inconsistent and unclear, leading to
8 concerns regarding how the Agency incorporates the
9 best available science, evaluates the quality of
10 that science, and applies 21st century knowledge
11 concerning cause and effect. The panel has
12 regularly met with EPA scientists related to the
13 IRIS program regarding its subjective use of
14 available science and resistance to moving away
15 from default linear low-dose extrapolations, even
16 when published scientific data support other
17 modeling alternatives, including threshold-based
18 approaches. This stance has often led to the
19 generation of EPA values that are below natural
20 background levels and not indicative of human
21 health risks associated with real world exposures.
22 Perhaps the most telling example can be found in

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1 the case of formaldehyde, where a draft IRIS
2 assessment sets values suggesting that human
3 breath could pose a cancer risk. Formaldehyde has
4 been the subject of scientific study for years and
5 large bodies of evidence show that the levels of
6 formaldehyde most people encounter on a daily
7 basis do not cause adverse health effects, a
8 conclusion reached by several international
9 agencies using alternative models other than a
10 default linear modeling approach. The evidence
11 demonstrates the biological implausibility of any
12 relationship between formaldehyde and leukemia, a
13 threshold mode of action for any potential adverse
14 health effects, and the importance of mode of
15 action information for understanding potential
16 impacts. We are encouraged by the Agency's
17 proposed rule's recognition that there is growing
18 empirical evidence of nonlinearity and that the
19 use of default models without consideration of
20 alternatives can obscure the scientific
21 justification for EPA actions. This
22 acknowledgement by EPA is especially relevant to

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1 formaldehyde given the several decades of
2 published literature illustrating preserved
3 thresholds for both noncancerous and cancerous
4 status.
5 In addition to the significant research and the
6 development of a biologically-based dose response
7 model for formaldehyde that also integrates the
8 available science and provides results
9 inconsistent with default linear dose response
10 modeling approaches typically apply for
11 carcinogenic end points. The importance of using
12 nonlinear and biologically based dose response
13 modeling, when the published data supports it,
14 cannot be overstated. In this review of a 2010
15 draft IRIS formaldehyde assessment, the National
16 Academy of Sciences noted the development of
17 several models to evaluate the risks associated
18 with formaldehyde exposure and recommended that
19 alternatives to EPA's default linear low-dose
20 extrapolation approach be considered.
21 In addition to incorporating modern scientific
22 knowledge, we also recognize the importance of

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1 adequate transparency in data access and ensuring
2 regulatory decisions are based on high quality and
3 reproducible data. For more than a decade, the
4 panel has conducted scientific research engaged
5 directly with EPA's IRIS program to understand the
6 scientific information being relied on to draw
7 conclusions regarding potential for health
8 effects. The panel has experienced considerable
9 difficulty in understanding what data is being
10 relied on and how the Agency has ensured the
11 highest quality and most relevant science is
12 informing its decisions. Importantly, in multiple
13 instances, sometimes after years of requests, once
14 the underlying data was made available, it was
15 found to have significant methodological and
16 quality issues. In several cases, the findings,
17 when reevaluated, did not support the original
18 study's conclusions. The issues identified were
19 not minor and highlight the need for greater
20 transparency and for EPA to have a mechanism in
21 place to evaluate the quality and reproducibility
22 of the data being relied upon for decisions.

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1 One notable example involved over six years of
2 repeated requests to access all the relevant data
3 from a National Cancer Institute study which was
4 relied upon by the IRIS program to draw
5 conclusions regarding formaldehyde and leukemia.
6 The data were requested from NCI for the purpose
7 of validating the author's conclusions and the
8 evaluation of that underlying data found that
9 changes reported by the study authors were not
10 exposure dependent and they did not follow their
11 own stated protocol. As demonstrated by
12 formaldehyde example, when the data access is
13 limited and modern scientific approaches aren't
14 used to move away from default assumptions, the
15 results can be conclusions that lack scientific
16 rigor and potentially provide the public with an
17 inaccurate picture about everyday chemicals which
18 have been used safely for years.
19 I hope that you find these comments useful and I
20 will provide a detailed set of comments by the
21 August deadline.
22 MR. RODAN: Thank you. I believe we have another

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1 speaker.
2 MS. HALL: Right, I don't have any details on that
3 yet.
4 MR. RODAN: What?
5 MS. HALL: I don't have any details on who it is
6 or -- standby. Speaker 3, Walter Tsou, please
7 come up to the speakers' table.
8 MR. RODAN: Around the far side. Take care of the
9 wire. I think you provided a copy at the front
10 desk, we'll take it here. Watch out for the cord
11 there, we don't want you falling over. Okay, so,
12 we went through some long instructions. You have
13 five minutes.
14 MR. TSOU: Okay. I'll be less. My name is Dr.
15 Walter Tsou. I serve as Executive Director of
16 Philadelphia Physicians for Social Responsibility
17 and a past president of the American Public Health
18 Association. Thank you for this opportunity to
19 testify on "Strengthening Transparency in
20 Regulatory Science". As many of my colleagues
21 have noted today, while the goal of transparency
22 in how studies are conducted, and the ability to

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1 reproduce scientific results are important, it can
2 offer a politically motivated administration a
3 convenient excuse for eliminating or ignoring
4 scientific studies that may go against the wishes
5 of a powerful industry group. All one has to do is
6 demand that the data sets be handed over for
7 "further scrutiny" or demand that the study be
8 repeated before basing a regulation on the study
9 in question.
10 The very nature of longitudinal public health
11 studies where health and toxins intersect are, by
12 design, large, expensive and require years or
13 sometimes decades before results are found. Sample
14 sizes can often number in the tens of thousands to
15 millions of data points and may need to be
16 collected over many years before a statistically
17 significant finding is identified. For example,
18 Curry, et al studied in Pennsylvania babies who
19 lived within 1 kilometer of active fracking wells.
20 She had to review over 1.1 million birth records
21 before demonstrating the relationship between
22 living close to gas wells and low birth weight

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1 babies. Because these studies are so big, they are
2 often too expensive to repeat. In our state of
3 Pennsylvania, scientific research on fracking is
4 actively stymied or suppressed. In a state where
5 billions are made on gas drilling, only one part
6 time contractor at the Health Department collects
7 data on health complaints from fracking. Those who
8 do have health complaints have to sign non-
9 disclosure agreements and not cooperate with any
10 research in order to get lifesaving water to
11 drink. This I consider extortion and this practice
12 is common in the industry in order to suppress any
13 health studies on the dangers of fracking. If the
14 transparency regulation was in place, all health
15 studies on fracking would be simply not considered
16 because the research could not be conducted due to
17 non-disclosure agreements.
18 Today there is no reputable scientist that doesn't
19 believe in the harmful effects of smoking. The
20 health studies on smoking were 15 years in the
21 making before the Surgeon General released his
22 landmark 1964 report and except for a handful of

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1 EPA administrators, there is no reputable
2 scientist who doesn't believe that climate change
3 is real and is man-made. The studies on climate
4 change and health have been known since Exxon
5 wrote about it in 1977. If these transparency
6 rules were in place when the EPA was founded,
7 smoking would still be in airplanes and no one
8 would have heard of "greenhouse gases" or "global
9 warming", the greatest threat to our planet's
10 existence.
11 Since the founding of the EPA, independent
12 scientific research has been the foundational
13 basis of your mission. Science is the cross
14 before the corporate devil. This Transparency Rule
15 would destroy the confidential nature of research
16 and make the burden of conducting research more
17 difficult and expensive. Finally, the real purpose
18 of these rules is to reverse regulations on
19 industries who have been harmful to public health.
20 We should let science speak for itself and speak
21 the truth and the EPA should hear from all
22 scientific studies, not just the ones the industry

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1 wants you to listen to. Thank you for your time.
2 MR. RODAN: Thank you very much. So, do we have
3 any other registered speakers waiting? So we'll
4 have a short recess and we have a one hour clock
5 ticking. The time now is 4:22.
6 [Off the record 4:22 p.m.]
7 [On the record 4:40 p.m.]
8 MR. RODAN: We are hereby reconvening this public
9 hearing. Come up to the -- go to the right there,
10 there's some steps.
11 MS. HALL: Speaker Number 4, Mark Mitchell.
12 MR. BRUCE RODAN: Thank you, you'll have five
13 minutes of time and you'll get a green light for
14 the first four, an orange light and then a red
15 light when the five minutes is up.
16 MR. MITCHELL: Okay, thank you. Thank you for
17 this hearing. My name is Mark Mitchell. I'm a
18 public health trained environmental health
19 physician. I am testifying on behalf of the
20 National Medical Association which represents the
21 interests of more than 30,000 African-American
22 physicians and our patients. We are a member

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1 society of the Medical Society Consortium on
2 Climate and Health.
3 I got into environmental health because I was
4 concerned about the health effects of environment
5 on public health. As a public health official, I
6 saw that a lot of the diseases that are common,
7 particularly those that are common in communities
8 of color, are associated with the environment. We
9 are opposed to the misnamed proposed new rule on
10 "Strengthening Transparency in Regulatory
11 Science." The proposed rule prohibits the Agency
12 from setting regulations that are supported in
13 part or in whole by data that is not publically
14 available for reanalysis or that cannot be
15 replicated. This rule, if enacted would limit the
16 consideration of perfectly good science in the EPA
17 regulatory process. What's more, it's retroactive
18 so the current regulations that are based on
19 previous studies that can no longer be replicated
20 for ethical or other reasons, could then be
21 voided. As physicians, we are particularly
22 concerned about our legal and ethical obligation

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1 to protect patient privacy under the Health
2 Insurance Portability and Accountability Act of
3 1996, otherwise known as HIPAA. We believe that
4 patient health data should be considered in EPA
5 regulations because it's necessary to consider the
6 health effects of environmental exposures in order
7 to protect human health, and that we should also
8 be able to guarantee patient privacy that should
9 be protected.
10 Currently, we do this in research publications
11 through the peer review process. The peer review
12 process has worked well to ensure an adequate
13 level of transparency while allowing science to
14 advance unencumbered. We do not need to reduce
15 the health protection that environmental
16 regulations provide in the name of so-called
17 "transparency." Thank you for this opportunity to
18 testify.
19 MR. RODAN: Thank you. So, we'll go into another
20 short recess, or maybe an hour, at 4:44. Thank
21 you.
22 [Off the record 4:44 p.m.]

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1 [Off the record 5:44 p.m.]
2 MR. RODAN: It's 5:44. I'll read the closing
3 statement. Thank you for taking the time today to
4 share your comments on the EPA proposed rule. The
5 time is now 5:45 p.m. No additional members of
6 the public have registered or are waiting to
7 speak. Therefore, this hearing is now officially
8 closed. Thank you.
9 [Off the record 5:45 p.m.]
10 Whereupon, the above-entitled matter is concluded.
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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
2
3 I, NaCorey Nichols, the officer before whom the
4 foregoing deposition was taken, do hereby certify
5 that the foregoing transcript is a true and
6 correct record of the testimony given; that the
7 witness was duly sworn by me; that said testimony
8 was taken by me electronically and thereafter
9 reduced to typewriting under my direction; and
10 that I am neither counsel for, related to, nor
11 employed by any of the parties to this case, and
12 have no interest, financial or otherwise, in its
13 outcome.
14 IN WITNESS WHEREOF, I have hereunto set my hand
15 and affixed my notarial seal this
16 30th day of July, 2018.
17
18 My commission expires:
19 October 14, 2021
20 NOTARY PUBLIC IN AND FOR THE
21 DISTRICT OF COLUMBIA
22 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Gary Euell, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that the witness was duly sworn by me; that said testimony was taken by me electronically and thereafter reduced to typewriting under my direction; and that I am neither counsel for, related to, nor employed by any of the parties to this case, and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 30th day of July, 2018.

My commission expires:
March 14, 2023
NOTARY PUBLIC IN AND FOR THE
DISTRICT OF COLUMBIA

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Attachment 3

Comments on EPA Proposed Rule –
Strengthening Transparency in Regulatory Science
Prepared by Pamela Miller, Executive Director, Alaska Community Action on Toxics
July 17, 2018

Good afternoon. My name is Pamela Miller. I serve as Executive Director and provide these comments on behalf of Alaska Community Action on Toxics (ACAT), a non-profit public interest environmental health research and advocacy organization dedicated to protecting public health. I also serve as a principal investigator of multi-year research studies involving several universities that investigate exposures and health outcomes concerning endocrine-disrupting chemicals in collaboration with Arctic Indigenous communities in Alaska. I traveled the distance to Washington DC from St Lawrence Island, Alaska in the northern Bering Sea (two full days of travel) where we are conducting summer field research and interrupted this because EPA did not make it possible to provide remote testimony.

Through a process known as global distillation, the Arctic has become a hemispheric sink for contaminants that are carried on atmospheric and oceanic currents into the north where they concentrate in the bodies of fish, wildlife, and people. Indigenous peoples of the Arctic are among the most highly exposed populations on earth to persistent, bioaccumulative and toxic chemicals because of their reliance on traditional foods, including fish and marine mammals, for their spiritual, cultural, and physical sustenance. The communities that I work with on St. Lawrence Island also have higher exposures to harmful chemicals from military operations associated with formerly used defense sites.

Our research elucidates exposure pathways, body burdens, and health outcomes associated with chemicals, including PCBs, PBDEs and other flame retardants, and PFAS, in homes, in air, water, traditional foods, and in blood serum of the Yupik people of St. Lawrence Island. Our studies have shown elevated body burdens, as well as disruption of thyroid function associated with exposure to certain PBDEs and PFAS chemicals. We are now beginning a research study to investigate exposures to PCBs, PBDEs, and currently used organophosphate flame retardants in young Yupik children because elders and other community leaders are concerned about possible adverse effects on the children's neurodevelopment. They are concerned that chemical exposures might harm the children's abilities to learn the language, songs, and stories that are so vital to the culture of the Yupik people.

Our research team submits each proposal to a rigorous review by the NIEHS. In the process of this research, we submit to several Institutional Review Boards for approval to collect sensitive and detailed information on health and behavior, as well as spatial, and

demographic data in an ethical manner that protects human subjects. We have published results of our research in eleven peer-reviewed journal articles after receiving approval from the tribal leadership. These findings help inform interventions and policies to reduce burdens of toxic exposures and prevent further harm to public health.

These studies are possible only because we guarantee to protect the medical privacy of participants. We gather detailed information about peoples' health and occupational histories, practices in their homes and communities that might relate to chemical exposures. If the EPA proposed rule were to go into effect, studies such as these would not be considered by EPA when it makes decisions about chemicals and pollutants that are poisoning the people of the Arctic, such as decisions to limit the production and use of persistent bioaccumulative toxics and other chemicals, including those regulated under TSCA and FIFRA; and in regulations that hold military and industrial polluters responsible for contamination of air, waters, and lands under CERCLA, the Clean Air Act, and Clean Water Act.

EPA indicates that the proposed rule is intended to strengthen transparency of EPA regulatory science, however we find this a duplicitous claim. It would favor industry data protected as confidential business information over public peer-reviewed research. We support the best scientific evidence to inform regulatory decisions. This rule would have a dangerous counter effect by limiting the science that should be used to inform decisions about public health. Furthermore, we disagree with the agency's conclusion as stated in the proposed rule document that this action does not have tribal implications as specified in Executive Order 13175 and requiring government to government consultation with tribes. This rule would disproportionately affect vulnerable populations, including American Indian and Alaska Native people and therefore is relevant and requires consultation.

Because the process and fundamental premises of the proposed rule are fundamentally flawed, EPA should end this rule-making promptly, withdraw the proposal, and base its decisions on the best available science as recommended in the letter by scientists and health professionals associated with Project TENDR and EPA's own Scientific Advisory Board.

Thank you for your consideration of my comments today.

Attachment 4

The Farmworker Association of Florida
La Asociación Campesina
Asosiyasyon Travayè Latè

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(407)886-5151 phone • (407)884-6644 fax
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August 16, 2018

Acting Administrator Andrew Wheeler &
Office of the Science Advisor
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: EPA-HQ-OA-2018-0259

Dear Acting Administrator Wheeler and Office of the Science Advisor:

The Farmworker Association of Florida (FWAF) is submitting these comments on what has been called the Strengthening Transparency in Regulatory Science proposed rule on behalf of our over 10,000 farmworker and rural community members in Florida and the estimated 150,000-200,000 famworkers in our state. Farmworkers harvest the food that feeds this nation. They risk exposure to toxic pesticides every day that they are in the fields where these pesticides are applied and where residues remain on the plants they touch and can contaminate the ground, drinking water and can be carried into living spaces on clothes and shoes. The men, women and children who perform this necessary and life-sustaining work deserve the strongest protections possible against threats to their health and well-being, yet, they are often victims of policies and practices of environmental injustice. That is why the role of the EPA in protecting farmworkers is absolutely critical to their lives and the lives of their children.

Rather than strengthening transparency, the proposed rule would limit or eliminate the very significant scientific studies that are crucial in reasoned EPA decision-making for protecting environmental and human health. Epidemiological studies produce vital and valid scientific information that is necessary to determine impacts on humans of various types of occupational and environmental exposures. Without these studies, real world impacts on individuals and communities would not be captured, and important data that could affect hundreds and thousands of people would be lost.

The Farmworker Association has engaged, for close to two decades, in various studies with academic institutions to conduct scientific research on health and safety risks to farmworkers from the conditions of their employment, including from pesticide exposure. We conduct these community-based studies by pairing the collaboration of researchers at the universities with community health workers and staff in our organization. The studies work, because the community has confidence and trust in our organization, and they see the benefit to themselves and their communities by participating in these studies. They also agree to participate, because they are guaranteed that their information will remain

anonymous, so that they do not risk retaliation for participating. Without that guarantee of anonymity, we would not have their cooperation to engage in this work.

Not only are the studies of significant importance to the overall body of scientific knowledge, but the information learned is shared with and given back to the communities in the form of community meetings and presentations and in popular education trainings that can be both protective and preventative in the information they convey. Basically, the studies provide information that the community can use to be safer in the workplace and to protect their family's health.

As an organization with a 35-year history of working in, with and for the farmworkers in Florida, we value, respect, and honor the trust that the community has in us. We are committed to maintaining that level of trust, as we understand the everyday realities that farmworkers face. Protecting people's identities is an important aspect of that trust, without which nothing can be accomplished. The "transparency" that is the basis for this rule would virtually undermine any studies that look at real world environmental health impacts to the people we work with every day. If that is the intent of this rule, then, the EPA is not living up to its mission of protecting environmental and human health.

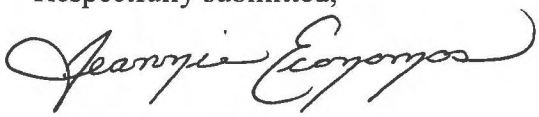
In proposing this rule, EPA is essentially discounting the scientific expertise, knowledge, experience, and integrity of tens of thousands of researchers around the country that engage in epidemiological research. The rule is also an attempt to invalidate the decades of research that has led to health protective regulation. Labeling the rule as enhancing transparency is a misnomer, and the public needs more transparency from EPA as to the underlying reasons the Agency is making this proposal.

The Farmworker Association of Florida is a statewide, grassroots, community-based, non-profit organization that works on issues of social and environmental justice for farmworkers in Florida and around the country.

We are in opposition to this proposed rule for the reasons stated above.

This is a public health issue. This is a justice issue.

Respectfully submitted,



Jeannie Economos
Pesticide Safety and
Environmental Health Project Coordinator

Attachment 6

COMMENTS SUBMITTED TO ENVIRONMENTAL PROTECTION AGENCY

Air Alliance Houston, Alaska Community Action on Toxics, American Bottom Conservancy, California Communities Against Toxics, California Safe Schools, The City Project, Community In-Power and Development Association, Deep South Center for Environmental Justice, Del Amo Action Committee, Downwinders At Risk, Earthjustice, Ironbound Community Corporation, Louisiana Bucket Brigade, Louisiana Environmental Action Network, Los Jardines Institute, Lower Mississippi Riverkeeper, Missouri Coalition for the Environment, Natural Resources Defense Council, Neighbors for Clean Air, New Mexico Environmental Law Center, North Carolina Environmental Justice Network, Oak Grove Neighborhood Association, Poverty & Race Research Action Council, Public Interest Law Center of Philadelphia, Royal Oak Concerned Citizens Association, Rural Empowerment Association for Community Help, Sierra Club, Southern Environmental Law Center, West End Revitalization Association

To: Office of the Science Advisor, U.S. Environmental Protection Agency
Cc: Bob Perciasepe, Acting Administrator, U.S. EPA
Re: Notice, Request for Information and Citations on Methods for Cumulative Risk Assessment, EPA-HQ-ORD-2013-0292; FRL-9807-5, 78 Fed. Reg. 25,440 (May 1, 2013)
Date: June 28, 2013 (Submitted via e-mail and regulations.gov)

SUMMARY

The dire reality is that environmental hazards affect some communities much more than others. Pollution and polluting sources are often concentrated together, overburdening and overwhelming communities and populations, and causing greater health effects.[1] Current risk assessment practices, which have failed to keep up with current science and do not account for real-world impacts, jeopardize the health of communities surrounded by sources of pollution – such as coal plants, refineries, cement kilns, chemical plants, metal smelters, incinerators, dry cleaners, highways, truck routes, Superfund and other hazardous waste sites.

In order to fulfill the agency's renewed commitment to environmental justice, as outlined in Plan EJ 2014 and the recommendations from the National Academy of Sciences, National Research Council, EPA must update its approach to account for the cumulative impacts and risks faced from early-in-life exposure (including childhood) and from exposure to multiple sources, as well as the increased vulnerability from socioeconomic stressors, and multiple pollutant and

[1] Cal. EPA, Office of Envtl. Health Hazard Assessment ("OEHHA"), "Cumulative Impacts: Building a Scientific Foundation" (Dec. 31, 2010), http://oehha.ca.gov/ej/pdf/CIReport123110.pdf (citing numerous research studies showing that exposure to pollution-emitting facilities, hazardous waste facilities and disposal, toxic releases, non-attainment air areas, high motor vehicle air pollution areas, and other types of pollution is more likely to be concentrated in communities with higher minority and lower income populations).

pathway exposures.[2] To this end, we urge the Risk Assessment Forum Technical Panel to do the following:

Incorporate the real-world experience and perspective of people who live in communities that are overburdened by pollution and other environmental hazards.

Too many communities of color and lower income communities are exposed to a disproportionate share of air pollution and all of the resulting health risks and impacts. We have attached statements that summarize the situation and provide stories from various example communities around the United States that describe the on-the-ground impact of EPA's scientific policy decisions and the urgency of reforms in risk assessment practices. (Appendix E)

Advance environmental justice and protect public health by establishing guidance which provides a means to reduce cumulative impacts in overburdened communities.

There is clear and mounting evidence that the concentration of environmental hazards in lower income communities and communities of color threatens public health and that current risk assessment practices contribute to environmental inequities and increase disparities. Experts have identified addressing cumulative impacts as a critical step to ensuring environmental justice and reducing disparities. At minimum, this must include:

(1) Immediately updating existing guidelines for conducting risk-based assessments to incorporate mechanisms for accounting for the cumulative impacts of multiple exposures and underlying vulnerabilities;

and

(2) Moving beyond current risk frameworks and incorporating alternate methods to assess health threats from environmental exposures in a way that will better capture the impacts faced by overburdened communities and support policies to reduce them.

We appreciate your time and careful consideration of all of these issues, and we urge you to show strong leadership and issue up-to-date guidance without delay so that EPA actions will finally reflect the best available science. Commenters also urge EPA to consider and incorporate the feedback of affected communities and of experts in the field, including the work of those cited in these comments, into EPA's effort.

For more information on the issues discussed in these comments, please contact: Miriam Rotkin-Ellman, Senior Scientist, Natural Resources Defense Council (mrotkinellman@nrdc.org), Emma Cheuse, Senior Associate Attorney, Earthjustice (echeuse@earthjustice.org), and Marianne Engelman Lado, Staff Attorney, Environmental Health Group, Earthjustice (mengelmanlado@earthjustice.org).

[2] EPA, Plan EJ 2014, http://www.epa.gov/compliance/ej/plan-ej/.

I. TO ADVANCE ENVIRONMENTAL JUSTICE, EPA MUST REDUCE CUMULATIVE IMPACTS IN OVERBURDENED COMMUNITIES.

The concentration of environmental hazards in lower income communities and communities of color threatens public health and results in disparities.

The scientific data show that environmental hazards affect some communities much more than others. Pollution and polluting sources are often concentrated together, overburdening and overwhelming communities and populations, and causing greater health effects.[3]

These same communities – with many polluting sources and toxic sites – are often cities, towns, or neighborhoods that have higher numbers of people of color and people with lower income than the national average (or city or state averages).[4] A growing body of scientific research shows that communities with significant populations of people of color and lower income people are more exposed to environmental hazards and face greater harm from exposure. This is because pollution exposures can combine, increasing the harm, and also can have a synergistic effect with other health stressors in people's daily lives.[5] As scientists have explained, these communities often have higher levels of biological susceptibility (such as due to higher rates of pre-existing health conditions like obesity, cardiovascular disease, diabetes, and certain kinds of cancer). They also have increased social vulnerability to environmental hazards because of their greater likelihood and duration of exposure to pollutants and other kinds of stress.[6]

These communities and populations often have less access to quality, affordable health care which only exacerbates the impacts of environmental hazards. Health problems in many communities are closely associated with both social and environmental factors – including adverse perinatal outcomes like prematurity and low birth-weight, cardiovascular disease, and self-rated health.[7] Socioeconomic disparities thus exacerbate the effects of environmental hazards.

Current risk assessment practices contribute to environmental inequities and increase disparities.

Although EPA has made strides in reducing pollution and the health threats caused by environmental contaminants, these benefits have not been equally distributed. Multiple research studies and EPA investigations have found increased pollution and contaminant burden in lower

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[3] Cal. EPA, OEHHA, "Cumulative Impacts," *supra* (citing numerous research studies showing that exposure to pollution-emitting facilities, hazardous waste facilities and disposal, toxic releases, non-attainment air areas, high motor vehicle air pollution areas, and other types of pollution is more likely to be concentrated in communities with higher minority and lower income populations).
[4] Rachel Morello-Frosch, Zuk, Jerrett, Shamasunder & Kyle, *Understanding The Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, 30(5) Health Affairs 879, 881 nn.24-26 (2011) (citing sources).
[5] *See, e.g.*, *id*. at 879 (citing Clougherty J. & Kubzansky L., *A Framework for Examining Social Stress and Susceptibility in Air Pollution and Respiratory Health*, 117(9) Environ. Health Perspect. 1351 (2009)).
[6] *Id*. at 881-82.
[7] *Id*. at 880.

income communities and communities of color that contribute to poor health outcomes. Risk assessments conducted by EPA as part of establishing regulations and implementing policies help determine the contaminant burden in these communities. EPA's failure to incorporate the current science on the impacts of cumulative exposures and population vulnerabilities into these risk assessments contributes to potentially unhealthy exposures.[8]

For example, EPA's own environmental justice analysis has found that sources of toxic air pollution listed under Clean Air Act ("CAA") section 112, such as lead smelters, chromium electroplaters, and many others, frequently create disproportionate health risks for minority and lower income communities.[9] This problem is exacerbated by the fact that multiple sources of pollution are likely to be more concentrated in minority and lower income communities, creating a serious environmental justice problem.[10] Currently, risk assessments performed under section 112 fail to adequately incorporate aggregate exposures from multiple sources, cumulative risk from multiple pollutants, exposure from multiple pathways, and underlying vulnerability due to individual or community factors.[11]

Additionally, when researchers evaluated the National Ambient Air Quality Standard (NAAQS) for lead they found that the standard was <u>not sufficient</u> to protect vulnerable populations from significant cognitive detriment – measured as the loss of more than 2 IQ points (*i.e.*, the metric EPA itself chose to use in the Lead NAAQS). These researchers found a consistent pattern among lead toxicity studies indicating that the degree to which lead exposure resulted in cognitive detriment (measured by the concentration-response function) was <u>greater</u> among populations with a lower socio-economic status (SES) than the general population. Specifically, the median estimate of the concentration response function among general population studies was -1.75 points/µg/dL blood lead as compared to that for the low SES studies of -2.40 points/µg/dL blood lead.[12] This increased susceptibility was not incorporated into the risk assessment that was used to derive the NAAQS and therefore did not provide adequate protections for this population.

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[8] *Id.*

[9] *See, e.g.*, EC/R Memo, Prepared for EPA, "Risk and Technology Review - Final Analysis of Socio-Economic Factors for Populations Living Near Secondary Lead Smelting Facilities" at 9-10 (Dec. 2011), EPA-HQ-OAR-2011-0344-016; EC/R Memo, Prepared for EPA, "Risk and Technology Review - Analysis of Socio-Economic Factors for Populations Living Near Hard Chromium Electroplating Facilities" at 7-8, EPA-HQ-OAR-2010-0600-0601.

[10] *See, e.g.*, Cal. EPA, OEHHA, "Cumulative Impacts," *supra* (citing numerous research studies showing that exposure to pollution-emitting facilities, hazardous waste facilities and disposal, toxic releases, non-attainment air areas, high motor vehicle air pollution areas, and other types of pollution is more likely to be concentrated in communities with higher minority and lower income populations).

[11] *See, e.g.*, EPA, OAQPS, "Residual Risk Assessment for the Secondary Lead Smelting Source Category" (Dec. 2011), EPA-HQ-OAR-2011-0344-0160; "Draft Residual Risk Assessment for the Mineral Wool Production and Wool Fiberglass Manufacturing Source Categories" at 23 tbl. 3.1-1; *id*. at 30 tbl. 4.1-1 (Sept. 2011), EPA-HQ-OAR-2010-1042-0086; "Residual Risk Assessment for the Chromic Acid Anodizing, Decorative Chromium Electroplating, and Hard Chromium Electroplating Source Categories" (Aug. 2012), EPA-HQ-OAR-2010-0600-0630; "Draft Residual Risk Assessment for 7 Chemical Source Categories" (Nov. 2011), EPA-HQ-OAR-2011-0435-0018; "Draft Residual Risk Assessment for the Ferroalloys Source Category" at 27-31 (Oct. 2011) EPA-HQ-OAR-2010-0895-0046; "Residual Risk Assessment for the Oil and Gas Production and Natural Gas Transmission and Storage Source Categories," (Apr. 2012) EPA-HQ-OAR-2010-0505-4558.

[12] Ramya Chari, Burke, White & Fox, *Integrating Susceptibility into Environmental Policy: An Analysis of the National Ambient Air Quality Standard for Lead*, 9 Int. J. Environ. Res. Public Health 1077, 1084 (2012).

In order to address current inequities in the burden of environmental pollution, EPA must update its risk assessment policies and guidelines which, as discussed later in these comments, fail to provide health protections by ignoring the cumulative impact of multiple sources and types of pollution, routes of exposure, and individual and population vulnerabilities.

Experts have identified addressing cumulative impacts as essential to ensuring environmental justice and reducing disparities.

EPA has recognized the scientific evidence on socioeconomic stressors and increased vulnerability in guidance documents.[13] EPA also has made an important commitment to finally implement the 1994 Executive Order 12898, issued by President Clinton, without delay, in the form of Plan EJ 2014.[14] In response to public comments on Plan EJ 2014, EPA made the point that cumulative risk assessment should include consideration of environmental justice, stating that "the RAF [Risk Assessment Forum] believes the application of CRA [Cumulative Risk Assessment] to issues of environmental justice is supportable, both now, and increasingly in the near future."[15] In Plan EJ 2014, EPA has recognized the need for a pragmatic approach which uses the best science available now to ensure that EPA finally starts to address the real-world impacts that communities face.[16]

The agency also has recognized that it has a broad range of legal requirements and tools to address and provide environmental justice.[17] To fulfill its commitment on environmental justice, EPA must address and reduce the cumulative impacts and risks caused by environmental hazards in overburdened communities, which are often communities of color and lower income communities.

EPA has acknowledged the importance of addressing multiple source exposures, by stating that it "understands the potential importance of considering an individual's total exposure to HAP [hazardous air pollutants] in addition to considering exposure to HAP emissions from the source category and facility," and that it is "interested in placing source category and facilitywide HAP risks in the context of total HAP risks from all sources combined in the vicinity of each source."[18] And, EPA has also recognized this need in its most recent risk report.[19] Yet, so far EPA has failed to follow through on this in air toxics and other

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[13] *See, e.g.*, Draft Technical Guidance on EJ in Rulemaking at 14-18 (2013).
[14] Plan EJ 2014, http://www.epa.gov/compliance/ej/plan-ej/index.html; Exec. Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," 59 Fed. Reg. 7629 (Feb. 16, 1994), http://www.epa.gov/compliance/ej/resources/policy/exec_order_12898.pdf.
[15] U.S. EPA, "Response to Public Comments on Plan EJ 2014 Strategy and Implementation Plans" at 15 (Public Comments Received: July 2010-Apr. 2011).
[16] *Id.* at 15-16 (explaining that information available should be used along with new science that "constantly expands the range of what is possible").
[17] *See, e.g.*, EPA, Ofc. of Gen. Counsel, Plan EJ 2014 Legal Tools (Dec. 2011), http://www.epa.gov/compliance/ej/resources/policy/plan-ej-2014/ej-legal-tools.pdf.
[18] NESHAP: Mineral Wool Production and Wool Fiberglass Manufacturing, 76 Fed. Reg. 72,770, 72,786 (Nov. 25, 2011).
[19] U.S. EPA, "Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document," at xxxii (2007), EPA/600/R-06/013F (defining a cumulative risk

rulemakings; although it has looked at a source category as a whole, and it has looked at collocated sources' total "facility-wide risk," it has not assessed total exposure (such as due to exposure to other known toxic sources across the street or within the area where residents are exposed to the source category), and EPA has not used the facility-wide risk number in setting standards.[20] That is why it needs sound guidance from EPA scientists to do so.

To provide equal protection from pollution to all Americans, EPA must recognize and address the disparities in exposure, and the greater harm it can cause, especially due to early-life exposure. EPA must incorporate all aspects of increased exposure and vulnerability into its approach to assess cumulative impacts.[21]

As summarized by Morello-Frosch and colleagues: health disparities, biological and physiological susceptibility, and social vulnerability all combine with environmental exposure inequalities to make the cumulative impact of environmental hazards greater for communities of color and lower income communities.[22] To assess cumulative impacts and gain the information it needs to protect public health in decision-making, EPA must integrate all four elements into its assessment framework, including social conditions and responses.[23]

Addressing the cumulative impact of these combined environmental and social stressors is essential for EPA to finally follow the 2009 recommendations of the National Research Council, National Academy of Sciences ("NAS").[24] As the NAS has recommended, "EPA should compile relevant data related to socioeconomic status (SES), which may serve as a proxy for numerous individual risk factors . . . and may be a more direct measure of vulnerability than could reasonably be assembled by looking at all relevant individual risk factors."[25] The Council has also advised EPA to address and evaluate "background exposures and vulnerability factors," and use "epidemiologic and toxicologic evidence" in its risk assessments.[26]

Finally, EPA's Science Advisory Board has advised EPA of the importance to finally assess the full cumulative impacts. The SAB stated that "RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate

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assessment as including "aggregate exposures by multiple pathways, media and routes over time, plus combined exposures to multiple contaminants from multiple sources").

[20] *See* examples cited, *supra* note 11.

[21] Peter L. deFur, Evans, Cohen Hubal, Kyle, Morello-Frosch & Williams, *Vulnerability as a Function of Individual and Group Resources in Cumulative Risk Assessment*, 115(5) Environ. Health Perspect. 817 (2007).

[22] Morello-Frosch *et al*., *supra* & Appendix.

[23] *Id.* at 883.

[24] National Research Council, National Academy of Sciences, "Science and Decisions: Advancing Risk Assessment" (2009) ("NAS 2009"), http://www.nap.edu/catalog.php?record_id=12209.

[25] NAS 2009 at 226 (citing O'Neill *et al*., *Health, Wealth, and Air Pollution: Advancing Theory and Methods*, 111(16) Environ. Health Perspect. 1861 (2003)).

[26] NAS 2009 at 221-23 (discussing Menzie *et al*. 2007 model); *id*. at 230 (discussing the role of epidemiology and surveillance data).

and cumulative risks, including background concentrations and contributions from other sources in the area."[27]

In order to fulfill EPA's and the Executive Branch's commitment to environmental justice, EPA must:

(1) Update guidelines for conducting risk-based assessments to incorporate mechanisms for accounting for the cumulative impacts of multiple exposures and underlying vulnerabilities;

and

(2) Move beyond current risk frameworks and incorporate alternate methods to assess health threats from environmental exposures in a way that will better capture the impacts faced by overburdened communities and support policies to reduce them.

[27] Sci. Adv. Bd., Review of EPA's draft entitled, "Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board – Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing,"at ii, 10 (May 2010), EPA-SAB-10-007 ("SAB May 2010").

II. WITHIN THE EXISTING RISK FRAMEWORKS EPA MUST USE THE BEST AVAILABLE SCIENCE TO ADDRESS THE FULL PICTURE OF HARM THAT COMMUNITIES EXPERIENCE FROM POLLUTION.

EPA is currently relying on outdated risk assessment methods that fail to incorporate the current science on the cumulative impacts of environmental exposures and community and individual vulnerability. As part of the development of guidelines for cumulative impacts, EPA must provide direction to those programs relying on outdated methods and develop new methods for conducting these risk assessments so as to provide public health protections.

The National Research Council, National Academy of Sciences has recommended that EPA perform a full "cumulative risk assessment."[28] We urge EPA to fully consider and incorporate the recommendations and information from the NAS, other independent scientists, and the example models from California EPA's Office of Environmental Health Hazard Assessment ("OEHHA"), in order to take immediate steps toward reforming existing practices to better assess cumulative risk and impacts as part of the agency's responsibilities.

As an important example, EPA is currently deciding whether the second generation of the Clean Air Act's air toxics program will bring meaningful protection to communities nationwide. In a set of community health air toxics rulemakings or "CHAT" rules (also known as residual risk standards, under section 112(f) of the Act, 42 U.S.C. § 7412(f)(2)), EPA must set emission limits that protect the people most-exposed to major industrial sources' pollution. EPA must prevent unacceptable health risk and provide an ample margin of safety to protect public health.

EPA can and must vastly improve its approach by updating existing risk assessment guidelines to incorporate the science of cumulative impacts. This should be done by implementing the following:

- Account for individual-level vulnerability in risk assessments by better incorporating the vulnerability of children, early-life exposures, and the developing fetus into risk assessment methods:
    - Account for increased susceptibility by using age-dependent adjustment factors for all carcinogens, not just known mutagens.
    - Pre-natal susceptibility: Account for increased susceptibility by using a pre-natal adjustment factor for all carcinogens of <u>at least 10X.</u>
    - For chronic non-cancer risk, consult and apply child-specific reference

[28] *See e.g.*, NAS 2009 at 224 (describing this as "evaluating an array of stressors (chemical and nonchemical) to characterize—quantitatively to the extent possible—human health or ecologic effects, taking account of such factors as vulnerability and background exposures"); *see also* Cal. EPA, OEHHA, "Cumulative Impacts," *supra*, at 3 (2010) (OEHHA has addressed this issue in terms of a "cumulative impacts" assessment which considers "the exposures, public health or environmental effects from the combined emissions and discharges, in a geographic area, including environmental pollution from all sources, whether single or multi-media, routinely, accidentally, or otherwise released. Impacts will take into account sensitive populations and socio-economic factors, where applicable and to the extent data are available").

values (such as those created by California EPA scientists), where available.

    - If child-specific reference values are unavailable, consult science on early exposure impacts, and use an additional default factor of <u>at least 10X</u>.

- Account for community level vulnerability by including factors to account for increased vulnerability based on demographic differences, as part of the risk assessment. EPA also must fully integrate the findings of its environmental justice analyses into its risk assessments and rulemakings, and set stronger pollution limits to provide environmental justice.
- Assess the cumulative burden of exposures to multiple pollutants and sources via multiple pathways:
    - Assess and aggregate exposure from multiple pathways – including by adding inhalation and non-inhalation-based cancer risks.
    - Include the interaction of multiple pollutants.
    - Account for exposure to multiple sources. Until EPA has a specific mechanism for estimating total exposures, a default or uncertainty factor of at least 10X should be used to provide overburdened communities with the protection they need now.
- Account for cumulative impacts of multiple exposures and vulnerabilities by shifting the level of risk which triggers policy action.
    - Reduce EPA's benchmark of what it considers acceptable lifetime cancer risk instead of relying on the outdated upper limit of 100-in-a-million.
    - Use a Margin of Exposure (MOE) framework for non-cancer impacts and adjust the target MOE according to known vulnerability factors.
- In the face of increasing evidence calling into question the assumption of a safe or acceptable level of exposure, EPA should also consider reforming risk assessments to support reducing risks to the lowest possible level, to protect public health, rather than suggesting that there is a safe or acceptable level.

Please see Appendix A for more detail on each of the above-listed issues. Although these have come up in the context of EPA's rulemakings on air toxics standards, many of these represent cross-cutting problems with EPA's risk assessment framework that the agency should address broadly to finally follow current science.

Community Involvement

As a notable, final recommendation on cumulative risk, the NAS also urged EPA to expand "stakeholder involvement" and community outreach in the planning, scoping, and problem formulation of risk assessments, and to better explain and provide information to

affected communities on the considerations and conclusions of risk assessments.[29] EPA's failure to publicize the current notice or contact affected communities to solicit input is a case in point. This is an extremely important issue for communities overburdened by pollution and we urge EPA to engage with communities on this issue as the agency moves toward issuing guidance.

As a general matter, EPA must involve community stakeholders in strengthening its risk assessment approach overall. It is especially necessary for EPA to communicate with and solicit input from local organizations and citizens in communities that will be affected by a given risk assessment. The most-exposed and most-affected people often have helpful information to offer EPA. Importantly, for EPA to fulfill its commitment to environmental justice it also must listen to and engage with affected communities. This means not just publishing something in the Federal Register and on the Internet. It requires EPA to find community members, leaders, and representatives. It requires EPA to make phone calls, to discuss the substantive issues in person and by phone, in a way that allows communities to provide meaningful input. It may require community outreach outside of EPA's usual approach, including translation into the relevant spoken languages, and events to reach affected people in their own communities, after hours and on weekends. As part of its work, EPA should set and achieve goals for both disseminating information, and soliciting broad-based community participation from diverse communities around the United States.

The very short comment deadline on EPA's notice on cumulative risk assessment and the lack of direct outreach from EPA mean that the agency, thus far, has not provided affected communities with a meaningful opportunity to engage in this process. The lack of advance notice and short comment period also have made it difficult for communities to engage with scientists in the academic field. Commenters urge EPA to integrate community involvement and perspectives into this process, and ensure that when draft guidance is proposed that there is sufficient public notice and time for comment.

[29] NAS 2009 at 234-35.

III. EPA MUST MOVE BEYOND CURRENT RISK FRAMEWORKS AND INCORPORATE ALTERNATE METHODS TO ASSESS HEALTH THREATS FROM ENVIRONMENTAL EXPOSURES THAT BETTER CAPTURE AND REDUCE THE IMPACTS FACED BY OVERBURDENED COMMUNITIES.

There is strong evidence that cumulative exposures to environmental contaminants and community and/or individual level susceptibilities increase health threats in communities overburdened by pollution.

These findings show a need both to reform existing risk frameworks in key ways, and to explore alternate mechanisms to assess and reduce the environmental burden in these communities.[30] Scientists have outlined new approaches that focus on health impacts and apply available data and research from the areas of epidemiology, exposure assessment, and environmental justice.[31] EPA's guidance should incorporate these new integrated approaches to address cumulative impacts and identify key ways to implement them such that they inform policy decisions and help reduce contaminant burdens which are threatening community health.

In particular, scientists have called for the incorporation of new "targeted place-based" approaches that identify and assess the cumulative burden of environmental stressors and vulnerabilities in communities, so that decision-makers can provide much-needed regulatory and other actions to better protect public health.[32] Unlike EPA's current risk assessment approach which often contains an implicit assumption of a threshold that can assure safety,[33] this type of approach is geared toward identifying and targeting actions to reduce the environmental threats in communities. EPA can and should use this type of model as a means to target interventions that can decrease the environmental hazards in the most exposed and most vulnerable communities to the greatest extent possible. For communities overburdened by toxic air and other kinds of pollution, a cumulative impact analysis will allow EPA, state regulators, and concerned citizens to have information they need to make decisions about how much to prevent and control current and potential new pollution and other environmental hazards.

Cumulative Impact Assessment Methods

Researchers and agencies have used geospatial analyses of available data on environmental threats and community characteristics to develop tools which can evaluate the relative distribution of contaminant burden. These tools, which can consist of an index or a screening assessment, combine environmental exposures or threats with both individual and community measures of vulnerability to come up with a combined score for a geographical unit

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[30] Morello-Frosch *et al*., *supra*; James L. Sadd, Pastor, Morello-Frosch, Scoggins & Jesdale, *Playing It Safe: Assessing Cumulative Impact and Social Vulnerability through an Environmental Justice Screening Method in the South Coast Air Basin, California*, 8 Int. J. Environ. Res. Public Health 1441 (2011); Jason Su, Rachel Morello-Frosch, Jesdale, Kyle, Shamasunder & Jerrett, *An Index for Assessing Demographic Inequalities in Cumulative Environmental Hazards with Application to Los Angeles, California*, 43(20) Environ. Sci. Tech. 7626 (2009).
[31] Morello-Frosch *et al.*, *supra* note 5, at 880.
[32] *Id.* at 883.
[33] *See, e.g.*, examples cited, *supra* note 11.

which provides a relative measure of the cumulative impacts compared to other areas included in the analysis.

EPA should apply and adapt a place-based targeting approach, shown by these examples, to assess and score affected communities with multiple listed sources on a cumulative impacts spectrum that includes environmental exposures, hazards, and vulnerability at the individual and community levels. US EPA should then use the cumulative impacts spectrum in all areas of agency decision-making to protect public health.

The California EPA cumulative impacts protocol provides a valuable model for how US EPA can do this.[34] California EPA has performed a targeted, place-based scoring analysis for California communities that could be applied nationwide. For example, the California EPA has outlined the following ways in which the information from the cumulative impacts tool could be used:

> Identification of communities with the highest cumulative impact scores would allow Cal/EPA programs to target them for additional environmental monitoring, increased pollution enforcement activities, or to prioritize them for available incentive programs that reduce emissions or provide clean-up funds. When intra-agency efforts are needed to address multi-media impacts, the application of such a screening tool could assist in identifying impacted areas. This information could be used to target enforcement programs to reduce violations of existing laws and regulations and deter future violations in highly impacted communities. Screening for highly impacted communities could be used to prioritize outreach efforts to communities most in need of financial assistance. This assistance could be used to increase public participation opportunities and other capacity-building efforts.[35]

As additional examples, EPA should consult:

(1) Jason Su, Rachel Morello-Frosch, *et al.*, An Index for Assessing Demographic Inequalities in *Cumulative Environmental Hazards with Application to Los Angeles, California*, 43(20) Environ. Sci. Tech. 7626 (2009), http://pubs.acs.org/doi/abs/10.1021/es901041p.

In this study, researchers offer "a method for creating an index capable of summarizing racial-ethnic and socioeconomic inequalities from the impact of cumulative environmental hazards," and apply this to Los Angeles County. *Id.* The paper focuses on air pollution, including: ambient concentrations of particulate matter, nitrogen dioxide, and estimates of cancer risk associated with modeled estimates for diesel particulate matter. The index proposed "provides a generalized framework that incorporates environmental hazards and socioeconomic

[34] Cal. EPA, OEHHA, California Communities Environmental Health Screening Tool (CalEnviroScreen 1.0) (April 2013), http://oehha.ca.gov/ej/ces042313.html.
[35] George Alexeef, Faust, Meehan August, Milanes, Randles, Zeise & Denton, *A Screening Method for Assessing Cumulative Impacts*, 9 Int. J. Environ. Res. Public Health 648 (2012).

characteristics to assess inequalities in cumulative environmental risks," and as such provides a model for how U.S. EPA should consider and address these same issues. *Id.*

(2) James L. Sadd *et al.*, *Playing It Safe: Assessing Cumulative Impact and Social Vulnerability through an Environmental Justice Screening Method in the South Coast Air Basin, California*, 8 Int. J. Environ. Res. Public Health 1441 (2011); doi:10.3390/ijerph8051441.

In this study, researchers proposed an "Environmental Justice Screening Method (EJSM) as a relatively simple, flexible and transparent way to examine the relative rank of cumulative impacts and social vulnerability within metropolitan regions and determine environmental justice areas based on more than simply the demographics of income and race." They applied 23 indicator metrics, in three main categories: (1) hazard proximity and land use; (2) air pollution exposure and estimated health risk; and (3) social and health vulnerability.

EPA should investigate these and other similar work happening in various states, including New Jersey.

Health Impact Assessment

Health Impact Assessment (HIA) is another tool which has the capacity to combine multiple measures describing diverse hazards with measures of community vulnerability and individual susceptibility. HIA is an approach to assess the human health implications of a proposed plan, project or policy which takes into consideration the existing environmental conditions and community characteristics that can influence health outcomes. As such, the methods developed in the service of conducting HIAs offer tools that can integrate multiple types of data including both quantitative and qualitative.[36] EPA should evaluate where the strategies and approaches of Health Impact Assessments could be incorporated into or added to existing environmental assessments to better capture cumulative threats to public health.

Strong Need for EPA to Address Real-World Cumulative Impacts

The following list provides examples of key EPA programs where affected communities greatly need EPA to gather health impact and demographic information and use an approach that integrates aggregate exposures with underlying vulnerabilities to strengthen policy decision-making.

1. It is urgent for EPA to address cumulative impacts in setting air, pesticides, hazardous waste, and other pollution limits in rulemakings.

EPA should use a scoring approach to guide its rulemakings on a number of important issues that are urgent for public health. EPA's air toxics rules are an area where EPA risk assessment practices have been failing to follow the current science. In addition, to making the

[36] Morello-Frosch *et al.*, *supra*.

essential updates within EPA's current risk assessment approach (as discussed further in Appendix A), EPA should also use the cutting-edge community impact scoring method in at least the following ways.

- After creating the scored spectrum of affected communities nationwide, EPA should incorporate this information into the standard-setting process under various statutes. This would help ensure protections for communities impacted by multiple pollutants and sources that are currently controlled under separate regulations and rules by identifying those areas where tighter pollution controls may be necessary to protect public health. For example, when EPA sets source-specific standards for each source category as required by Clean Air Act section 112, it should also look at other sources and standards to assess their combined community impact. EPA can then set source-specific standards that target that source's contribution in the broader context of its cumulative impact on public health. EPA should engage in a similar approach for other types of pollution that can impact communities, such as pesticides, household chemicals, or hazardous waste sites, under its relevant statutory authorities (e.g., TSCA, FQPA, CERCLA, RCRA, CWA).[37]

- Under the Clean Air Act, and other statutes where EPA is setting standards for a specific source category or type of pollution that emits into a community with multiple sources of pollution, EPA should recognize that the impact of that source's pollution is larger and more harmful because it is emitting in combination with other sources. This is further discussed below in connection with the air toxics standards as an example. (See Appendix A).

2. Permit and Siting Decisions.

EPA must provide protection for communities from the cumulative impacts of all sources located there. When there is a proposal for a new or modified permit or siting change in a community that already faces combined harm from other kinds of pollution, EPA must take that into account. EPA cannot pretend that each new proposed permit or siting decision is occurring in a vacuum.

For example, permitting officials sometimes try to use significant impact levels to obviate the need for multi-source modeling.[38] Similarly, they may try to allow a permit to move forward largely on the rationale that a national ambient air quality standard for a particular criteria pollutant has not been exceeded in the air shed as a whole. These types of permitting approaches do not consider cumulative impacts, including due to vulnerabilities that may exist in a particular community, effectively allowing a permit to go forward without the effective look at local impacts necessary to protect public health.

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[37] *See* EPA, Ofc. of Gen. Counsel, Plan EJ 2014 Legal Tools (Dec. 2011), http://www.epa.gov/compliance/ej/resources/policy/plan-ej-2014/ej-legal-tools.pdf.

[38] *But see Sierra Club v. EPA*, 705 F.3d 458 (D.C. Cir. 2013) (vacating and remanding EPA rules on significant impact levels and significant monitoring concentrations for PM2.5).

Instead, EPA must ensure that the agency and other permitting agencies, including the states, recognize the full impact of pollution that already exists in a community that has other sources of pollution. Cumulative impacts already faced by a community may merit denial of a permit or the requirement to install additional pollution controls, additional monitors, and additional compliance provisions in a permit, such as back-up power, community notification, and corrective steps, like immediate shut-down, that must be taken whenever there is an accident or upset.

3. Enforcement and Monitoring Decisions.

Using a scoring mechanism to assess where a community stands on the spectrum of exposure and vulnerability would be the most efficient way for EPA to target its enforcement and monitoring resources to communities that have the greatest need, based on cumulative impacts and risk from pollution.

EPA regularly makes decisions about how to allocate resources for enforcement and what cases to prosecute. EPA should target its enforcement actions in those communities that are the most overburdened and face the greatest risk from pollution.

Communities need more state-of-the art fenceline monitoring tools and systems set up by EPA near places where people live and children go to school in the midst of pollution and polluting sources.[39] Communities affected by pollution have a right to know what is in their air, water, and soil. Where EPA is unable to or does not bring enforcement cases, affected communities have a particular need for up-to-date information on air emissions, water pollution, and soil and hazardous waste testing. This allows community members and organizations to make decisions locally to try to protect their own health, and to consider bringing citizen enforcement suits, where possible.

Community Spotlight

These comments include stories that provide a snapshot of the experience of local communities around the country that many EPA staff and panel members may never have visited, including from Houston, Midlothian, and Port Arthur, TX, Los Angeles County, CA, Delaware City, DE, Southeast Louisiana, Detroit, MI, Camden, NJ, Washington, D.C., Memphis, TN, Mebane, NC, and the Navajo Nation. The following are excerpts from Appendix E.

<u>Northern Delaware</u>
Amy Roe, Conservation Chair, Sierra Club, Delaware Chapter

In northern Delaware, where I live, the air is unsafe to breathe. Ozone action days are commonplace and toxic releases from the numerous chemical plants and the nearby oil

[39] *See, e.g.*, USA Today, *The Smokestack Effect: Toxic Air and America's Schools*, http://content.usatoday.com/news/nation/environment/smokestack/index (providing information on schools most exposed to hazardous air pollution around the U.S.).

refinery occur regularly. The groundwater in eastern New Castle County has been contaminated, and just this month a drinking water well near the town of New Castle was closed because of 1,4-dioxane from a nearby Superfund site. The fish in our rivers and streams are unsafe to eat and most of the water bodies in New Castle County have a "no consumption" advisory. We are forced to endure the legacy pollution from past manufacturing and hazardous waste disposal, while new pollutants are added to our environment from existing facilities.

The response that I have received from state regulators for air pollution concerns that made me ill and nauseated during the restart of the Delaware City Refinery was that the "air" I am breathing is just "air." The air that I am breathing is not just air! It is filled with fine particles and toxic vapors from many industrial facilities, including but not limited to the Delaware City Refinery, Formosa Plastics, FMC Biopolymer, AI Dupont Sulfuric Acid Regeneration Plant, Kuehne Chemical Company, DuPont Edgemoor and the DuPont Experimental Station.

This month I learned that my city has been negotiating to build a 248 MW power plant at the edge of my neighborhood, just a few blocks away, and a stone's throw from the playground where I played on the swings as a child. Past and present threats to public health are being added to with plans for future development. The regulatory oversight of air and water pollution needs dramatic improvement. Science-based standards for cumulative risk assessment would result in the dramatic improvement of our lives and health. It would dramatically improve the way that pollution standards are assessed to consider the health impacts to our communities as part of the regulatory process.

Houston Ship Channel, Houston, TX:

Houston's Ship Channel hosts one of the largest concentrations of petrochemical facilities in the world, which in addition to the area's refineries, other chemical facilities, and constant fleets of shipping barges and diesel trucks, contaminates regional air quality. The negative health impacts on the community, which is overwhelmingly Latino, are undeniable. A study of nearly 300 residents by Air Alliance Houston in partnership with Healthy Port Communities Commission conducted between March and April 2013 found that communities near the Port of Houston experience higher than average rates of allergies, cancer, and respiratory illnesses. In comparison to state statistical averages, residents near the Port of Houston reported rates of asthma twice as high in adults and children, and reported rates of cancer ten times as high. Eighty-six percent of respondents expressed concern about pollution from local refineries in the survey, and 89% of respondents expressed concern about the effects of pollution on their health. Problematically, 54% of respondents did not have health insurance and nearly half of residents have an unemployed household member. The combination of high pollution exposure and lower access to health care in this community shows the need for EPA to look at and reduce the cumulative impacts people here face.

Detroit, Michigan:

Michigan's most polluted zip code is 48217, located in the southwest of Detroit.[40] Wedged between a major highway and polluting factories, this community has acutely felt the burden of living so close to industrial plants. The residents experience acrid odors, masses of floating dark particles, and thick layers of metallic dust that settle over the area. The community, which is roughly 85% African American, has experienced deteriorating health due to its proximity to multiple industrial sites.[41] Asthma, sarcoidosis, and multiple types of cancer, including leukemia and brain cancer, have affected many local families. Despite all this, the city continues to allow the industrial sector to expand, further elevating the level of pollution. In the past decade alone, air permits for an asphalt plant have been approved, the nearby water and sewer plant have expanded, and a composting facility was erected. In 2007, the community opposed the $2-billion project to expand the Marathon Refinery and lost. The State asserts that each industrial plant complies with the emissions limits, but the State fails to take into account the cumulative effects of the multiple facilities that are spewing out toxins into the air. Although Detroit has seven state air monitors, none are located in this neighborhood, spurring the local residents to initiate their own sampling. Their results showed high levels of lead and methyl ethyl ketone, a toxin that can irritate the lungs and affect the nervous system, in the air. The cumulative effects of the nearby facilities must be considered for communities like Detroit to account for the level of harm associated with close proximity to these industrial sites and, ultimately, to finally bring relief to communities inundated with pollution.

Cancer Alley, Louisiana:

The 80 mile stretch of Mississippi River between Baton Rouge and New Orleans, once revered by Mark Twain, is now dubbed "Cancer Alley."[42] This Louisiana area has the highest concentration of manufacturers, users, and disposers of toxic chemicals in the nation.[43] Hundreds of industrial plants are located near low-income communities of color and have been spewing out dangerous air toxins for decades.[44] The residents experience high rates of asthma, cardiovascular disease, diabetes, infant mortality, and cancer, including rare childhood cancers.[45]

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[40] Tina Lam, *48217: Life in Michigan's Most Polluted Zip Code*, DETROIT FREE PRESS (June 20, 2010), http://www.freep.com/article/20100620/NEWS05/6200555/48217-Life-Michigan-s-most-polluted-ZIP-code.
[41] Andrea Newell, *Environmental Justice in Detroit: Hope Arises Amid Toxic Communities*, TRIPLE PUNDIT (Jun. 10, 2013), http://www.triplepundit.com/2013/06/detroit-environmental-justice/.
[42] *Cancer Alley, Louisiana*, H2G2, Jul. 4, 2002, http://h2g2.com/approved_entry/A760420 (last updated Dec. 11, 2005).
[43] Heidi E. Kluber, "Cancer Alley and Infant Mortality: Is There a Correlation?" (Dec. 2011) (unpublished M.P.A.F.F. thesis, University of Texas) (on file with University of Texas Libraries), available at http://repositories.lib.utexas.edu/bitstream/handle/2152/ETD-UT-2011-12-4417/KLUBER-MASTERS-REPORT.pdf?sequence=1.
[44] H2G2, *supra*.
[45] Cancer Alley and Infant Mortality, *supra*, at 1.

The reality faced by these and other communities requires EPA's urgent attention to current science. Many additional examples are included in the attached Appendix E, and we urge EPA to consider each of these community stories as part of this review and its development of guidance.

CONCLUSION

We encourage EPA to follow the best available science on cumulative impacts and risk, and to issue strong new guidance on the issues these comments discuss, without delay. Please contact us if we can provide any additional information that would be helpful. Please also let us know what EPA's planned timeframe and next steps are to issue draft guidance, when possible.

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APPENDIX A: SPECIFIC RECOMMENDATIONS TO REFORM EXISTING RISK ASSESSMENT GUIDELINES

I. ACCOUNT FOR INDIVIDUAL-LEVEL VULNERABILITY IN RISK ASSESSMENTS BY BETTER INCORPORATING THE VULNERABILITY OF CHILDREN, EARLY-LIFE EXPOSURES, AND THE DEVELOPING FETUS INTO RISK ASSESSMENT METHODS.

The National Academy of Sciences ("NAS") reports and other new scientific and policy developments direct that EPA must better account for vulnerability and variability. *See* Appendix B-C. In particular, the science is now clear that "children are not 'little adults'" when it comes to toxic chemicals.[46] They are both susceptible to greater harm from exposure to toxic chemicals, because they are still growing and developing, *and* they are exposed to such chemicals at a greater rate than adults because of age-specific behaviors and physiological characteristics. Second, EPA must also better account for other types of human variability because some people exposed to the same amount of a pollutant experience greater health risk due to other factors, such as genetics and baseline health status. Socioeconomic status has been shown to act as a proxy for other types of human variability to chemical risk that EPA has not adequately addressed in its risk assessments.

This section discusses key ways in which EPA must better address both the greater risk to children (including from early-in-life exposure to toxic chemicals), and other important types of human variability. Appendix B and C of this document summarize the significant body of scientific and policy developments on children's health and environmental justice which illustrates the need for updates to EPA's risk assessment approach.

A. Children's Risk and Early-Life Exposures

1. Account for increased early life susceptibility by using age-dependent adjustment factors for all carcinogens.

Most of EPA's cancer risk assessments do not account for early-life exposure or the greater risk to and susceptibility of children. For cancer risk assessment, EPA should follow the science and account for increased early-life susceptibility by applying age-dependent adjustment factors for *all carcinogens* emitted by a source category.

In past rulemakings, EPA has restricted its application of age-dependent adjustment factors, as discussed in the 2005 *Guidelines* and *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*, to those hazardous air pollutants ("HAPs") included in EPA's list of carcinogens that act by a mutagenic mode of action.[47] It

[46] National Research Council, "Pesticides in the Diets of Infants and Children" at 3 (1993).
[47] *See* EPA, "Guidelines for Carcinogen Risk Assessment," EPA/630/P-03/001F, at 1-19 to 1-20 (Mar. 2005), http://www.epa.gov/raf/publications/pdfs/CANCER_GUIDELINES_FINAL_3-25-05.PDF; EPA, "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens," EPA/630/R-03/003F (2005), http://www.epa.gov/raf/publications/pdfs/childrens_supplement_final.pdf; *see, e.g.*, EPA OAQPS, "National

therefore has not applied age-dependent adjustment factors to assess cancer risk from all of the carcinogens emitted by a source category. The NAS recognized this as a "missing" default in EPA's approach that it should address and account for.[48]

Instead of taking the approach of the 2005 *Guidelines* and *Supplemental Guidance* to limit the use of age-dependent adjustment factors to only some carcinogens, EPA must follow the lead of OEHHA by using age-dependent adjustment factors for all carcinogens.[49] Because OEHHA has provided robust scientific support for this approach, using these factors to assess cancer risk for all carcinogens would be consistent with the NAS recommendations. As the NAS explained: "EPA needs methods for explicitly considering in cancer risk assessment . . . chemicals that do not meet the threshold of evidence that the agency is considering for judging whether a chemical has a mutagenic mode of action . . . . Special attention should be given to hormonally active compounds and genotoxic chemicals that do not meet the threshold of evidence requirements."[50]

The 2005 Guidelines recognized that updates would be needed if more data become available.[51] Now that such data are available, including from the NAS and OEHHA, the agency must update its approach promptly. EPA should immediately implement the OEHHA age-dependent adjustment factors for all carcinogens, and EPA should also update the 2005 Guidelines to fully reflect current science as described in OEHHA's 2009 review of the scientific literature on increased susceptibility to carcinogens from early life exposures.[52]

2. Pre-natal susceptibility: Account for increased susceptibility to pre-natal exposures by using pre-natal adjustment factors for all carcinogens.

Current EPA risk assessment procedures do not take into account increased susceptibility to carcinogens due to pre-natal exposures. The 2005 Supplemental Guidance recognized the scientific findings of increased susceptibility to carcinogens resulting from pre-natal exposure, but did not develop adjustment factors to account for increased cancer risk resulting from pre-natal exposures.[53] For example, EPA recognized that "[e]xposures that are of concern extend from conception through adolescence and also include pre-conception exposures of both

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Emissions Standards for Hazardous Air Pollutants: Secondary Lead Smelters, Summary of Public Comments and Responses," at 72-73 (11-14-11), EPA-HQ-OAR-2011-0344-0167.

[48] NAS 2009 at 196 (Tbl. 6-3 - Examples of "Missing" Defaults in EPA "Default" Dose-Response Assessments).

[49] Cal. EPA, OEHHA, "Technical Support Document for Cancer Potency Factors: Methodologies for Derivation, Listing of Available Values, and Adjustments to Allow for Early Life Stage Exposures" 3-4, 50-51 (May 2009), http://www.oehha.ca.gov/air/hot_spots/2009/TSDCancerPotency.pdf, and http://oehha.ca.gov/air/hot_spots/tsd052909.html.

[50] NAS 2009 at 112 (ch. 4) (describing the fact that "*in utero* periods and nonmutagenic chemicals were not covered" by EPA's 2005 guidelines, as significant omissions).

[51] *See* EPA, 2005 Supp. Guidance at 21, 31 ("EPA expects to expand this Supplemental Guidance to specifically address modes of action other than mutagenicity when sufficient data are available and analyzed.").

[52] Cal. EPA, OEHHA, TSD for Cancer Potency Factors, *supra* note 49.

[53] EPA, 2005 Supp. Guidance at 4-5, 14 & tbl. 1a (A-1) (discussing research on human and animal cancer risks from prenatal exposure).

parents."[54] The NAS identified the lack of accounting for "*in utero* periods" of exposure as a major omission in EPA's 2005 cancer guidelines.[55]

OEHHA conducted its own review of the scientific literature to account for pre-natal susceptibility and exposures, which EPA should also consult and use.[56] It has also developed methods and adjustment factors to account for pre-natal susceptibility and exposures that EPA should use.[57] In its new risk assessment guidelines, OEHHA includes procedures for exposure assessment during fetal development, which EPA should evaluate.[58] OEHHA specifically discusses the use of a 10X adjustment factor for cancer risk due to pre-natal to age 2 exposures, and EPA should consider using at least this same factor.[59]

EPA should consult the science OEHHA has used to develop this well-supported factor, and should then use at least a 10X adjustment factor for all carcinogens to assess health risk due to pre-natal exposure.

3. For chronic non-cancer risk, consult and apply child-specific reference values, where available.

Most of EPA's IRIS toxicity threshold values (reference concentrations and reference doses) used for chronic non-cancer risk assessment do not incorporate the latest science on increased susceptibility of children.[60] EPA needs to account for early exposure and the greater risk to and susceptibility of children in its risk assessments.

OEHHA child-specific health values include reference doses for cadmium, chlordane, heptachlor, manganese, methoxychlor, nickel, and pentachlorophenol, and a benchmark for lead. A full list, with links to each scientific determination document, is available here: OEHHA, Table of all child-chRDs Finalized to Date (last updated 06/22/09), http://oehha.ca.gov/public_info/public/kids/chrdtable.html. OEHHA has generated these child-specific reference values based on the latest science to take into account children's greater

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[54] EPA 2005 Guidelines for Carcinogen Risk Assessment, EPA/630/P-03/001F, at 1-16.
[55] NAS 2009 at 112-13; *see also id.* at 112, 196 (noting that it is a "missing" default that EPA recognizes in utero carcinogenic activity, but fails to take account of it or calculate any risk for it as "EPA treats the prenatal period as devoid of sensitivity to carcinogenicity").
[56] *See* Cal. EPA, OEHHA, "Technical Support," *supra* note 49, App. J: "In Utero and Early Life Susceptibility to Carcinogens: The Derivation of Age-at-Exposure Sensitivity Measures" – conducted by OEHHA's Reproductive and Cancer Hazard Assessment Branch," .http://oehha.ca.gov/air/hot_spots/2009/AppendixJEarly.pdf.
[57] *Id.* App. J at 7-8 & tbl. 1.
[58] *See* Cal. EPA, OEHHA, Air Toxics Hot Spots Program Risk Assessment Guidelines, Technical Support Document for Exposure Assessment and Stochastic Analysis, Scientific Panel Review Draft at 1-6 to 1-7 (Feb. 2012) ("OEHHA 2012 Guidelines").
[59] *See id.*
[60] OEHHA has explained why child-specific reference doses or values are needed and provided a list of chemicals. *See, e.g.*, Cal. EPA, OEHHA, "Prioritization of Toxic Air Contaminants - Children's Environmental Health Protection Act" (Oct. 2001), http://oehha.ca.gov/air/toxic_contaminants/pdf_zip/SB25%20TAC%20prioritization.pdf; Cal. EPA, OEHHA, "Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code 901(g): Identification of Potential Chemical Contaminants of Concern at California School Sites, Final Report" (June 2002), http://oehha.ca.gov/public_info/public/kids/pdf/ChildHealthreport60702.pdf.

exposure and greater vulnerability.

At least until the IRIS values fully account for the increased risk caused by early-life exposure to an emitted pollutant, EPA should use the OEHHA child-specific reference doses or benchmarks available to assess chronic non-cancer health risk from ingestion for certain pollutants. EPA should also assess such risk from inhalation by using standard methods to translate these values into child-specific reference concentrations to assess inhalation-based risk.

4. Where child-specific reference values are unavailable, consult science on early exposure impacts and use an additional default or uncertainty factor.

The increased susceptibility of children, while known to exist, has not been quantified for many toxic chemicals. Until EPA has child-specific or child-based reference values available for a given pollutant, EPA should apply a default or uncertainty factor of at least 10 to account for increased risk from early-life exposures for non-cancer risk assessments.

This would be consistent with the NAS recommendation on the need for EPA to use default factors to account for greater risk,[61] with the science developed and considered by OEHHA, and with the 10X factor enacted by Congress in the Food Quality Protection Act. Specifically, as the SAB report explained:

> California EPA/OEHHA has determined that inhalation dosimetry for children is sufficiently different from adults to warrant a full 10-fold intra-individual pharmacokinetic uncertainty factor (i.e., an extra 3-fold PK uncertainty for children relative to the IRIS method) as a default approach. In setting non-cancer reference exposure levels (RELs), Cal EPA/OEHHA also considers that children may be outliers in terms of chemical susceptibility and on a case-specific basis adds a children's pharmacodynamic factor of 3-fold, making the inhalation risk for children as much as 10 times greater than adults[62]

In addition, Congress has recognized this science in its unanimous vote on toxics legislation passed in 1996 – the Food Quality Protection Act ("FQPA") – in which Congress found the need to use and enacted a Ten-fold Margin of Safety, or "10X factor." Specifically, the Act provides that "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children."[63] Congress's recognition of the need to use this default factor provides a model that EPA should consider and incorporate into residual risk assessments. It

[61] NAS 2009 at 190-93, 203.
[62] SAB May 2010 at 34 (May 2010) (citing Cal. EPA, OEHHA, "Technical Support," *supra*.)
[63] 21 U.S.C. § 346a(b)(2)(C) (requiring that, in establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, "for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied" to protect infants and children).

would be appropriate and within EPA's authority under the Clean Air Act section 112(f)(2) to determine that EPA must similarly use a children's ten-fold margin of safety factor here, consistent with the Clean Air Act's "margin of safety" requirement.[64] In doing so, EPA may rely directly on the science itself, and also on the unanimous guidance from Congress, provided in the FQPA, that the existing evidence of increased harm requires significant action to protect children from toxic exposure.

Further, the child-specific reference doses that OEHHA has created for some pollutants provide support for the use of an additional Ten-fold Margin of Safety Factor. EPA's current reference values are generally one order of magnitude less protective (*i.e.*, larger) than the values that California has recognized as needed to protect children, based on the currently available science and a specific assessment of research relevant to early life exposures, as shown in the chart attached as Appendix D.

B. Account for community level vulnerability by including factors to account for increased vulnerability based on demographic differences, as part of the risk assessment.

The NAS report identified significant flaws in EPA's assessment of individual variability in risk assessments that could result in significant underestimation of risk. In particular, EPA must fully account for the fact that people can be more vulnerable to toxic pollution due to various physiological, societal, demographic, and exposure history differences and can therefore experience greater health risk from the same amount of a toxic chemical exposure.[65] As the NAS has observed, performing risk assessment that is meaningful for communities that already face a significant amount of pollution and communities concerned about environmental justice "requires an ability to evaluate multiple agents or stressors simultaneously—to consider exposures not in isolation but in the context of other community exposures and risk factors."[66] Addressing this issue is particularly important for EPA because of the need to consider and address environmental justice as mandated by Exec. Order 12898.

Communities that have minority and lower income populations and communities with higher than average levels of cancer, respiratory, and other health problems, as well as a lack of access to health care, are likely to be more vulnerable to the impact of toxic air pollution.[67] Where a rule affects communities that are disproportionately minority or lower income, EPA

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[64] 42 U.S.C. § 7412(f)(2).

[65] *See, e.g.*, NAS 2009 at 135-39, 145-51 (explaining that "[h]ow the population responds to chemical insults depends on individual responses, which vary among individuals"; and "[i]f the sensitive people constitute a distinct group either because of their numbers or because of identifiable characteristics—such as ethnicity, genetic polymorphism, functional or health status, or disease—they should be considered for separate treatment in the overall risk assessment"); *id*. at 112 (noting that EPA's guidelines do not address variability due to factors "such as age, ethnic group, socioeconomic status, or other attributes," and explaining that "there is a need for a nonzero default to address the variation in the population expected in the absence of chemical-specific data"); *see also id*. at 134 (discussing various factors and recommending that "much more emphasis needs to be placed on describing the ranges of susceptibility and risk"); *see also id.* at 177-82, 196.

[66] *Id*. at 214-15.

[67] *See, e.g.*, Chari *et al*., *Integrating Susceptibility*, at 1078 & nn.5-10 (citing research); *see also* Cal. EPA, OEHHA, "Cumulative Impacts,"*supra*, at 6, 10, 12-17.

cannot ignore this greater risk in its assessment. As a key starting point, EPA must assess the greater health risk based on socioeconomic status found in epidemiological research studies.[68] As the NAS recognized, "there is growing epidemiologic evidence of interactions between environmental stressors and place-based and individual-based psychosocial stressors, driven in part by the spatial and demographic concordance between physical and chemical environmental exposures and socioeconomic stressors," and there is also a growing field of information on social epidemiology, which addresses the relationship between social factors and disease in human populations.[69] Data describing these factors are available from the Center for Disease Control's Environmental Public Health Tracking ("EPHT") Program, the U.S. Agency for Toxic Substances and Disease Registry, state and local health agencies, and academic researchers,[70] and EPA must consider and use such information in its risk assessments.

Further, EPA must recognize and evaluate the need to consider socioeconomic factors not only as part of an environmental justice analysis, but also as part of EPA's consideration of both vulnerability and variability, as core elements of the risk assessment itself. EPA has been assessing the demographics of affected communities, pursuant to CAA § 112(f) and the Environmental Justice Executive Order 12898.[71] This is necessary and important to continue. However, in addition to looking at the demographic census data on race, ethnicity, poverty level, and similar factors, EPA must also assess the starting point or baseline overall health status of the affected individuals and communities using the best available data at a local and national level, including the baseline cancer levels, respiratory problems, and health problems associated with the toxic chemicals emitted by a source category. Doing so would be consistent with the 1999 Residual Risk Report.[72] Further, EPA has significant research available on which it must draw to incorporate "overall health" into its risk assessments. For example, the American Lung Association has published research showing that African Americans are at a much higher risk of lung cancer than white Americans, and that African-American men have a 37 percent higher risk of lung cancer than white men.[73] EPA must collect and consider this type of health information as part of each risk assessment that disproportionately affects particular minority groups and communities.

Thus far, EPA has failed to adequately assess human variability, particularly the

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[68] NAS 2009 at 109-10 & tbl. 4-1 (describing the need to consider increased susceptibility due to prior and concurrent exposures; and to "social and economic factors"); *id.* at 220-21 (describing ways to assess cumulative risk including by consideration of "epidemiologic concepts" and information, and by considering "what the burden of disease is in the context of simultaneous exposure to a number of stressors"); *id.* at 230 (discussing the role of epidemiology and surveillance data).

[69] *Id*. at 230-33.

[70] *Id*. at 232 (describing data available on health status, and patterns of diseases and exposures).

[71] Exec. Order 12898, "Federal Actions To Address Environmental Justice," *supra*.

[72] U.S. EPA, "Residual Risk Report to Congress" at 42, 67 (Mar. 1999), EPA-453/R-99-00 (discussing factor of "overall health" and recognizing the need to consider sensitive subpopulations that "consist of a specific set of individuals who are particularly susceptible to adverse health effects because of physiological (e.g., age, gender, pre-existing conditions), socioeconomic (e.g., nutrition), or demographic variables, or significantly greater levels of exposure," based on various demographic factors).

[73] Am. Lung Ass'n, "Too Many Cases, Too Many Deaths: Lung Cancer in African Americans" at 1 (2010), http://www.lungusa.org/assets/documents/publications/lung-disease-data/ala-lung-cancer-in-african.pdf (explaining higher risk to African Americans even though primary factor for lung cancer, *i.e.*, cigarette smoke exposure, is lower than for whites); *see also* State of Lung Disease in Diverse Communities: 2010, available at www.LungUSA.org.

increased vulnerability of different socioeconomic groups, or to incorporate the information gained from the environmental justice analysis into its risk assessment. As a typical example of how EPA has handled this issue in many recent rulemakings, in promulgating the Secondary Lead Smelting air toxics rule, EPA recognized that there are greater impacts on communities of color and lower income communities.[74] However, EPA did not incorporate the additional vulnerability this represents at all into its risk assessment.[75] As the NAS discussed, "EPA should compile relevant data related to socioeconomic status (SES), which may serve as a proxy for numerous individual risk factors . . . and may be a more direct measure of vulnerability than could reasonably be assembled by looking at all relevant individual risk factors."[76] EPA should follow the NAS recommendations and science to do so in its residual risk assessments.

In addition, EPA should simply develop and use a default factor to account for socioeconomic and other community-based stressors, just as it does to account for intrinsic biological factors.[77] For example, it traditionally uses a factor of 100 to account for the use of animal studies, when translating such studies to assess human impacts. The Food Quality Protection Act directed EPA to use a factor of 10 to account for in utero exposure. California's Office of Environmental Health Hazard Assessment uses a similar factor to account for in utero exposure. EPA also uses age-dependent adjustment factors in other contexts. EPA should do the same to account for increased vulnerability based on socioeconomic factors or the presence of multiple sources to which a community is exposed.

II. ASSESS THE CUMULATIVE BURDEN OF EXPOSURES TO MULTIPLE POLLUTANTS AND SOURCES VIA MULTIPLE PATHWAYS

A. Perform multipathway assessment for all persistent and all bioaccumulative pollutants.

EPA must assess multipathway (*i.e.*, non-inhalation) risk for all metals and all other pollutants with a persistent or bioaccumulative impact, as OEHHA does. Instead, EPA generally restricts its multipathway risk screening assessment to only those contaminants identified in the 2003 Risk Assessment Guidance as being both persistent and bioaccumulative in the

[74] EC/R Memo, Prepared for EPA, "Risk and Technology Review - Final Analysis of Socio-Economic Factors for Populations Living Near Secondary Lead Smelting Facilities at 9-10" (Dec. 2011), EPA-HQ-OAR-2011-0344-0161 (finding minority population facing an elevated cancer risk due to secondary lead smelters' emissions was more than one-and-a-half times higher than the national minority percentage; Hispanic was 3 times higher than national; "Other and Multi-Racial" was three times higher than national; and lower income measures were also higher) (also describing disproportionate exposure of Hispanics).

[75] EPA, OAQPS, "Residual Risk Assessment for the Secondary Lead Smelting Source Category" (Dec. 2011), EPA-HQ-OAR-2011-0344-0160 (not addressing vulnerability or disproportionate socioeconomic impact in the health risk assessment); National Emissions Standards for Hazardous Air Pollutants From Secondary Lead Smelting, 77 Fed. Reg. 556, 579 (Jan. 2012) (not describing any action EPA took in view of disproportionate effect of source category's pollution, and stating only that the rule "increases the level of environmental protection for all affected populations").

[76] NAS 2009 at 226 (citing O'Neill *et al*. (2003)).

[77] Morello-Frosch *et al.*, *supra* note 4, at 883.

environment (*i.e.*, PB-HAPs).[78] EPA's 2003 list of 14 PB-HAPs is incomplete, however, because it ignores other HAPs which present a multipathway risk.[79]

EPA's choice to restrict its analysis to only certain contaminants that bioaccumulate is not supported by the 2003 Guidance which states that "multipathway risk assessment may be appropriate generally when air toxics that persist and which also *may* bioaccumulate and/or biomagnify are present in releases."[80] This guidance does not direct that the multipathway assessment be limited to only those contaminants listed as PB-HAPs, but that is how EPA has applied it. The choice to exclude those contaminants which persist and accumulate in soils underestimates risks from HAPs. The 2003 guidance document recognized deposition of *persistent* HAPs as a source of soil contamination presenting a potentially significant route of exposure, particularly for children.[81]

Based on EPA's own guidance, and based on recent scientific information compiled by OEHHA, EPA must perform a full multipathway risk assessment for all metals. California OEHHA has recommended a multipathway assessment for metals based on scientific research.[82] EPA should consider and apply this science in its risk assessments.

EPA simply may not assume that the ingestion and other multipathway risks are zero for persistent pollutants when science shows otherwise. The failure to assess multipathway risk from exposure to all PB-HAPs, both individually and cumulatively, results in an underestimate of the health risks of HAP emissions.

The following is a list of top priority pollutants for EPA to add to its list of 14 chemicals for which multipathway risk should be evaluated. These chemicals have been shown to have a significant potential for deposition and retention within the environment. Air emissions of these compounds therefore present a risk to nearby communities via dermal, ingestion, and other non-inhalation pathways that are currently not being considered in residual risk assessments. For extensive documentation on the rationale for multipathway analysis for these compounds and multipathway exposure parameters please review the OEHHA 2012 Guidelines for Exposure Assessment.[83]

i. Arsenic
ii. Hexavalent chromium
iii. Nickel
iv. Diethylhexylphthalate
v. Beryllium

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[78] *See, e.g.*, "Draft Residual Risk Assessment for the Ferroalloys Source Category" (Oct. 2011) at 10, EPA-HQ-OAR-2010-0895-0046 (only analyzing multipathway risk for pollutants on EPA's outdated PB-HAP list even though arsenic is a persistent pollutant and is also emitted).
[79] EPA, "PB-HAP Compounds, Risk Assessment and Modeling – Air Toxics Risk Assessment Reference Library, Vol. I Tech. Resource Manual, Ch. 4 Air Toxics: Chemicals, Sources, and Emissions Inventories," at 4-10, Exhibit 4-2 (2003), http://www.epa.gov/ttn/fera/risk_atra_vol1.html; http://www.epa.gov/ttn/fera1risk_atra_vol 1.html.
[80] *Id*., Part III, Ch. 14"Human Health Risk Assessment: Multipathway," at 14-1(emphasis added).
[81] *Id.* ch. 20.
[82] OEHAA 2012 Guidelines, Appendix E, at E-5, E-10 to E-12, http://oehha.ca.gov/air/hot_spots/SRP/index.html.
[83] *Id.* App. E.

vi. Selenium

In addition to these six listed by OEHHA, we also urge EPA to assess the persistent effects of manganese and naphthalene and add these to the PBT list for similar reasons. Manganese is a pollutant to which children have particular exposure and vulnerability, and there is evidence that it can pose a multipathway risk due to elevated levels in soils around major emission sources.[84] Naphthalene is a polycyclic aromatic hydrocarbon (PAH) and as such must be considered in the POM category which is listed as a PB HAP. Naphthalene has been demonstrated to be persistent and to bioaccumulate in biota, particularly shellfish.[85]

2. Perform multipathway assessment for all pathways of exposure, including those that particularly affect children.

EPA should recognize that the science shows *additional pathways* that it has not addressed for certain pollutants, for which it does recognize the need for a multipathway assessment. For example, OEHHA has recognized that breast milk exposure can be a pathway that creates health risk due to lead.[86] EPA should evaluate the research on various pathways of toxic exposure discussed by OEHHA.

In addition, science shows that EPA has been relying on outdated estimates of incidental soil ingestion exposures and EPA must update these values to ensure that it considers the urban child scenario in its multipathway risk assessment.[87] Risk assessments of exposure to soil contaminants should evaluate both direct exposure, hand-to-mouth, and indirect, object-to-mouth exposure. Indirect hand-to-mouth activity is the exposure from young children who touch an object or food with soil contaminated hands and then put that object or food into their mouths. Published studies show that there is noticeable indirect hand-to-mouth activity in infants and children. In fact, one study found that, on average, a toddler will touch an object and then put that object into his or her mouth 15 times in one hour. At the high end of the study's

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[84] *See, e.g.*, ATSDR, "Draft Toxicological Profile for Manganese" at 12 (Sept. 2012) ("Manganese concentrations in soil may be elevated when the soil is in close proximity to a mining source or industry using manganese and may therefore pose a risk of excess exposure to children who ingest contaminated soil.") http://www.atsdr.cdc.gov/ToxProfiles/tp151.pdf ; *see also* Cal. EPA, OEHHA, "Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code Section 901(g): Child-Specific Reference Doses (chRDs) for School Site Risk Assessment: Manganese and Pentachlorophenol," at 10 (June 2006) (discussing science showing that manganese can accumulate in the brain and showing that ingestion of high levels of manganese is associated with harm).

[85] R. Yender *et al.*, NOAA, "Managing Seafood Safety after an Oil Spill," (Nov. 2002).

[86] OEHHA 2012 Guidelines, *supra* note 58, App. E, at E-12, tbl. E3.

[87] As an additional problem, California's lead in soil standard is more stringent than EPA's due to more recent science on the harm of lead exposure. EPA has recognized that its standard is based on out-dated information about lead, that previously assumed children's blood-lead levels below 10.0 ug/dL was safe. EPA now admits that number is not protective, but has not updated its soil standard. *See, e.g.*, "EPA fails to revise key lead-poisoning hazard standards," USA Today (Mar. 10, 2013), http://www.usatoday.com/story/news/nation/2013/03/10/epa-has-not-revised-lead-hazard-standards-for-dust-and-soil/1971209 ("The EPA has not revised key hazard standards that protect children from lead poisoning since 2001, despite science showing harms at far lower levels of exposure than previously believed."); Children's Health Advisory Protection Comm., Letter to Administrator Jackson Regarding Childhood Lead Poisoning (Mar. 29, 2012), http://yosemite.epa.gov/ochp/ochpweb.nsf/content/chpac_childhood_lead_poison_letter.htm.

distribution (90th percentile), that rate rises to 66 times per hour.[88] This same study found a statistically significant positive correlation between the frequency of object or food in mouth activity and blood lead levels. The 2011 update to EPA's Exposure Factors Handbook includes more recent studies and estimates of hand-to-mouth behavior, which must be used to assess risks from exposures to contaminated soils.[89]

3. Better account for the aggregate impact of inhalation and multipathway cancer and chronic non-cancer risk by adding each type of similar risk together for all pollutants.

The purpose of the multipathway assessment is to allow EPA to look overall at a person's exposure – not just inhalation, and not just other exposure pathways, in isolation. To do so, EPA must add inhalation and multipathway risk. Failing to add up each type of risk in order to come up with a *total* cancer risk number and a *total* non-cancer number, and then (as further discussed below), a *cumulative* burden metric makes EPA's overall risk assessment incomplete.

A major problem in past risk assessments is that EPA does a screening exercise for multipathway risk and then often decides not to do a full multipathway risk assessment.[90] This is problematic for two reasons. First, it withholds information from the public on the amount of non-inhalation risk. Second, it hampers EPA's ability to perform a full, cumulative analysis taking into account all the relevant exposures. EPA should ensure that for each risk assessment it fully assesses multipathway or non-inhalation risk, and that it also combines this with inhalation risk, to come up with a cumulative risk level that EPA and the public can then analyze in the rulemaking process.

B. Include Multiple Pollutants.

1. Assess the combined total of each type of risk for multiple pollutants.

EPA must assess the total and synergistic cancer risk and total chronic non-cancer risk for different pollutants. For example, as OEHHA found, "[t]he potential neurotoxicity of arsenic in children, possibly in combination with other environmental agents, is also a concern. Studies in mice (Meija et al., 1997) indicate combined effects of lead and arsenic on the central nervous system that were not observed with either metal alone."[91]

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[88] Ko, S., Schaefer *et al*., *Relationships of Video Assessments of Touching and Mouthing Behaviors During Outdoor Play in Urban Residential Yards to Parental Perceptions of Child Behaviors and Blood Lead Levels*, 17 J. of Exposure Science and Environ. Epidemiology 47 (2007).

[89] EPA, Exposure Factors Handbook, 2011 Edition (http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252).

[90] "Draft Residual Risk Assessment for the Ferroalloys Source Category" (Oct. 2011) at 27-31, EPA-HQ-OAR-2010-0895-0046 (although the screening analysis showed mercury levels that were 4 times EPA's screening threshold and POM levels that were 60 times EPA's screening threshold, EPA did not perform a full multipathway analysis or add the multipathway risks to the inhalation risks for POM, which EPA also identified as an inhalation-based cancer risk driver).

[91] Cal. EPA, OEHHA, "Prioritization of Toxic Air Contaminants - Children's Environmental Health Protection Act, Arsenic and Arsenic Compounds" at Arsenic-2 (Part II) (Oct. 2001).

In addition, EPA evaluates total cancer risk (using the maximum individual risk or "MIR") and chronic non-cancer risk (using the target-organ specific hazard index "TOSHI") based on the combined exposure to pollutants with a common health impact.[92] EPA should apply these same principles to create a mechanism for assessing the total acute risk to chemical mixtures, such as a TOSHI, that aggregates the acute impacts on the same organ systems for all pollutants.

2. Assess the total cumulative risk burden from all pollutants.

EPA must create a metric to assess the total and cumulative risk burden, rather than only looking at each type of risk in a discrete, separate way.[93] EPA should be integrating its assessments and performing a "comprehensive risk assessment" as the NAS has emphasized.[94] After first assessing the total cancer, chronic non-cancer, and acute risks, for both inhalation and multipathway exposure, EPA also must create a metric to assess the total bundle of risks.[95] EPA must aggregate health risk for each pollutant, and each type of health risk, to create a cumulative risk determination for the individual "most exposed" to emissions as the Act requires.[96]

Unless and until EPA creates a combined health risk metric, it is unclear how it can make an ample margin of safety determination that is based on the full picture of health risk for a source category and that can be compared to other source categories. EPA must assess the full cumulative burden for public health. By failing to perform a full, cumulative risk assessment, EPA fails to gather the information needed to assess whether the risk to public health is acceptable under CAA § 112(f)(2).

C. Account for Multiple Sources.

EPA must assess and account for the cumulative impact and risk caused by exposure to multiple source categories' toxic air emissions. In many communities containing sources of toxic air emissions, there are many other nearby sources of toxic air emissions within the 3, 5, 10, and the full 50 km radius of EPA's residual risk assessment. Such exposures increase the vulnerability of a community to new and additional toxic air emissions, as discussed in Part I.E, above.[97] Further, EPA's own environmental justice analysis has found that sources of toxic air pollution listed under CAA section 112, such as lead smelters, chromium electroplaters, and many others frequently create disproportionate health risk for minority and lower income communities. This problem is exacerbated by the fact that multiple sources of pollution are more

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[92] *See, e.g.*, EPA, OAQPS, "Residual Risk Assessment for the Secondary Lead Smelting Source Category" at 26 (Dec. 2011), EPA-HQ-OAR-2011-0344-0160.
[93] *See, e.g.*, NAS 2009 at 177 ("The underlying scientific and risk-management considerations point to the need for unification of cancer and noncancer approaches in which chemicals are put into a common analytic framework regardless of type of outcome.").
[94] *Id.* at 131; *see also id.* at 132-33 (discussing related issues).
[95] Cal. EPA, OEHHA, "Cumulative Impacts," *supra* at 19-21, 25 (describing total "pollution burden" as sum of exposures, public health effects, and environmental effects); EPA, "Concepts, Methods and Data Sources," *supra*, at 4-42 to 4-46.
[96] 42 U.S.C. § 7412(f)(2).
[97] *See, e.g.*, NAS 2009 at 214.

likely to be more concentrated in minority and lower income communities, creating a serious environmental justice problem.[98]

Therefore, in addition to performing a cumulative assessment from each source category alone, EPA also must perform a cumulative analysis that considers source categories' individual impact and risk with that of other sources to which people are exposed.[99] EPA has acknowledged the importance of addressing multiple source exposures, by stating that it "understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility," and that it is "interested in placing source category and facility-wide HAP risks in the context of total HAP risks from all sources combined in the vicinity of each source."[100] And, EPA has also recognized this need in its recent risk report.[101] Yet, so far EPA has failed to follow through on this. Although EPA has looked at all sources within a source category, it generally has not looked at other exposures. Although EPA has calculated what it calls "facility-wide" risk for different sources collocated at the same address, it has not used that number to set standards, and it has ignored different sources across the street or in close proximity.[102]

EPA's failure to assess the combined, cumulative impact on health risk from multiple pollution source categories conflicts with the recommendation from the Scientific Advisory Board that in May 2010 urged EPA to incorporate cumulative risk into its residual risk analysis. The SAB stated that "RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area."[103]

To perform a cumulative risk or impact analysis, EPA should combine current baseline emissions, exposures, and health impacts in addition to those of the specific source category EPA is reviewing. The NAS explained the need for "[i]ncorporation of background additivity to account for . . . [a]dditional sources of exposure to the same chemical or to similarly acting chemicals (including endogenous sources). . . ."[104] As part of this analysis, EPA should aggregate or add the emissions for the most-exposed communities coming from: (1) the source category (including all individual sources within it); (2) facility-wide risk from collocated sources outside of this category; and (2) all other sources of toxic air pollution in the area.

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[98] *See, e.g.*, Cal. EPA, OEHHA, "Cumulative Impacts," *supra*.

[99] We support EPA's recognition of the need to assess whether the maximum exposed individual is exposed to emissions from more than one source *within* each source category, as it does using the AERMOD modeling tool. We also appreciate that EPA has considered facility-wide risk in some rulemakings. However, those assessments offer only part of the picture. And, even on both of these issues, EPA has provided very little information about what it included in such assessments. EPA often just states numbers found for facility-wide risk, without explaining where those numbers came from, how they were calculated, or what emission sources they cover.

[100] NESHAP: Mineral Wool Production and Wool Fiberglass Manufacturing, 76 Fed. Reg. 72,770, 72,786 (Nov. 25, 2011).

[101] U.S. EPA, "Concepts, Methods and Data Sources," *supra*, at xxxii (defining a cumulative risk assessment as including "aggregate exposures by multiple pathways, media and routes over time, plus combined exposures to multiple contaminants from multiple sources").

[102] *See* examples cited, *supra* note 11.

[103] SAB May 2010 at ii, *supra* note 62, at 10.

[104] NAS 2009 at 180 (explaining that this may require the use of default factors).

Virtually all of the existing federal air toxics standards (under section 112(d)) require periodic testing and monitoring, and this is something EPA must ensure is included in all rules as it updates them. Using these data, EPA can aggregate the community's exposure and assess the full health threats faced by the affected community, including from the source under review.

EPA must also consider the research that has already occurred to assess health risk from toxic air pollution in urban communities nationwide.[105] EPA should also draw on the OEHHA cumulative assessment approach.[106] EPA should consult with OEHHA and investigate the scientific approach it is using to address cumulative impacts, and consider and apply a similar science-based approach in residual risk assessments.

Further, the NAS has recommended that EPA evaluate "background exposures and vulnerability factors," as well as use "epidemiologic and toxicologic evidence" in its risk assessments.[107] Rather than separating an environmental justice analysis and considerations of inequality from the risk assessment, considering these factors as part of the cumulative risk assessment – because of the increased vulnerability created (as also discussed in Part I.E above) – would be a more effective, meaningful, and scientific approach.

In assessing a source category's emission contributions in affected communities and considering whether these contributions cause the most-exposed people to experience an unacceptable level of public health risk when combined with the existing baseline from past emissions, other HAP emissions, and the community's health status, EPA can describe and manage uncertainties, as it does and other federal agencies do for many other analyses.[108] Uncertainties do not justify failing to assess and address the severe cumulative harm and risk to local communities from air toxics sources. Rather, there is no excuse for treating an unknown amount of additional risk as a missing default, to use the NAS term.

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[105] *See, e.g.*, Rachel Morello-Frosch & Bill M. Jesdale, Envtl. Health Perspectives, *Separate and Unequal: Residential Segregation and Estimated Cancer Risks Associated with Ambient Air Toxics in U.S. Metropolitan Areas*, 114(3) Envtl. Health Perspectives 386 (2006) (assessing toxic air pollution cancer risk for 309 metropolitan areas encompassing 45,710 tracts); "National Air Toxics Program: The Integrated Urban Strategy," 64 Fed. Reg. 38,706, 38,738 (July 19, 1999).

[106] *See, e.g.*, Cal. EPA, "Cumulative Impacts," *supra*.

[107] NAS 2009 at 221-23 (discussing Menzie et al. 2007 model); *id.* at 230 (discussing the role of epidemiology and surveillance data).

[108] *See, e.g.*, 42 U.S.C. §§ 7475(a)(3), 7503(a)(1) (requiring a localized, cumulative assessment of whether or not a new or modified source's additional emissions will cause an attainment area to deteriorate, or will make it difficult for a nonattainment area to make progress toward achieving the national ambient air quality standards); *New York v. EPA*, 443 F.3d 880, 883 n.1 (D.C. Cir. 2006) (citing *New York v. EPA*, 413 F.3d 3, 11-14 (D.C. Cir. 2005)); *see also* 40 C.F.R. § 1508.27(b)(7) (requiring a consideration of "[w]hether the action is related to other actions with individually insignificant but cumulatively significant impacts. Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts"); *see also* 40 C.F.R. § 1508.7; *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 930 (9th Cir. 2008) (applying 16 U.S.C. § 1536(a)(2) to enforce the Endangered Species Act duty to ensure against jeopardy which includes the requirement to assess a newly proposed action in the context of all other impacts, and determine whether or not the specific action will "tip a species from a state of precarious survival into a state of likely extinction," or, where baseline conditions already jeopardize a species, whether it will "deepen[] the jeopardy by causing additional harm").

As a scientific and policy matter, where there is exposure to air toxic emissions beyond the individual source category, the level of total risk that is occurring, including the baseline health risk and the risk from other sources, is greater. Thus, the total risk that is unacceptable for the most-exposed person must in fact be lower for each source category that person is exposed to, because it combines with other risks to create a *total* risk from all regulated source categories which must be minimized. Looking at a source category's contribution of risk in isolation is equivalent to ignoring the facts and pretending other health risks are not occurring. EPA may not decide that it is okay for a person to be exposed at a higher level simply because they live in a community where they are exposed to multiple sources of air pollution. That is the opposite of what EPA is required to do – protect the people in local communities who are most exposed and most vulnerable to air pollution. It also conflicts with EPA's own commitment to consider and provide environmental justice to overburdened communities.

At minimum, until EPA develops a data-driven approach to comprehensively model cumulative risk or impacts from multiple sources, EPA must not treat multiple source exposure as a missing default, or ignored amount of health risk. EPA must incorporate an explicit default or uncertainty factor to adjust the degree to which each individual source category is contributing to the total risk experienced by the most-exposed individuals. For example, wherever there is evidence that the source category is contributing pollutants on top of a history of other exposures or is contributing pollutants in addition to other source categories, the "unacceptable" level of cancer, non-cancer chronic, and acute risk from the source category must be adjusted downward based on the number of other facilities contributing HAP exposure risks (such that no single source category could consume all of it, when the most-exposed person is exposed to many other source categories). For a source category in an area with up to 10 other HAP-emitting facilities, this default or uncertainty factor should equal at least 10, consistent with the common scientific use of this factor for other kinds of vulnerability.[109]

D. Account for Additional Risk and Uncertainty.

In addition to and related to many of the issues already discussed, EPA must stop treating various types of risk as zero when the science shows risk is present; simply because EPA has not yet developed a risk function for a pollutant, type of exposure, or type of risk, does not mean risk does not exist and can be ignored.[110] As the NAS explained, EPA should develop "explicitly stated defaults to take the place of implicit or missing defaults," and "[k]ey priorities should be development of default approaches to support risk estimation for chemicals lacking chemical-specific information to characterize individual susceptibility to cancer . . . and to develop a dose-response relationship."[111]

1. EPA must not treat risk as zero for a pollutant for which it has no reference value.

[109] For areas with more facilities, which cause an even greater level of health risk combined, the UF should be adjusted accordingly, *i.e.*, 11-20 facilities would result in an UF of 20, and more than 20 would result in an UF of 100, so the source category's contribution is no higher than 1/100 of the threshold.
[110] *See, e.g.*, NAS 2009 at 203-04, 207.
[111] *Id*. at 207.

As the NAS explained, it is a problem that "agents that have not been examined sufficiently in epidemiologic or toxicologic studies are insufficiently included in or even excluded from risk assessments" by EPA.[112] Many chemicals have no cancer slope factor, RfD, RfC.[113] It is not appropriate to treat such compounds "as though they pose no risk that should be subject to regulation."[114] The NAS has recommended that EPA develop "explicit defaults to use in place of missing defaults," including for its "untested-chemical assumption," *i.e.*, that a chemical with no reference value poses no risk.[115]

Where there is no reference value for a pollutant, EPA may not simply *ignore* health risks associated with these pollutants completely in its analysis by hiding behind uncertainty. Section 112 requires EPA to address and regulate all emitted HAPs. EPA states that "an understatement of risk for these pollutants at environmental exposure levels is *possible*," in its rulemakings due to the lack of reference values.[116] In fact, an understatement of risk for pollutants that are excluded from the analysis is *certain* because EPA has performed no quantitative assessment of health risk for those pollutants *at all*. The absence of a reference value means that EPA does not know by how much it is *underestimating* risk to human health, but it does know that its assessment is an underestimation.

In the absence of an available reference dose, EPA must, at minimum, add an uncertainty factor to account for the additional risk that a HAP likely causes, until such time as EPA does have a reference value to use. Using a protective uncertainty factor – developed based on the best available science – would allow EPA to satisfy its legal duty under section 112(f)(2) to prevent unacceptable health risk, and ensure an "ample margin of safety to protect public health."[117] The NAS has described an approach EPA can use to account for this risk, and explained that this approach "is based on the notion that for virtually all chemicals it is possible to say *something* about the uncertainty distribution regarding dose-response relationships."[118] For example, EPA can use information on chemical structure, available toxicologic tests and model or experimental data, and data on similar chemicals that have been well-studied.[119]

Section 112(f)(2) of the CAA creates a critical duty and opportunity for EPA to conduct a comprehensive and protective analysis of risk to public health and the environment. In view of this, it is a serious problem for EPA's analysis that some pollutants continue to have no reference values.[120] Over twenty years after the Clean Air Act was amended, sufficient studies for some pollutants have not been conducted to calculate reference doses, reference concentrations, or potency values. Moreover, the Integrated Risk Information System ("IRIS") review process has been bogged down for many pollutants as the Government Accountability Office recently

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[112] *Id*. at 193.
[113] *Id*. at 203.
[114] *Id.* at 193.
[115] *Id.* at 203.
[116] EPA, "National Emission Standards for Hazardous Air Pollutant Emissions: Group IV Polymers and Resins; Pesticide Active Ingredient Prod.; and Polyether Polyols Prod., Proposed Rule," 77 Fed. Reg. 1268, 1282 (Jan. 9, 2012) (emphasis added).
[117] 42 U.S.C. § 7412(f)(2).
[118] NAS 2009 at 203 (emphasis added).
[119] *Id.* at 204.
[120] *See, e.g.*, 77 Fed. Reg. 1268, at 1282.

documented.[121] As the Center for Progressive Reform ("CPR") has recognized, EPA should prevent the delay in this process from undermining its residual risk analysis for source categories under review.[122]

For pollutants currently under IRIS assessment, EPA must use the best available scientific information from the IRIS review during current rulemakings.[123] At minimum, EPA must account for the lack of reference values or the lack of an up-to-date final IRIS assessment rather than just allowing important rulemakings to go by without any consideration of health risk due to such pollutants.[124]

2. EPA must account for the cumulative risk of upsets and malfunctions, instead of ignoring this risk.

As another example of the problem of ignoring health risk in its assessment, EPA generally ignores the higher emissions caused by malfunction or upset emissions, which can accumulate and combine to increase public health impacts and risk. "Upsets are a significant problem for many areas, including rural ones, but they are a particular problem for the predominantly lower income communities of color surrounding many refinery and chemical complexes."[125] Malfunction or upset events increase emissions and thereby pose increased

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[121] U.S. Gov't Accountability Office, GAO-12-42, Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program 17-18 (2011).

[122] *See* Rena Steinzor *et al*., *Setting Priorities for IRIS: 47 Chemicals that Should Move to the Head of the Risk-Assessment Line*, Ctr. For Progressive Reform (Dec. 2010), (http://www.progressivereform.org/articles/IRIS_Priorities_1010.pdf. CPR's analysis of IRIS offers a critical expose of these problems. *EPA's IRIS: A Database With Blind Spots*, Ctr. For Progressive Reform, http://www.progressivereform.org/iris.cfm (last visited June 27, 2013). *See also* Gov't Accountability Office, GAO-11-278, "High Risk Series: An Update" (2011); Gov't Accountability Office, GAO-09-774T, http://www.gao.gov/new.items/d11278.pdf; Gov't Accountability Office, "EPA Chemical Assessments: Process Reforms Offer the Potential to Address Key Problems," (2009); Gov't Accountability Office, GAO-08-743T, http://www.gao.gov/new.items/d09774t.pdf; Gov't Accountability Office, "Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals" (2008); Gov't Accountability Office, GAO-08-440, 29, (2008), http://www.gao.gov/new.items/d08743t.pdf; Gov't Accountability Office, "Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System" (2008), http://www.gao.gov/new.items/d08440.pdf.

[123] Integrated Risk Information System (IRIS); Announcement of 2012 Program, 77 Fed. Reg. 26,751 (May 7, 2012).

[124] *See, e.g.*, Draft Residual Risk Assessment for the Mineral Wool Production and Wool Fiberglass Manufacturing Source Categories at 23 tbl. 3.1-1; id. at 30 tbl. 4.1-1 (Sept. 2011), EPA-HQ-OAR-2010-1042-0086 (due to lack of reference value for hydrogen fluoride (HF), antimony, and other pollutants, EPA failed to account for any health risk from these pollutants). Similarly, there is no reference value for lead, and no safe level of lead exposure. Although information exists regarding how EPA could try to address this (such as using California's benchmark for action of avoiding a blood-lead level increase of 1.0 ug/dL), EPA regularly assesses only whether a source, alone, will cause an exceedance of the 2008 Lead National Ambient Air Quality Standards, instead of evaluating how to prevent harm from the lead emissions of a a source category, in combination with other pollutants and other sources. *See, e.g.*, *id.* at 11; "Secondary Lead Smelting Residual Risk Assessment" at 12 (Dec. 2011), EPA-HQ-OAR-2011-0344-0160.

[125] Envtl. Integrity Project, Gaming the System: How Off-the-Books Industrial Upset Emissions Cheat the Public Out of Clean Air at 1-2 (Aug. 2004) (finding significant likelihood of an upset at refineries, chemical plants, gas plants and a carbon black plant, and finding that the resulting emissions release is many times higher than the amount of otherwise-reported annual emissions), http://www.environmentalintegrity.org/news_reports/Report_Gaming_System.php.

health risks which EPA must consider. Where control equipment fails, emissions could be at least 100 times greater (*e.g.*, in the circumstance where a control device has 99% efficiency, such that an uncontrolled release would cause 100 times the usual amount of emissions).

Failing to look at the true potential for spikes in emissions over a person's lifetime may underestimate acute risk, cancer risk and the amount of chronic risk based on pollutants that persist in the environment, such as PCBs, POM, lead, and cadmium. Ignoring these emission spikes is equivalent to treating additional health risk caused by exceedances as zero. EPA knows that there is additional risk from malfunctions and violations, and that this additional risk should not be ignored in risk assessments.

To assess the health risk from malfunctions, EPA has information available or can collect information on major sources' malfunction and violation histories.[126] Moreover, EPA regularly uses statistical methods and probability factors, which are readily available tools that EPA can also use to assess health risk due to malfunctions, to set clean air standards. Further, to calculate acute health risk, EPA uses what it calls a "worst case" scenario approach that attempts to account for some variability under the existing standard, which (although this does not fully do so) shows that the agency could similarly add a factor to account for malfunctions for acute and other types of health risk.

III. ACCOUNT FOR CUMULATIVE IMPACTS OF MULTIPLE EXPOSURES AND VULNERABILITIES BY SHIFTING THE LEVEL OF RISK WHICH TRIGGERS POLICY ACTION.

EPA has a longstanding policy of assuming that it is possible to find a safe or acceptable level of cancer and other kinds of health risks. Currently available science debunks this assumption because there is so much uncertainty built into EPA's risk assessments, and because EPA lacks information on so many pollutants. For communities overburdened by pollution, this policy is especially problematic.

As a major example, EPA should recognize that cancer risk from a major industrial source category of toxic air pollution (listed under CAA § 112) that is 100-in-1 million or less cannot be presumed safe or "acceptable." Since 1990, however, EPA has made this assumption. EPA based this assumption not on scientific information about cancer risk, but on an unusual study of people's perceptions of their own risk from 1988, known as the Survey of Societal Risk (July 1988), to consider various types of health risks at that time.[127] Using a comparison of cancer risk to other kinds of hazards Americans then faced in their daily lives, EPA effectively

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[126] *See, e.g.*, EPA, Enforcement and Compliance History Online (ECHO), www.epa.gov/echo; Kelly Haragan, Envtl. Integrity Project, "Gaming the System: How Off-the-Books Industrial Upset Emissions Cheat the Public Out of Clean Air" (Aug. 2004), 1-2, 5, http://www.environmentalintegrity.org/news_reports/Report_Gaming_System.php (finding significant likelihood of an upset at refineries, chemical plants, gas plants and a carbon black plant, and finding that the resulting emissions release is many times higher than the amount of otherwise-reported annual emissions and that "releases from upsets actually dwarf a facility's routine emissions.").

[127] Benzene Rule Docket No. OAQPS 79-3, Part I, Docket Item X-B-1, EPA Air Docket (cited at Nat'l Emission Standards for Hazardous Air Pollutants; Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants, 53 Fed. Reg. 28,496, at 28,512-13 (July 28, 1988)).

chose a number out of a hat that it would consider acceptable. EPA looked at an odd collection of risks, such as dangers from driving a car, and found that "the presumptive level established for MIR [maximum individual risk of cancer] of approximately 1 in 10 thousand is within the range for individual risk in the survey, and provides health protection at a level lower than many other risks common 'in the world in which we live.'"[128]

EPA has failed to revisit or update this number for the decades since, even though scientists have made breakthroughs on early-life exposure and children's vulnerability; biomonitoring and other data on adult body burdens of chemicals; the vulnerability of overburdened communities, including socioeconomic disparities; and on ways to analyze and control the impacts of pollutants on human health.

LANDMARKS SINCE 1990

1990 Clean Air Act Amendments required technology-based control for hazardous air pollutants and 8-year review of residual health risk to ensure protection of communities.

1993 National Research Council published *Pesticides in the Diets of Infants and Children*, finding that children are not little adults, and have greater exposures and susceptibility.

1994 President Clinton signed Executive Order 12898 on Environmental Justice.

1996 Food Quality Protection Act passed unanimously with a 10-Fold Children's Safety Factor.

Safe Drinking Water Act amendments required attention to susceptibility of children.

EPA announced a new National Agenda to Protect Children's Health.

1997 President Clinton signed the Children's Environmental Health Executive Order 13045.

2000 EPA first published *America's Children and the Environment.*

2009 National Academy of Science published *Science and Decisions: Advancing Risk Assessment*.

2009 Then-EPA Administrator Jackson declared environmental justice and children's health priorities.

2011 EPA announced Plan EJ 2014 including rulemaking and science goals.

[128] 54 Fed. Reg. 38,044, 38,046 (Sept. 14, 1989) (emphasis added) (quotation omitted).

It is time for EPA scientists and science policymakers to revisit the outdated assumption EPA makes regarding what level of cancer risk triggers policy interventions. EPA's own policy regarding carcinogens recognizes that they have no safe threshold of exposure. EPA has appropriately recognized that cancer risks add up to increase lifetime risk. EPA cannot reconcile what it knows – and does not know – about carcinogens with its outdated presumption that a cancer risk of 100-in-1 million is acceptable.

Importantly, EPA's presumption regarding cancer risk ignores the experience of communities exposed to multiple sources and types of sources of pollution. Even if some level of risk might otherwise be acceptable, that cannot be assumed to be true for communities exposed to more than one source that is causing that level of health risk. EPA has a responsibility to address the science on cumulative impacts and risk and update its assumptions accordingly, to acknowledge that cancer risks below 100-in-1 million cannot be presumed safe.

EPA should also reform how it evaluates chronic and acute hazard indices, in which a risk number below 1 does not result in policy changes or standards. EPA should instead factor in uncertainties and vulnerability factors that adjust the "acceptable level of risk." This is currently done under FQPA when EPA uses factors to determine a Target Margin of Exposure and risks below this level warrant increased scrutiny and changes to allowable exposures.[129]

In the face of increasing evidence which challenges the assumption of a safe or acceptable level of exposure, EPA should also consider reforming risk assessments to support reducing risks to the lowest possible level, to protect public health, rather than suggesting that there is a safe or acceptable level.

[129] *See, e.g.*, EPA, Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, Proposed Rule, 76 Fed. Reg. 3422, 3427 (Jan. 19, 2011) (explaining use of MOE).

APPENDIX B: KEY SOURCES

In general, for further information on each of the topics discussed here, the agency should consult the following sources:

1. George Alexeef *et al.*, *A Screening Method for Assessing Cumulative Impacts*, 9 Int'l Journal of Envtl. Research and Pub. Health 648-659 (2012); doi:10.3390/ijerph9020648.

2. Ramya Chari *et al*., Integrating Susceptibility into Environmental Policy: An Analysis of the National Ambient Air Quality Standard for Lead, 9 Int'l Journal of Envtl. Research Pub. Health1077-1096 (2012).

3. Peter L. deFur *et al.*, Vulnerability as a Function of Individual and Group Resources in Cumulative Risk Assessment, 115(5) Envtl. Health Perspectives, 817-24 (2007).

4. Kelly Haragan, "Gaming the System: How Off-the-Books Industrial Upset Emissions Cheat the Public Out of Clean Air," Envtl. Integrity Project (Aug. 2004), http://www.environmentalintegrity.org/news_reports/Report_Gaming_System.php.

5. Sarah Janssen *et al*., Strengthening Toxic Chemical Risk Assessments to Protect Human Health, NRDC, Sci. & Envtl. Health Network, Issue Paper (Feb. 2012).

6. Kristen Lombardi, "'Upset' emissions: Flares in the air, worry on the ground," The Ctr. for Pub. Integrity, http://www.publicintegrity.org/2013/05/21/12654/upset-emissions-flares-air-worry-ground.

7. Paul Mohai, Byoung-Suk Kweon, Sangyun Lee & Kerry Ard, *Air Pollution Around Schools Is Linked to Poorer Student Health And Academic Performance*, 30(5) Health Affairs 852 (published online May 4, 2011; 10.1377/hlthaff.2011.0077).

8. Rachel Morello-Frosch *et al.*,, Understanding *the* Cumulative Impacts of Inequalities In Environmental Health: Implications for Policy, 30(5) Health Affairs (2011).

9. Rachel Morello-Frosch & Bill M. Jesdale, Separate and Unequal: Residential Segregation and Estimated Cancer Risks Associated with Ambient Air Toxics in U.S. Metropolitan Areas, 114(3) Envtl. Health Perspectives 386 (2006).

10. Nat'l Research Council, Nat'l Acad. of Sciences, *Science and Decisions: Advancing Risk Assessment* (2009).http://www.nap.edu/catalog.php?record_id=12209.

11. Nat'l Acad. of Sciences, *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (2008).

12. Office of Envt'l Health Hazard Assessment, "Air Toxics Hot Spots Risk Assessment Guidelines*:* Technical Support Document for Exposure Assessment and Stochastic Analysis, Scientific Review Panel Draft," Cal. EPA (June 20, 2012), http://oehha.ca.gov/air/hot_spots/SRP/index.html.

13. Office of Envt'l Health Hazard Assessment, California Communities Environmental Health Screening Tool (CalEnviroScreen 1.0), Cal. EPA (April 2013), http://oehha.ca.gov/ej/ces042313.html.

14. Office of Envt'l Health Hazard Assessment, Technical Support Document for Cancer Potency Factors: Methodologies for Derivation, Listing of Available Values, and Adjustments to Allow for Early Life Stage Exposures, Cal. EPA (May 2009), http://oehha.ca.gov/air/hot_spots/tsd052909.html.

15. Office of Envt'l Health Hazard Assessment, Appendix J: "In Utero and Early Life Susceptibility to Carcinogens: The Derivation of Age-at-Exposure Sensitivity Measures," Cal. EPA (May 2009), http://oehha.ca.gov/air/hot_spots/tsd052909.html,http://oehha.ca.gov/air/hot_spots/2009/AppendixJEarly.pdf.

16. Office of Envt'l Health Hazard Assessment, "Cumulative Impacts: Building a Scientific Foundation," Cal. EPA (Dec. 31, 2010), http://oehha.ca.gov/ej/pdf/CIReport123110.pdf.

17. Office of Envt'l Health Hazard Assessment, Child-specific Health Reference Doses, Cal. EPA (June 22, 2009), http://oehha.ca.gov/public_info/public/kids/chrdtable.html

18. Dawn Reeves, Sierra Club Calls For EPA To Address Cumulative Impacts Under NEPA, Inside EPA, Vol. 33, No. 5 (Aug. 31, 2012).

19. James L. Sadd *et al*., Playing It Safe: Assessing Cumulative Impact and Social Vulnerability through an Environmental Justice Screening Method in the South Coast Air Basin, California, 8 Int'l Journal of Envtl. Research and Pub. Health 1441-1459 (2011).

20. Elizabeth Shogren & Robert Bennincasa, "Baton Rouge's Corroded, Overpolluting Neighbor: Exxon Mobil," Nat'l Pub. Radio, (May 30, 2013, 4:29 PM), http://www.npr.org/2013/05/30/187044721/baton-rouge-s-corroded-overpolluting-neighbor-exxon.

21. Letter from Pamela Shubat, Chair, Children's Health Protection Advisory Committee, to Lisa Jackson, Administrator, EPA (Oct. 21, 2010), http://yosemite.epa.gov/ochp/ochpweb.nsf/content/CHPAC_NRC_Report.htm.

22. Sierra Club, "The State of Detroit's Environment: An Initial Assessment Using the Framework of Environmental Justice (2013).

23. Letter from Sierra Club North Star Chapter to William Lynott, Minnesota Pollution Control Agency, (on file with author).

24. Jason Su *et al.*, *An Index for Assessing Demographic Inequalities in Cumulative Environmental Hazards with Application to Los Angeles, California*, 43(20) Envtl. Sci. Tech. 7626–7634 (2009)).

25. U.S. EPA, “Report of the Task Group of the Children’s Health Protection Advisory Comm. on America’s Children & the Env’t,” 3d Ed. (2010)

26. U.S. EPA, Sci. Advisory Bd., Review of EPA’s draft entitled, “Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA’s Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing,” EPA-SAB-10-007 (May 2010).

For additional reference, commenters have also attached a bibliography on cumulative impacts and a bibliography on environmental justice, prepared by the Coalition For A Safe Environment, for EPA’s review and consideration.

APPENDIX C: SCIENTIFIC AND POLICY DEVELOPMENTS

Summary of Major Developments Relevant to
Children's Health Risk and Environmental Justice

In recent decades, many major scientific and policy developments have occurred, all directing that the federal government – and, in particular, EPA – must fully account for health risk to children due to early-in-life exposure, and for the need to consider and provide environmental justice. Science now shows that "[e]nvironmental contaminants can affect children quite differently than adults, both because children may be more highly exposed to contaminants and because they may be more vulnerable to the toxic effects of contaminants."[130]

In 1993, the National Research Council published *Pesticides in the Diets of Infants and Children*, finding that children are not little adults, and have greater exposures and susceptibility.[131]

In 1994, President Clinton signed Executive Order 12898 on Environmental Justice.[132]

In 1996, Congress enacted the Food Quality Protection Act and the Safe Drinking Water Act amendments, which explicitly require consideration of the susceptibility of children and due to early exposure.[133] This same year, EPA announced a new National Agenda to Protect Children's Health.

In 1997 the President issued the Children's Environmental Health Executive Order (No. 13045) on the need to address risks to children.[134]

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[130] U.S. EPA, "America's Children & the Env't," 3d Ed. at 8 (2013).
[131] Nat'l Research Council, "Pesticides in the Diets of Infants and Children" (1993); *see also* Hugh A. Barton *et al.*, *Assessing Susceptibility from Early-Life Exposure to Carcinogens*, 113(9) Envtl. Health Perspectives 1125 (2005); Dale Hattis *et al.*, *Age-Related Differences in Susceptibility to Carcinogenesis: a Quantitative Analysis of Empirical Animal Bioassay Data*, 112(11) Envtl. Health Perspectives 1152 (2004).
[132] Exec. Order No. 12898, 3 C.F.R. 859 (1995), *reprinted as amended in* 42 U.S.C. § 4321 (1998).
[133] 21 U.S.C. § 346a(b)(2)(C) (requiring that, in taking certain actions on pesticides "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure *shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children*") (emphasis added); 42 U.S.C. § 300g-1(b)(1)(C) (requiring that, in selecting unregulated contaminants for consideration, EPA "shall take into consideration, among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as *infants, children, pregnant women*, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population") (emphasis added); *id.* § 300j-18(a)(1) (requiring EPA to "identify groups within the general population that may be at greater risk than the general population of adverse health effects from exposure to contaminants in drinking water. The study shall examine whether and to what degree *infants, children, pregnant women*, the elderly, individuals with a history of serious illness, or other subpopulations that can be identified and characterized are likely to experience elevated health risks, including risks of cancer, from contaminants in drinking water. . . .") (emphasis added).
[134] Exec. Order 13045, 62 Fed. Reg. 19,885 (Apr. 21, 1997).

In 2000, EPA first published *America's Children and the Environment*, which it has since updated.[135]

In 2006, EPA issued new guidance on protecting children from environmental health risks as part of the rulemaking process.[136] Among other things, this Guide, at 8, recognized the problem of disproportionate risk to children because they may be more sensitive to pollution and exposed at a higher rate than adults because of their developmental stage. This Guide also recognized the need "to think in terms of the broad range of early life, pre-natal and post-natal, environmental exposures that may affect the incidence of disease or alter development."[137]

In 2008, EPA updated the Child-Specific Exposure Factors Handbook.[138]

In 2008 and 2009, the major National Academy of Sciences reports – *Science and Decisions: Advancing Risk Assessment* ("NAS 2009"), and *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (2008) – were released, re-emphasizing the importance of addressing real-world risk to children and cumulative health risk.

In 2009, EPA Administrator Jackson declared environmental justice and children's health priorities.

In 2010, EPA Administrator Jackson issued *EPA's Action Development Process: Interim Guidance on Considering Environmental Justice During the Development of an Action*.[139]

In 2011, EPA Administrator Jackson announced Plan EJ 2014 including rulemaking and science goals to finally achieve the goals of the 1994 Environmental Justice Executive Order.[140] EPA continues to work to issue guidance that will advance these goals.

In addition, in recent years, EPA's Children's Health Protection Advisory Committee has recommended addressing the developmental origins of adult disease that come from childhood exposure to air pollution and other environmental contaminants.[141] Similarly, the Committee has

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[135] U.S. EPA, "American's Children and the Env't" (3d ed. 2013), http://www.epa.gov/opeedweb/children/publications/index.html.
[136] U.S. EPA, "Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children" (2006), http://yosemite.epa.gov/ochp/ochpweb.nsf/content/ADPguide.htm/$File/EPA_ADP_Guide_508.pdf.
[137] *Id.*
[138] U.S. EPA, Child-Specific Exposure Factors Handbook (2008).
[139] U.S. EPA, "EPA's Action Development Process: Interim Guidance on Considering Environmental Justice During the Development of an Action" (2010). http://www.epa.gov/compliance/ej/resources/policy/ej-rulemaking.html.
[140] Plan EJ 2014, U.S. EPA, http://www.epa.gov/compliance/ej/plan-ej/index.html.
[141] U.S. EPA, *Report of the Task Group of the Children's Health Protection Advisory Comm. on America's Children & the Env't*, 3d Ed. (2010).), http://yosemite.epa.gov/ochp/ochpweb.nsf/content/ACETask.htm/$file/ACE%20Task%20Group%20Report.pdf.

recommended that EPA incorporate a more robust analysis of childhood and pre-natal exposure to environmental contaminants into its risk assessment method.[142]

The Science Advisory Board (SAB) has also urged EPA to address the greater risk to children from hazardous air pollution.[143] As the SAB further explained: "California's Office of Environmental Health Hazard Assessment (OEHHA) has very recently updated its methodology in ways that could affect the development of RfC and URE (unit risk estimate) values. EPA should examine these developments to make sure that the RTR process adequately covers children's risks."[144]

Finally, during the last decade, OEHHA has also released a number of groundbreaking scientific determinations and protocols to consider and address children's health, early life exposure, and cumulative impacts, which are cited in this document, above, and are all available at http://oehha.ca.gov/.

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[142] Letter from Pamela Shubat, Chair, Children's Health Protection Advocacy Council,CHPAC to Lisa Jackson, Administrator, U.S. EPA, (Oct. 21, 2010) ("CHPAC recommends that EPA staff scientists participating in the upcoming discussions bring the concern of early life stage exposure and sensitivity to the conversations that will take place concerning optimizing risk assessment practice."), http://yosemite.epa.gov/ochp/ochpweb.nsf/content/CHPAC_NRC_Report.htm.

[143] U.S. EPA, Sci. Advisory Bd., Review of EPA's draft entitled, "Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing, EPA-SAB-10-007 (May 2010), at 7 (stating that "an overarching concern with the Agency's chronic inhalation exposure estimates is that children's exposures do not appear to have been adequately addressed"); *see also id.* at 34 n.13 ("In particular is the question of whether the interindividual variability factor for non-carcinogens and the standard cancer unit risk derivation adequately covers children. If it does not, it is a potentially significant uncertainty given the greater intake rate of children via inhalation and sensitivity to carcinogens and other toxicants.").

[144] *Id.*

APPENDIX D: CHILD-SPECIFIC NON-CANCER CHART

Non-Cancer Health Risk:
Comparison of Cal. EPA OEHHA Child-specific health reference values to U.S. EPA reference values

Chemical	OEHHA Child-health Reference Dose (chRD) or value*	U.S. EPA Chronic Oral Reference Dose (RfD)	Difference Between OEHHA and U.S. EPA	Order of Magnitude Difference between OEHHA and U.S. EPA
Atrazine	0.006	0.035	6	1
Cadmium	0.000011	0.0005 (water)	45	1
		0.001(food)	91	2
Chlordane	0.000033	0.0005	15	1
Chlorpyrifos	0.0001	0.0003	3	-
Deltamethrin	0.0001	0.01	100	2
Heptachlor	0.00003	0.0005	17	1
Heptachlor epoxide	0.000013	0.000013	1	-
Manganese	0.03	0.14	5	1
Methoxychlor	0.00002	0.005	250	2
Nickel	0.011	0.02	2	-
Pentachlorophenol	0.001	0.005	5	-
Lead	OEHHA action level*	*EPA has not updated its action levels; CDC has reduced (2012).*		
	1 (as a blood-level increase)	10 (5 - as a total)	10 (5 - as a total)	1

* All units are in mg/kg-day except lead which is in µg/dL blood. The lead value is not a dose. For lead this is a health benchmark indicating the increase in a child's blood lead concentration showing protective action is needed.

Source: Office of Environmental Health Hazard Assessment (OEHHA), Cal. EPA
(Table of all child-specific reference doses finalized as of 06/22/09, http://oehha.ca.gov/public_info/public/kids/chrdtable.html)

Appendix E:
STORIES FROM COMMUNITIES OVERBURDENED BY POLLUTION

Cynthia Babich, Del Amo Action Committee, Torrance , CA (Los Angeles County):

I've been working in my community for 23 years. For us, it's easy to see that we have multiple impacts, but the EPA has yet to take action.

I work in an old industrial WWII complex in a part of unincorporated Los Angeles County. Most of the people in the community are Latino and comprised of multigenerational immigrants. We are surrounded on three sides by industry: Dow Chemical Plastics and Exxon Mobil are on a list of top 10 emitters in the country. There are two Superfund sites—some of the more toxic sites in the country. One of the sites is Montrose Chemical Corporation of California,[145] at one time the largest manufacturer of DDT in the county. Montrose disposed of its manufacturing waste in a drainage ditch that ran alongside the plant property. DDT contaminated the entire community, because they used to grind it outside, and the wind blew it right into the community. Most of it settled into people's attics 50, 60 years ago, and it continues to poison them to this day. Next door to Montrose is the other Superfund site, Del Amo, which was a synthetic rubber plant during WWII. When they were making tires for the war planes, they would take the waste product and dump it into unlined pits, contaminating the soil and groundwater. The vapors from the soil escape into buildings and homes today.

We also have three groundwater plumes that are all being looked at separately because they are from different facilities. We have the plumes coming from the two Superfund sites, and a huge one from Exxon Mobil refinery and another one from Jones Chemical, a chlorine transfer station. If there was a hole, someone filled it—whether it was DDT, construction debris, or metal slag. Not to mention, this community is adjacent to two freeways. We've been calling for these toxic sources to be looked at combined for years.

When I moved into my neighborhood, I looked for everything except toxic waste sites. Soon after moving, I started getting fistulas, and I had heart problems and trouble breathing, and it took so long for the doctors to figure out what was wrong. At one point, my husband I thought I was going to die. We didn't know that the house we had moved into abutted a waste pit site and technical grade DDT was buried in our backyard. All the time I was thinking, "People get sick—it's the law of averages." When I was home healing from one of my surgeries, I found out about the Superfund sites. And then I got upset. This wasn't the law of averages, I was being poisoned. People knew about this and did nothing. Not long after this discovery, doctors found a dermoid cyst on my ovary and I had to get it removed. Now, I am unable to have children. When I go into the neighborhood to work, my face breaks out—I always get rashes. My husband operates his machinery repair business, and now gets violently ill. It's difficult for me to watch someone to get sick like that, especially my husband.

Most people in this community are very concerned about our health. Our group has done our own studies by going door-to-door, and found that individuals in 1 in 4 homes have severe asthma problems. The community has higher than state average rates of asthma and respiratory issues. The symptoms that most people reported were bloody noses, rashes, vomiting, miscarriages, and joint pains. Twin boys were born in 1994 to a family born near the Montrose Superfund site. One was born with hypospadias, the other twin has developmental problems. One family had an infant die, and not long after, another was born without a brain stem.

[145] http://industriallosangeles.org/sites/montrose.html

Until the EPA measures the cumulative impacts of pollution, my community will suffer. People aren't asking for much—they just want to be able to live in our community, breathe air, put a glass under the tap and not want to think about whether it's contaminated or not.

It is upsetting that no one is looking at the cumulative impacts when all of this is happening and has happened to us.

Northern Delaware
Amy Roe, Conservation Chair, Sierra Club, Delaware Chapter

In northern Delaware, where I live, the air is unsafe to breathe. Ozone action days are commonplace and toxic releases from the numerous chemical plants and the nearby oil refinery occur regularly. The groundwater in eastern New Castle County has been contaminated, and just this month a drinking water well near the town of New Castle was closed because of 1,4-dioxane from a nearby Superfund site. The fish in our rivers and streams are unsafe to eat and most of the water bodies in New Castle County have a "no consumption" advisory. We are forced to endure the legacy pollution from past manufacturing and hazardous waste disposal, while new pollutants are added to our environment from existing facilities. This month I learned that my city has been negotiating to build a 248 MW power plant at the edge of my neighborhood, just a few blocks away, and a stone's throw from the playground where I played on the swings as a child. Past and present threats to public health are being added to with plans for future development. It's hard to keep up with the extent of the risk in the heart of America's chemical industry.

The regulatory oversight of air and water pollution needs dramatic improvement. The response that I have received from state regulators for air pollution concerns that made me ill and nauseated during the restart of the Delaware City Refinery was that the "air" I am breathing is just "air." The air that I am breathing is not just air! It is filled with fine particles and toxic vapors from many industrial facilities including, but not limited to, the refinery, Formosa Plastics, FMC Biopolymer, AI Dupont Sulfuric Acid Regeneration Plant, Kuehne Chemical Company, DuPont Edgemoor and the DuPont Experimental Station.

The EPA has the ability to update its approach to use the best available scientific information for cumulative risk, including under the Clean Air Act. It is the cumulative risk from multiple sources of exposure that concerns me most. Each plant and factory has mastered the art of blaming the others nearby for foul smells and pollution. Because we are surrounded by so many factories and chemical plants, no one takes responsibility for air pollution, water pollution, or the contamination of our fish. The cumulative risk of exposure is not used to cap pollution in our area, and new projects seem to pop up all the time. State regulators have bought into this passing of the blame, by allowing permits for increasing amounts of pollution because, as individual sources, they are seen as small amounts that are insignificant to the whole. Our regulators do not have to take a holistic approach, so they do not.

Science-based standards for cumulative risk assessment would result in the dramatic improvement of our lives and health. It would dramatically improve the way that pollution standards are assessed to consider the health impacts to our communities as part of the regulatory process. We can take steps to eat right, to exercise, and to be as healthy as possible, but we cannot take individual steps to shield ourselves from the polluted landscape that surrounds us. We need your help to improve our lives. Please assess the full impact of pollution on our communities and increase our protection.

Midlothian, Texas

As the self-proclaimed cement capitol of Texas, Midlothian is home to three major cement manufacturing facilities. Texas Industries (TXI), Holcom, and Ash Grove contaminate the air with a combined yearly total of 57 million pounds of mercury, nitrogen oxides, sulfur dioxide, and other dangerous chemicals. Gerdau Ameristeel, a large steel plant, is adjacent to TXI's cement plant. Some of the fuel sources used by these plants were approved without an opportunity for public comment or requirements for testing emissions and cumulative impacts.

The cumulative effects of the aforementioned sources are of great concern to community residents who are exposed to the resulting combined air contaminants.

After moving to Midlothian, Texas in July 2001, "my three children and I got sick," says former resident Alex Allred:

> "Within a few months of our move, my two-year old son was constantly in and out of the hospital—first, with bronchitis, then pneumonia, then double bronchitis. It was not until I began speaking to school nurses, other parents, and at last, a physician at Children's Medical Center in Dallas that we understood. The air in Midlothian was literally harming our child. My son's elementary school would go on to be named in the upper 1% of most toxic elementary schools in the nation. After 12 years of one health crisis after the next, we relocated to Waxahachie, Texas, only 20 miles south of Midlothian. Within a week of moving, I noticed dramatic changes to Tommy's health, and within two months of moving, my son was off half of his medicines. I would say it's a miracle but it is not. It is a sad reality of where we were living, and now, we can all breathe easier—no pun intended. Not only are we saving Tommy's life by moving away from the cement plants but we are saving money as well—I spent roughly $10,000 on medical expenses while living in Midlothian. Cement plants often talk about the economics of 'business as usual,' forgetting the cost of human life and suffering."

Scientific data support residents' concerns. The Agency for Toxic Substances and Disease Registry (ATSDR), which has been evaluating health risks in Midlothian, stated in its recent report entitled "Assessing the Public Health Implications of the Criteria (NAAQS) Air Pollutants and Hydrogen Sulfide" that "...sufficient information exists to warrant concern for multiple air pollutant exposures to sensitive individuals …." In its study, ATSDR found that ozone exposure in recent years has reached harmful levels for active children and adults, and people with asthma. Additionally, ATSDR emphasized a need for more scientific research in order to fully understand the cumulative impacts of multiple pollutants.

Assessing cumulative impacts is also important to individuals downwind of the Midlothian plants.

Dallas-Fort Worth area resident Becky Bornhorst is a volunteer for Downwinders at Risk:

> "My family enjoys outdoor activities such as sailing, canoeing, and swimming in Texas lakes and rivers, but such recreation is already curtailed by the fact that Texas has fish advisories or bans on 22 bodies of water." (Joe Poole Lake, where her family enjoys recreation activities was recently found to have a mercury level of .5ppm, just under the Texas Department of Health warning level of .7ppm.) "Mercury poisoning is a threat to me and my family when we are at the lake, the supermarket, or just breathing when the wind is blowing from the wrong direction," says Bornhorst. "We cannot escape it."

Houston Ship Channel, Houston, TX:

Since 1988, Air Alliance Houston has worked to reduce air pollution in the Houston region and protect public health and environmental integrity through research, education, and advocacy. Air Alliance is the Houston region's leading environmental health and air quality nonprofit. Air Alliance's vision is clean air so our economy, quality of life, and children can thrive.

A significant amount of the organization's work has focused on environmental justice issues in communities along the Houston Ship Channel. The Ship Channel hosts one of the largest concentrations of petrochemical facilities in the world, which in addition to the area's refineries, other industrial facilities, and high traffic of shipping barges and diesel trucks, leads to poor regional air quality and complex health and environmental challenges.

As Adrian Shelley, Executive Director of Air Alliance Houston, explains, "The communities of the Ship Channel disproportionately suffer the impacts and are not enjoying the opportunities of these chemical facilities."

The negative health impacts on these communities, which include overwhelmingly low income communities of color, are undeniable. A study of nearly 300 residents by Air Alliance in partnership with the Healthy Port Communities Coalition conducted between March and April 2013 found that communities near the Port of Houston experience higher than average rates of allergies, cancer, and respiratory illnesses. In comparison to state statistical averages, residents near the Port of Houston reported rates of asthma twice as high in adults and children, and reported rates of cancer ten times as high. Eighty-six percent of respondents expressed concern about pollution from local refineries in the survey, and 89% of respondents expressed concern about the effects of pollution on their health. Problematically, 54% of respondents did not have health insurance and nearly half of residents have an unemployed household member. The combination of high pollution exposure and lower access to health care in this community shows the need for EPA to look at and reduce the cumulative impacts these environmental justice communities face.

Port Arthur, Texas

Port Arthur, a small town with just under 60,000 residents located 90 miles south of Houston on the Gulf Coast of Texas, hosts a large number of industrial sources that release some of the harshest toxic contaminants for public health. Heavy metals and toxic chemicals are released into the air by the Valero Port Arthur Refinery, Huntsman Petrochemical, and the Chevron, as well Flint Hills Resources LLC. Nearby in East Port Arthur, Total Petrochemicals USA, Premcor Refining, and BASF Fina Petrochemicals. Motiva Enterprises, owned jointly by Shell Oil Products and Saudi Refining, Inc. and located in Port Arthur, is the largest oil refinery in the United States.

Right across the fence-line from Motiva Enterprises, are the residents of Carver Terrace, a local community on the West Side of Port Arthur. Largely African-American and low income, the approximately 200 families of this community have long experienced the symptoms of the airborne toxic chemicals, marked by marginally higher incidences of asthma, reparatory illnesses, and cancer than state statistical averages.

"People are breathing benzene out here," says Hilton Kelley. "That's a known carcinogen. They're breathing sulfur dioxide, a toxin that messes with your respiratory system—people call that the rotten-egg smell. Clean, breathable air is a basic human right the folks out here have been deprived of."

Hilton Kelley is the Founder and CEO of Community In-Power & Development Association, Inc. (CIDA). Kelley spent most of his childhood and currently lives in the town of Port Arthur.

Describing an example experience, "The odors from the refineries were pungent," Kelley recalled in an interview with Oprah Magazine in 2011.[146] "There was a large number of people sick with cancer and respiratory problems. Kids were just running, unsupervised, in the streets. It seemed all anybody could do was pray."

This disparate impact of negative health effects related to industrial pollution is partly a function of inequality. Refineries have expanded their profits and kept the price of gas low in part by refusing to invest in pollution control equipment at the expense of the health of local communities.

To bring awareness to these inequalities, Kelley and CIDA began to challenge the regulatory agencies, and the policies and environmental violations of the plants that loom over the community. Over the last decade, Kelley has helped set Port Arthur's West Side neighborhood on a healthier, more sustainable path. It has been a long road – and still is, for those living next door to some of the petrochemical facilities and refineries that supply other parts of the United States, but Kelley pushes on. "These are my people," said Kelley. "They were my teachers, my coaches. They go to my church. These could be my own kids. I really need to be here."

A serious problem Kelly and CIDA have long faced is the fact that it is so difficult to get anyone to look at the whole impact of all of the polluting sources in Port Arthur, TX. Although EPA recently named Port Arthur an "Environmental Justice Showcase Community,"[147] local residents are still waiting for meaningful, lasting relief from petrochemical flaring and other kinds of pollution that combine each day in their local air and environment.

Louisiana Bucket Brigade, Anna Hyrbyk

We work with communities that live on fence-lines of oil and gas industry throughout the state. Our mission is to use grassroots action to create informed, sustainable communities that are free from industrial pollution. The "Bucket" is an EPA-approved bucket kit that tests for organic compounds. This is similar to something EPA regulators normally use. We train communities to use the buckets, and we send off the air samples into labs.

Right now we are active in two communities that are surrounding refineries: Exxon Mobil refinery in Baton Rouge and Calumet Lubricants refinery in Shreveport. Both of those communities are large urban areas. Shreveport has 56,000 people living within two miles of the plant. Baton Rouge has 59,000. In both cases, the large majority of the population is African American and the poverty level is very high. In both communities, roughly 50% of children are living in poverty. Parish-wide, child poverty is nearly half of that.

The individuals that work in the plant do not live anywhere near these facilities. If people in the community are able to secure the jobs in these factories, they are contracting jobs that are only temporary,

[146] http://www.oprah.com/spirit/Environmental-Activist-Hilton-Kelley-Port-Arthur-Texas.
[147] http://www.epa.gov/compliance/ej/grants/ej-showcase.html

offering low pay and no health benefits. These temporary jobs are also the most dangerous. For example, they might be asked to clean a tank, but are not told what was in the tank, or given any protective gear to clean it in. Even though the wages are comparatively high, they tend to leave after not very long, because they soon learn that they are putting their lives at risk.

People in these industrial communities are very concerned about their health. People are most concerned about respiratory issues and cancer. For people living near these facilities, whenever there is a strong odor being emitted, it's pretty much a given that this will cause an associated health issue. Because of this, people are afraid to go outside. Many times, people have reported that they've been out barbecuing on holidays, and yellow or black soot has fallen out of the air and all over the food and their kids. The younger kids that can't stand to stay inside all day often walk through the neighborhood with their shirts over their noses. For more details, see the reports available from the iWitness Pollution Map, http://oilspill.labucketbrigade.org.

It is very important for EPA to start assessing the cumulative impacts of multiple sources, particularly in the city of Baton Rouge. Currently, they are permitting by facility and not looking at the cumulative impact of the 19 chemical plants all being in one area, and with 59,000 people surrounding them. When you're only looking at one facility or one chemical at a time, you're never going to be able to protect the people who live around these types of complexes from the full impact of all of the sources and all of the pollution.

Cancer Alley, Louisiana:

The 80 mile stretch of Mississippi River between Baton Rouge and New Orleans, once revered by Mark Twain, is now dubbed "Cancer Alley."[148] This Louisiana area has the highest concentration of manufacturers, users, and disposers of toxic chemicals in the nation.[149] Hundreds of industrial plants are located near low-income communities of color and have been spewing out dangerous air toxins for decades.[150] The residents experience high rates of asthma, cardiovascular disease, diabetes, infant mortality, and cancer, including rare childhood cancers.[151] But the struggle to alleviate the strain of the cumulative effects of the pollution is continually impeded.

One iconic example is Convent, a mostly African American community, where 13.8% of the residents live below the poverty line.[152] Convent is on the East bank, and is the site of a new Nucor Steel plant, currently under construction. Sierra Club has raised a number of concerns during the permitting process about the impact of this plant on the community. Convent also is near the Motiva 'Donaldsonville Plant; a 'mid-stream' grain transfer facility; an Occidental Chemical Corporation facility producing Chlorine; and 2 large Fertilizer plants: one directly across the Mississippi River, and one downstream about 1.5 miles, which according to EPA documents, "may contain significant quantities of naturally occurring radioactive materials (NORM)."

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[148] H2G2, *supra*, note 49
[149] Kluber, "Cancer Alley and Infant Mortality," *supra*, note 50
[150] H2G2, *supra* note 49.
[151] Kluber, "Cancer Alley and Infant Mortality," *supra* note 50, at 1.
[152] U.S. Census Bureau, *State and County QuickFacts:Convent, Louisiana*, U.S. Department of Commerce, http://factfinder2.census.gov/faces/nav/jsf/pages/community_facts.xhtml.

Subjected to a constant barrage of industrial air pollution, in 1996 the tiny town banded together when a Japanese company announced the opening of yet another polyvinyl chloride (PVC) plant. [153] Shintech, Inc. had applied for an air permit to build a $700 million PVC plant, which included three chemical factories and an incinerator; the permit would allow Shintech to release over 600,000 pounds of air pollutants annually.[154] Among these pollutants would be dioxin, a highly toxic substance known to cause reproductive and developmental problems, and increase the risk of cancer, diabetes, and heart disease.[155] Shintech would also be receiving nearly $130 million in subsidies from Louisiana, while providing only 165 jobs, most too technical for the surrounding poorly educated communities.[156]

Tulane University Law Clinic filed a Title VI complaint on behalf of the community affected by the Shintech Plant, and in 1999, Shintech rescinded its plans to build a plant in Convent.[157] This victory was short-lived, however, when just over a decade later, Nucor Steel succeeded in building a facility in Convent.[158] The iron-producing facility was permitted to release fine particulate matter, benzene, carbon dioxide, carbon monoxide, nitrogen oxide, sulfur dioxide, and ammonia into the air.[159]

Like Convent, the cities in "Cancer Alley" have been in constant struggle to strengthen protection for local communities, but are too often blocked by those who consider industrial development more important than local health. Without appropriate studies of the cumulative health impact on the local community, the residents will continue to be powerless to halt any further pollution encroachment.

The predominantly African-American neighborhoods of North Baton Rouge face the combined impact of point and non-point sources of pollution, and they need the permitting process to fully account for these impacts, as well as the additional burden caused by petro-chemical plant accidents.[160] In updating EPA policy on assessing the impacts of pollution on communities, there also needs to be analysis of emissions from transportation for the petrochemical plants, which also add significant pollution.

North Baton Rouge and Convent are joined by many communities and neighborhoods along the Mississippi River in Louisiana's Cancer Alley. The following are a few:

1. Plaquemine, LA, just a few miles down river on the west bank, is located near one of the largest Dow Chemical facilities in the United States. In addition to toxic air pollution, this plant has

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[153] Louisiana Envtl. Action Network and Greenpeace USA, *Shintech Environmental Racism*, CorpWatch (Sept. 1, 1999), http://www.corpwatch.org/article.php?id=989.
[154] *Id.*
[155] National Institute of Envt'l Health Sciences, *Dioxins*, http://www.niehs.nih.gov/health/topics/agents/dioxins/#geninfo (last reviewed Jun. 5, 2013).
[156] *Shintech Environmental Racism*, *supra* note 6.
[157] *Id.*
[158] Tegan Wendland, *Nucor Breaks Ground on Plant in St. James Parish*, WRKF (Mar. 7, 2011), http://archives.wrkf.org/batonrouge&newsID=980.
[159] Jim Motavalli, *Shintech: The Battle Continues*, E Magazine, Mar. 1, 1999, *available at* http://www.highbeam.com/doc/1G1-54233048.html.
[160] Common Ground report (La Bucket Brigade & United Steelworkers 2012) is an analysis of refineries' reports to the state. The goal is to identify trends of problems so that accidents can be reduced. With over 200,000 people living within 2 miles of a refinery in Louisiana, there is a clear need to reduce accidents and eliminate exposure to hazardous chemicals; ExxonMobil Baton Rouge plant inspection report raises concerns; activists request full accounting of June benzene spill 12 Dec 2012 Times-Picayune; ExxonMobil Baton Rouge safety issues 'prevalent throughout refining sector:' United Steelworkers 27 February 2013 Times-Picayune.

serious ongoing ground water contamination issues, which impact a nearby drinking water well in a trailer park. Shintech PVC plant, and a host of others are within a 5 mile radius of the city.

2. St. Gabriel, located on the East bank, neighbors the only plant producing atrazine in the United States, and has a history of environmental-related health issues.
3. Geismar, also on the east bank, has a petro-chemical complex with 15 different plants, including BASF, Shell Chemical, and Williams Chemical, which had a major chemical accident just 2 weeks ago.[161] [162]
4. Donaldsonville, on the west bank, has a number of ammonia plants, including the CF Industries plant, which had a major accident last week[163]. The town's elementary school is less than ¾ of a mile from this plant.
5. Garyville and Loins, both on the East bank, are next door to the large Marathon Refinery. Lions, once a small community of freed slaves, has been largely displaced due to resulting impacts.
6. Taft and Hahnville, both on the west bank, are alongside Dow Chemical; Occidental Chemical Corporation; Waterford III, a nuclear power plant; Waterford I & II, natural gas power plants; Gypsy I & II, also natural gas power plants. Directly across the Mississippi River is the NORCO chemical complexes of Shell Oil, Motiva Refinery, and Valero Refinery.
7. Norco, located on the east bank, is near a Shell Chemical Plant, Motiva Refinery, and Valero Refinery. The community environmental justice struggles are well documented in two books: Diamond: A Struggle for Environmental Justice in Louisiana's Chemical Corridor Steve Lerner, and Night Fire: Big Oil, Poison Air, and Margie Richard's Fight to Save Her Town .
8. Kenner, on the east bank, has the Cytec Industries plant, which was formerly called American Cyanamid Company. This plant injects by a 'deep well,' the largest amount of chemical waste in Louisiana.
9. Chalmette is on the Eastbank below New Orleans, and has the ExxonMobil and Valero Refinery plants there. These plants have had serious spills over the last 10 years. The largest by volume was over one million gallons of crude oil by Murphy Oil, now Valero, during Hurricane Katrina. The ExxonMobil plant has had a series of leaks. A judge ruled in a Clean Air Act lawsuit, that the plant had violated the Clean Air Act 27,000 times in ten years. Earlier this year, there were a series of leaks.[164]
10. Chemical plant leaks during hurricanes add to the overall chemical exposure of residents of coastal Louisiana.[165]

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[161] "Geismar explosion and fire released more than 62,000 pounds of toxic chemicals, company reports" 26 June 2013 Times-Picayune

[162] "'Cancer Alley' is on fire—where were the watchmen?" http://www.stuarthsmith.com/cancer-alley-is-on-fire-where-were-the-watchmen/#sthash.DhyIZ925.dpuf

[163] "Donaldsonville fertilizer plant blast leaves one dead, seven injured," 14 June 2013 Times-Picayune

[164] "ExxonMobil Chalmette Refinery likely cause of odor in city on Wednesday, Coast Guard says," 4 April 2013 Times-Picayune

[165] "Oil, chemical, coal releases during Hurricane Isaac should have been avoided, environmental groups say," 6 Sept 2012 Times-Picayune

Camden, New Jersey:

Camden, New Jersey once boasted a booming manufacturing industry. It is now known as the poorest city in the nation, with 38% of the population living below the poverty line.[166] Consisting primarily of African Americans and Latinos, this community is also plagued with high rates of asthma and cancer, including the second highest rate of cancer in the state and eighth in the nation.[167] The Camden area is home to over 100 toxic waste sites, many of which are localized around an impoverished neighborhood of Camden called Waterfront South.[168] Waterfront South encompasses 20% of the city's contaminated sites, and houses more than double the amount of pollution-generating facilities than the average New Jersey neighborhood.[169] The air toxins generated by these facilities include arsenic, lead, nickel, manganese, and cadmium, as well as fine particulate matter.[170] These air pollutants are often associated with respiratory illnesses, learning disabilities, and cancer.[171] Yearly, the area is also subjected to over 400 diesel ships in Camden Harbor and heavy diesel truck traffic throughout the neighborhood, adding to the overall levels of air pollution.[172]

In the early 2000s, when yet another cement plant obtained a building permit from the New Jersey Department of Environmental Protection ("NJDEP"), a small local organization persuaded Camden residents to band together to throw off the yoke of air toxins that has been choking their community.[173] In 2002, at the urging of the Waterfront South residents, the NJ Department of Environmental Protection initiated a study to analyze the impact of the toxic emissions on the air quality of neighborhood.[174] The study confirmed that the areas contained "relatively high particulate levels." [175] In 2011, the Health Effects Institute reported that Waterfront South qualified as a hotspot for fine particulate matter (PM 2.5), benzene, toluene, xylenes, aldehydes and methyl tert-butyl ether.[176]

The residents of Camden continue to be concerned about the cumulative effects of the multiple pollution-emitting facilities surrounding the area. Without further analysis of the cumulative risks of the air toxins, there is little to prevent additional facilities from opening.

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[166] U.S. Census Bureau, *State and County QuickFacts: Camden, New Jersey*, U.S. Department of Commerce, http://quickfacts.census.gov/qfd/states/34/3410000.html (last updated Jun. 6, 2013). *See e.g.*, Shoshana Guy, *America's "Invincible' City Brought to its Knees by Poverty, Violence*, N.B.C. News (Mar. 7, 2013), http://inplainsight.nbcnews.com/_news/2013/03/07/17225824-americas-invincible-city-brought-to-its-knees-by-poverty-violence?lite.

[167] Rollback Campaign, *Racial Discrimination and Environmental Justice*, YouTube (Apr. 14, 2008), http://www.youtube.com/watch?v=CA4vL0bFd18&feature=player_embedded.

[168] *Id; See also, S. Camden Citizens in Action v. New Jersey Dept. of Envt'l. Protection*, 274 F.3d 771, 774-75 (3d Cir 2001) ("Waterfront South contains two Superfund sites, several contaminated and abandoned industrial sites, and many currently operating facilities, including chemical companies, waste facilities, food processing companies, automotive shops, and a petroleum coke transfer station.")

[169] *Id.* at 775.

[170] Office of Environmental Justice, *Camden Waterfront South Air Toxics Pilot Project*, N.J. Dep't of Envt'l Protection, Division of Air Quality at 5 (2005), *available at* http://www.state.nj.us/dep/ej/camden/docs/finalreport.pdf.

[171] *Id.* at 4, 38, 46, 75.

[172] *Id.* at 21-22.

[173] Olga Pomar, *Fighting for Air*, National Housing Institute (December 2002), http://www.nhi.org/online/issues/126/camdenair.html.

[174] *Camden Waterfront South Air Toxics Pilot Project*, *supra* note 177.

[175] *Id.* at 5.

[176] Paul J. Lioy et al., *Personal and Ambient Exposures to Air Toxics in Camden, New Jersey*, Health Effects Institute at 2 (Aug. 2011), http://pubs.healtheffects.org/getfile.php?u=659.

Detroit, Michigan:

Michigan's most polluted zip code is 48217, located in the southwest of Detroit.[177] Wedged between a major highway and polluting factories, this community has acutely felt the burden of living so close to industrial plants.[178] The residents experience acrid odors, masses of floating dark particles, and thick layers of metallic dust that settle over the area.[179] The community, which is roughly 85% African American, has experienced deteriorating health due to its proximity to multiple industrial sites.[180] Asthma, sarcoidosis, and multiple types of cancer, including leukemia and brain cancer, have affected nearly every family in the area.[181]

Despite all this, the city continues to allow the industrial sector to expand, further elevating the level of pollution. In the past decade alone, air permits for an asphalt plant have been approved, the nearby water and sewer plant have expanded, and a composting facility was erected.[182] In 2007, the community opposed the $2-billion project to expand the Marathon Refinery and lost.[183] The State asserts that each industrial plant complies with the emissions limits, but the State fails to take into account the cumulative effects of the multiple facilities that are spewing out toxins into the air.[184] Although Detroit has seven state air monitors, none are located in this neighborhood, spurring the local residents to initiate their own sampling.[185] Their results showed high levels of lead and methyl ethyl ketone, a toxin that can irritate the lungs and affect the nervous system, in the air.[186] The cumulative effects of the nearby facilities must be considered in order to ascertain the level of harm associated with close proximity to these industrial sites and, ultimately, to finally bring relief to this industrial-inundated neighborhood.

Mebane, North Carolina:
Omega Wilson
West End Revitalization Association – WERA

In and around Mebane, North Carolina, there are multiple communities without access to basic amenities, such as sewage lines, paved roads, and clean drinking water.[187] These historic communities were established by freed slaves, and remain 85-95% African American. Over half of the population earns below $20,000 a year. [188]

In 1994, the City of Mebane intended to cleave these communities by charting a highway through Mebane's neighborhoods.[189] For an area already overburdened by leaking septic tanks and fetid

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[177] Tina Lam, *supra*, note 39.
[178] *Id.*
[179] *Id.*
[180] Andrea Newell, *Environmental Justice in Detroit: Hope Arises Amid Toxic Communities*, Triple Pundit (Jun. 10, 2013), http://www.triplepundit.com/2013/06/detroit-environmental-justice/.
[181] *48217*, *supra* note 39.
[182] *Id.*
[183] *Id.*
[184] *Id.*
[185] *Id.*
[186] *Id.*
[187] Sacoby M. Wilson et al., *Use of EPA Collaborative Problem-Solving Model to Obtain Environmental Justice in North Carolina*, 1 Progress in Cmty. Health P'ship: Research, Educ., and Action 327 (2007), http://rogersroad.files.wordpress.com/2008/05/14wilson.pdf.
[188] Id. at 328.
[189] *Timeline of Obstacles and Accomplishments*, WERA http://www.wera-nc.org/timeline.htm (last visited Jun. 20, 2013).

drinking water, the four-lane highway would be adding an additional level of pollution from the vehicles passing through the neighborhoods. In response, local residents established the West End Revitalization Association ("WERA") to contest the building of the highway.[190] In 1999, WERA filed civil rights and environmental justice complaints to the U.S. Department of Justice, asserting that the proposed highway disproportionately affected the African American communities. As a result, the plans for the highway were put on hold.[191]

Even though the community prevented the building of a highway, they still face widespread failing septic systems and contaminated water.[192] The City of Mebane, while controlling the land use of these communities, continually refuses to annex the neighborhoods or provide basic amenities.[193] In 2002, WERA received a small grant from the EPA to conduct a study of the water in the African American communities.[194] A study of the surface water showed the presence of *E. coli* and *Enterococci*, bacteria caused by human fecal matter.[195] These levels exceeded EPA's maximum containment limits and violated the North Carolina statute limiting fecal coliforms in waters used for recreation purposes.[196] This surface water flows through the land of the African American residents, is accessible to children, adults, and animals, and has been attributed to the death of pets that drank the water.[197] The community is also concerned about the many abandoned factories – some of which are being used as residential housing without adequate cleanup.[198]

The understanding of cumulative impact must be broadened to include the lack of compliance by local and state federal officials, planned construction projects, and the lack of basic amenities in low-income communities of color, such as safe drinking water, sewage systems, and stormwater management.

Washington, D.C.: Anacostia River Area

The Anacostia River, frequently referred to as the "Forgotten River," has suffered neglect over the past 100 plus years, leading it to being placed on the list of the 'Ten Most Polluted Rivers in the Nation." Challenged by a mix of deforestation due to rapid development, and dense population growth in the watershed, the river is extremely sedimented, with over 35 feet of fine silt lying along its forty foot depths. The river is no longer used for commerce and the silting is not an issue for navigation, but it serves as a base of a toxic soup. Toxic chemicals have leaked into the river from former industrial sites along its shores, millions of gallons of untreated sewage from the city's antiquated combined sewer outfall system flush into it annually, and tens of thousands pounds of trash and debris float downstream after each rainstorm or snow melt.

The problems associated with the river have been the result of the accumulation of pollutants from point and non-point sources, including federal and local governments, and local companies. The issues of the Anacostia are further complicated by the fact that though the tidal river is largely in the confines of the District of Columbia (a small segment of the headwaters lies within Maryland), the vast

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[190] *Failing Septic Systems and Contaminated Well Waters: African-American Communities in Mebane, North Carolina*, West End Revitalization Association 5 (Dec. 30, 2002), http://www.wera-nc.org/News/epa/epaej_1202.htm.
[191] *Id.*
[192] *Id.* at 6.
[193] *Id.*
[194] *Id.*
[195] *Id.* at 14
[196] *Id.* at 15
[197] *Id.*
[198] *Failing Septic Systems*, *supra* note 197, at 17.

majority (80 percent) of the watershed spans the Maryland counties of Montgomery and Prince George's County.

Until recently, this span of sources has been addressed piecemeal. With all of the various sources, multiple, sometimes overlapping, the problems facing the river can often seem overwhelming to the local community. A comprehensive problem requires comprehensive actions. Pollution, especially in our air and waters, does not respect political boundaries. The EPA needs to exercise oversight in cooperation with the District's Department of the Environment, the Maryland Department of the Environment, and their counterparts in the local counties, in assessing cumulative impact and taking the appropriate actions to address these types of problems.

Ivy City, Washington, D.C

In the very heart of Washington, D.C. lies Ivy City, a small neighborhood that is unrecognizable from the iconic tree-lined streets of the nation's capital.[199] This neighborhood is home to a largely African American community. Unemployment nears 50 percent. [200] This pocket of the city is sandwiched between three major D.C. roads, which create high amounts of vehicular pollution.[201] The neighborhood also hosts countless government vehicles, including snowplows, salt trucks, and school buses, all of which add to the cumulative air pollution.[202] Vehicle exhaust is known to contain multiple toxins, such as nitrogen oxides, sulfur oxides, and particulate matter, such as metal and soot.[203] These toxins are known to increase the risk of cardiovascular disease, asthma, respiratory failure, and lung cancer.[204]

The elevated vehicular pollution levels have already yielded multiple cases of respiratory problems in the neighborhood.[205] In 2012, the mayor decided to build a bus depot in the lot adjacent to a historic century-old school in the heart of Ivy City.[206] This uptick of diesel-burning vehicles would add yet another layer of pollution in an already overburdened community. Diesel exhaust contains over 40 air toxins, including known carcinogens such as benzene, arsenic, and formaldehyde.[207] Exposure to diesel can aggravate asthma attacks and cause respiratory illnesses and cancer.[208] Furthermore, the residents had successfully campaigned to designate the school a historic site a decade earlier, and had hoped to use the building as a recreation and education center with activities for children and job training for adults.[209] The planned bus depot, an abrupt departure from the city's promise to revitalize the community, incited

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[199] David Alpert, *Environmental Justice for Ivy City*, Washington Post Opinions (Dec. 14, 2012), http://articles.washingtonpost.com/2012-12-14/opinions/35846642_1_street-trees-neighborhood-environmental-justice.
[200] Darryl Fears, *Ivy City, Tired of Being a D.C. "Dumping Ground," Takes on Gray Over Bus Depot*, Washington Post (Aug. 12, 2012), http://articles.washingtonpost.com/2012-08-12/national/35492485_1_bus-depot-boltbus-suit-claims.
[201] *Environmental Justice for Ivy City*, *supra*, note 206.
[202] *Ivy City, Tired of Being a D.C. "Dumping Ground," supra* note 207.
[203] Doug Brugge et al., *Near-highway Pollutants in Motor Vehicle Exhaust*, 6 Envt'l Health 23 (Aug. 9, 2007), *available at* http://www.ehjournal.net/content/pdf/1476-069X-6-23.pdf.
[204] *Id.*
[205] *Ivy City, Tired of Being a D.C. "Dumping Ground," supra* note 207.
[206] *Id.*
[207] Cal. EPA, OEHHA, *Health Effects of Diesel Exhaust*, http://oehha.ca.gov/public_info/facts/dieselfacts.html.
[208] *Id.*
[209] *Ivy City: Community Fact Sheet and Needs Assessment*, Empower DC (February 2012), http://empowerdc.org/images/Ivy%20City%20Facts.Needs%20Assessment.pdf.

the residents of Ivy City to fight back in court.[210] In December 2012, the judge, after taking a tour of the neighborhood,[211] granted a preliminary injunction and admonished the city administration for circumventing "environmental screening by mischaracterizing the project."[212] Despite this victory, the struggle continues for these residents as they attempt to breathe life into an over-polluted neighborhood that is described as the vehicle "dumping ground" of Washington, D.C.[213]

Cumulative Impacts on the Navajo Nation

EPA is well aware that resource extraction on the Navajo Nation, particularly uranium mining, has left a toxic legacy of contamination from waste material and abandoned mines that has not yet been remediated. The Environmental Justice department of the Sierra Club in Flagstaff, AZ, agrees that there is ongoing work to remediate the toxic effects of uranium mining. We would also like to speak to the exceptional risks that uranium pollution in the water, air, and soil, pose to communities on the Navajo Nation and surrounding communities.

For example, the five-year plan that the EPA is currently proposing in the Grants Mineral Belt region, should be re-evaluated and expanded. Residents in small, rural communities face extreme pollution threats. The residents, who live, raise livestock and garden on soil that releases radon, must pay for municipal water in order to avoid the contaminated local wells that traditionally provided water for free. Starting in 1958, a company, now owned by the Barrick Gold Corporation, placed 21 million tons of uranium tailings into an unlined pond. They promised nearby residents of Bluewater Valley that no contamination would spread beyond the alluvial water aquifer into underlying aquifers on which the residents relied. But by 1995, the contamination had spread from the alluvial into three lower aquifers, effectively ending residents' use of wells.[214] The EPA's attention to this region today, recognition of the need for safe, local water for the Grants Mineral Belt communities, and the agency's efforts in the community are greatly appreciated, but EPA's plan should recognize that the community's private property has already been destroyed and water use now is expensive and must be curtailed, changing the way people in the community can live.

Bluewater Valley also requires additional support, due to existing health conditions related to living with over 30 years of contamination—the extent and impact of which has not been fully documented. Only recently has the area been assessed for human health risks. The EPA's report found residents south of the tailings site face "cancer risks 18 times higher than EPA's 'generally acceptable risk' range for radionuclides in outdoor air among other increased risks," and the area north of the tailings site still lacks sufficient monitoring wells to determine if contamination from the Ambrosia Lake region is affecting the community.[215] The monitoring wells that do show contamination from the Anaconda/Arco/Bluewater site entering the community from the west, may be inadequate to fully understand the problem. No measures have been taken to protect the San Andres aquifer that grows food

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[210] Sherrie Johnson, *Ivy City Community Demands Job Training Not Bus Parking at Crummel School*, ABC2 News (Jul. 17, 2012), http://www.abc2news.com/dpp/news/education/ivy-city-community-demands-job-training-not-bus-parking-at-crummell-school

[211] Tom Sherwood, *Ivy City Residents Fight Bus Depot at Crummel School Site*, NBC4 Washington News (Nov. 26, 2012), http://www.nbcwashington.com/blogs/first-read-dmv/Ivy-City-Residents-Fight-Bus-Depot-at-Crummell-School-Site-180938721.html

[212] Courtland Milloy, *For Ivy City, 'The Plan' Isn't Paranoia*, Washington Post Local (Dec. 11, 2012), http://articles.washingtonpost.com/2012-12-11/local/35767596_1_bus-depot-low-income-people-residents

[213] *Ivy City, Tired of Being a D.C. "Dumping Ground," supra* note 207.

[214] (Candace Head-Dylla, 2013, personal communication, 2013)

[215] (TAG grant summary of EPA Draft Human Health Risk Assessment, 2013)

for the livestock in Murray Acres.[216] In order to adequately address the risks of contamination in Bluewater Valley and in the Grants Mineral Belt as a whole, the Sierra Club Environmental Justice Department asks that the EPA take pre-existing health risks from contamination and social factors—including, in this case, the ways air, water, and soil sustain rural lives—into account.

We ask that the EPA recognize that communities around power plants, especially communities with significant Native populations, are at extreme risk of industrial pollution, as a result of social factors that pressure the community to accept pollution in exchange for jobs. The EPA's support is vital to enforcing workplace health standards, protecting surrounding communities from pollution from the mine, and developing economic alternatives, such as solar or wind energy, to provide communities with productive pathways to economic independence.

Bluewater Valley Downstream Alliance. (2013). *Summary of the USEPA Draft Human Health Risk Assessment*. Community newsletter funded by a Technical Assistance Grant from the USEPA.
Sierra Club. (2012). DRAFT: *Socioeconomic and demographic indicators: identifying and enumerating the state of EJ communities*. Dave O'Donnell.
United States Environmental Protection Agency. (2013). *EPA five-year plan progress report on cleaning up uranium contamination*. San Francisco: Dana Barton.
United States Environmental Protection Agency. (2013). *Assessment of health and environmental impacts of uranium mining and milling five-year plan—Grants Mining District, New Mexico*. Dallas: Mark Purcell.

Memphis, TN:

The Memphis Metropolitan Statistical area is typical of most large and mid-sized urban southern cities, in that they historically attracted heavy industrial areas. These industrial areas are usually in or around neighborhoods where a majority of residents are people of color.

While the City of Memphis is burdened with air pollution coming from a wide variety of sources, there are two parts of the city that bear a disproportionate burden compared to other sections of the city, or Shelby County. The Douglass neighborhood located in a section of north Memphis, has eight polluting facilities including the Hollywood Dump Superfund site and Velsicol Chemical Company's hazardous waste incinerator and a six-lane interstate highway runs alongside its northern border. Many of the polluting facilities have been present in the community and operating (under different names/owners) for more than 50 years. The Douglass neighborhood makes up the majority of the 38108 zip code area. The 38108 zip code area is an historically African-American neighborhood with a huge number of low-birth weight babies and a high infant mortality rate. Infant mortality should be a health indicator that calls attention to the negative health exposures from the cumulative industrial pollution and contamination sources. EPA must protect children and all communities exposed to pollution early in life, or the cycle of chronic illness and poor health will increase.

The south west area of Memphis, TN, is comprised of several historically African-American neighborhoods that are in close proximity to the Presidents Island industrial corridor, the Valero (oil) Refinery, and the fifty-five year old TVA Allen coal-fired power plant. These two areas of the city are dealing with multiple pollution sources.

[216] (Candace Head-Dylla, 2013, personal communication)

In addition, community members have complained for years about the strong odors coming from the area facilities, as well as the asthma, various cancers, miscarriages, and even deaths that they attribute to the environmental exposure to hazardous substances in their community.

Because pollution is considered to be a serious community health problem, the Sierra Club Environmental Justice Program office in Memphis monitors emissions coming from local facilities and compiles an annual report entitled, "Shelby County's Terrible Ten Report."[217] This report uses Toxic Release Inventory (TRI) data that the facilities are required to report to EPA each year estimating their emissions. Additionally, the report combines TRI data with health effects information on each of the toxic chemicals emitted, to help educate the community about the complex issue of air pollution. This easy-to-understand report has for ten years made an effort to raise awareness and draw attention to the top ten major sources of pollution to our air, water, and land.

Because we know the health effects of the many hazardous substances that are emitted, we are very concerned about the cumulative and synergistic health effects. We know based on the science that toxic air pollution particularly affects the elderly, pregnant women, and children. Even so, EPA does not mandate hazardous air monitors; not even in 'hot spot' areas. Air pollution, land pollution, and water pollution usually go hand-in-hand. Whether we are considering the health effects from air pollution, solid waste facilities, or from eating fish from contaminated rivers and streams, the health effects are cumulative ones in most environmental justice communities. Yet, community residents are faced with on-going pollution as well as the renewal of facility permits, continuously exposed.

[217] An example can be found at http://www.sierraclub.org/ej/downloads/terrible10.pdf

Attachment 7

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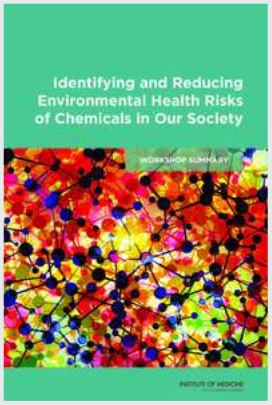

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Attachment 9

EARTHJUSTICE

March 22, 2016

Administrator Gina McCarthy
Dr. Thomas Burke, Science Advisor
Dr. Michael Broder, Office of the Science Advisor
ORD Docket
Environmental Protection Agency
ord.docket@epa.gov

Submitted online via Regulations.gov
Docket ID: EPA-HQ-ORD-2015-0684

Re: Draft Guidelines for Human Exposure Assessment

Dear Administrator McCarthy, Dr. Burke, and Dr. Broder:

We appreciate that the U.S. Environmental Protection Agency is in the process of updating its Guidelines for Human Exposure Assessment. We support EPA's proposed update and also urge EPA to strengthen these guidelines further than it has proposed in order to address the key issues identified below and as elaborated in the attached comments previously submitted to the agency. We also urge EPA to bring other important risk assessment guidelines up to date, before another year passes with EPA offices using obsolete and incomplete guidelines to make important decisions about human health.

The update in EPA's guidelines at hand is long overdue and greatly needed by all Americans exposed to toxic chemicals, including pesticides. The prior EPA guidelines were created more than twenty years ago, in 1992. Many other guidelines EPA is using – such as its guidance on age-dependent adjustment factors for only mutagenic carcinogens; its guidance failing to apply an *in utero* adjustment factor; and its list of persistent, bioaccumulative toxins, among others – are also seriously out of date and not in line with current science.

- Since the 1990s, scientific research and knowledge have advanced dramatically. EPA knows much more now about human exposure to chemicals and contaminants, and the harm this can cause.

- EPA now knows that children are not little adults. Babies and children, particularly *in utero*, are both more exposed and more vulnerable to harm from toxic exposure because they are growing and developing.

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- The onslaught of toxic chemicals in our air, water, soil, food, and consumer products affects all Americans, but often hits communities of color and low-income communities the most. In recent years, EPA has affirmed its commitment to advance environmental justice. Updating outdated risk assessment protocols to ensure better assessment of community impacts, improve transparency, and require public review and comment of all draft risk assessments are important and necessary ways to fulfill this Administration's promise to continue working toward environmental justice.

- During the last two decades, it is also true that more and more chemicals – many known to be harmful and others virtually untested and unassessed – have been released into commerce and into the environment. It is urgent for EPA to use current scientific research to assess and regulate these chemicals. It is also critical that EPA use current scientific research when it considers whether to register pesticides and during registration review.

- And, during this time, methods to address and prevent exposure have been continuing to improve, as industries innovate in response to a growing call from the public for less chemical exposure, and as technological advancements make it possible to reduce human exposure to a greater extent. There is no good reason why EPA should be using outdated information to protect health when tools are available both to assess risks and to avoid them.

It is essential that EPA bring these Guidelines, and other risk assessment guidelines that are also obsolete or incomplete, up to date based on current scientific advice and knowledge. Since 2009, EPA has had before it the advice of independent scientists at the National Academy of Science.[1] The NAS advised EPA to update its approach to close serious gaps in assessing human health risks from chemical exposure. It is not acceptable science to recognize health risks exist and not account for them at all – whether they stem from a particular pathway of exposure, a particular chemical, a kind of vulnerability or from combined impacts for disproportionately exposed and vulnerable communities of color and low-income communities who are bombarded by multiple sources of contaminants. Uncertainties do not justify inaction. EPA must use the best available information to account for risks, through the use of default factors where necessary to fill gaps so that action relying on risk assessments will not fail to protect public health by ignoring risks.

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[1] *See* National Research Council of the National Academies of Science, Science and Decisions: Advancing Risk Assessment (2009) (authored by Committee on Improving Risk Analysis Approaches Used by the U.S. EPA; Board on Environmental Studies and Toxicology; Division on Earth and Life Studies; National Research Council), DOI: 10.17226/12209, http://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.

In recent decades, expert state regulators (such as California's Office of Health Hazard Assessment) have surpassed EPA in addressing early life exposure and vulnerability, as well as aggregate and cumulative exposure to multiple chemicals, multiple pathways, and multiple sources. There is a wealth of information and advice before the agency from its own internal experts, such as the Children's Health Advisory Protection Committee which has spoken extensively on lead, and individual offices that have acknowledged the need in some instances to account for *in utero* exposure (even as offices like OAR and OPPT continue to fail to account for such exposure in certain actions).[2] For example, the Office of Pesticide Programs has agreed to consider aggregate risks from the same pesticide used in agricultural, commercial, and/or residential settings; cumulative risks from exposure to pesticides with common mechanisms of toxicity; and the unique risks posed to infants and children due to their potentially increased sensitivity to pesticides. In updating these guidelines and others, EPA must act based on current information to protect children, and not continue to ignore *in utero* and early-life exposures that its guidelines do not currently consider.

EPA also should engage with scientific experts and affected community members and work to update its approach overall to acknowledge that many chemicals, from lead to arsenic and many others, do not have a safe level of exposure for carcinogenic, neurological, or other kinds of chronic risk. If EPA's risk assessment guidelines are to have any meaning going forward, they must follow the most current science.

EPA's guidelines on risk assessment decide how much health protection people receive from toxic chemicals they are exposed to in the air, water, soil, food, workplace, and in everyday products in their homes and schools. EPA must ensure that its staff makes decisions under the Clean Air Act, Toxic Substances Control Act (TSCA), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and other statutes pursuant to the best available current science, as discussed in the example recent comments attached as an Appendix to this letter.

In recent years, Earthjustice, working closely with national and local allies, has raised these concerns and provided important examples where EPA's approaches and guidelines are outdated and must be strengthened, especially in action to address toxic air pollution under the Clean Air Act (42 U.S.C. § 7412(f)(2)), toxic chemicals under TSCA, and pesticides under FIFRA. We have provided those comments again, here, and respectfully urge the Office of Science Advisor to address and incorporate the scientific information they contain – from peer-reviewed scientific research and expert state regulators – into the guidelines at hand, and other guideline updates in progress. We also request that the Science Advisor follow through on its

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[2] *See, e.g.*, EPA, Notice of Availability, Policy Paper on Revised Risk Assessment Method for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses, 74 Fed. Reg. 65121 (Dec. 9, 2009); Letter from Sheela Sathyanarayana, Chair of Children's Health Protection Advisory Committee, to Administrator McCarthy, Re: National Ambient Air Quality Standards for Lead (Jan. 8, 2015), https://www.epa.gov/sites/production/files/2015-01/documents/naaqs_for_lead_letter.pdf.

plan to ensure the best possible treatment and consideration of cumulative risks based on available science, in response to the 2013 request for comment that this Office issued.

More than 100 local, regional, and national organizations across the United States with whom Earthjustice is working on these issues believe that updating EPA's guidelines to ensure the agency addresses real-world health risks and impacts, and fully implementing the current science in EPA's rulemakings and other actions are critical priorities to protect public health. There is a particular shared concern for the people most exposed and most likely to be harmed from this exposure, including vulnerable children, overburdened communities, and workers. Addressing this issue this year would help advance the Administrator's objectives to make a visible difference for all local communities with toxic exposure and workers exposed to chemicals and pesticides on the job, and to provide long-overdue environmental justice for communities highly exposed to toxic contaminants.

Before this Administration leaves office, we therefore call on you to complete all necessary and important updates to EPA's risk assessment guidelines. Please exercise the leadership necessary to bring these guidelines and others like them in line with the best available current scientific advice. We would welcome the opportunity to meet with the Office of the Science Advisor and other agency staff working on these important concerns to discuss these comments.

We have provided the major sources cited, all of which themselves summarize and include further scientific citations, as an accompanying Appendix. Please contact us if we can provide any additional information or to arrange a meeting at your convenience.

Thank you for your time and consideration of this matter.

Sincerely,

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SOURCES PROVIDED AS AN APPENDIX

1. Sarah Janssen et al., NRDC Issue Paper: Strengthening Toxic Chemical Risk Assessments to Protect Human Health (Feb. 2012), http://www.nrdc.org/health/files/strengthening-toxic-chemical-risk-assessments-report.pdf.

2. Comments of Earthjustice, NRDC, et al. on Request for Information and Citations on Methods for Cumulative Risk Assessment, EPA-HQ-ORD-2013-0292 (May 1, 2013), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-ORD-2013-0292-0132 (filed June 28, 2013). Earthjustice submitted these comments on behalf of the following organizations: AIR ALLIANCE HOUSTON, ALASKA COMMUNITY ACTION ON TOXICS, AMERICAN BOTTOM CONSERVANCY, CALIFORNIA COMMUNITIES AGAINST TOXICS, CALIFORNIA SAFE SCHOOLS, THE CITY PROJECT, COMMUNITY IN-POWER AND DEVELOPMENT ASSOCIATION, DEEP SOUTH CENTER FOR ENVIRONMENTAL JUSTICE, DEL AMO ACTION COMMITTEE, DOWNWINDERS AT RISK, IRONBOUND COMMUNITY CORPORATION, LOUISIANA BUCKET BRIGADE, LOUISIANA ENVIRONMENTAL ACTION NETWORK, LOS JARDINES INSTITUTE, LOWER MISSISSIPPI RIVERKEEPER, MISSOURI COALITION FOR THE ENVIRONMENT, NATURAL RESOURCES DEFENSE COUNCIL, NEIGHBORS FOR CLEAN AIR, NEW MEXICO ENVIRONMENTAL LAW CENTER, NORTH CAROLINA ENVIRONMENTAL JUSTICE NETWORK, OAK GROVE NEIGHBORHOOD ASSOCIATION, POVERTY & RACE RESEARCH ACTION COUNCIL, PUBLIC INTEREST LAW CENTER OF PHILADELPHIA, ROYAL OAK CONCERNED CITIZENS ASSOCIATION, RURAL EMPOWERMENT ASSOCIATION FOR COMMUNITY HELP, SIERRA CLUB, SOUTHERN ENVIRONMENTAL LAW CENTER, WEST END REVITALIZATION ASSOCIATION.

3. Earthjustice *et al.* Comments on EPA's Draft EJ 2020 Action Agenda Framework at 22-25 (filed July 14, 2015), https://www3.epa.gov/environmentaljustice/ej2020/. Earthjustice submitted these comments on behalf of the following organizations: AIR ALLIANCE HOUSTON; ALASKA'S BIG VILLAGE NETWORK; APOSTOLIC FAITH CENTER; CALIFORNIA COMMUNITIES AGAINST TOXICS; CALIFORNIA KIDS IAQ; CALIFORNIA SAFE SCHOOLS; CATA – THE FARMWORKERS SUPPORT COMMITTEE; CENTER FOR EFFECTIVE GOVERNMENT; CITIZENS AGAINST RUINING THE ENVIRONMENT; CITIZENS' ENVIRONMENTAL COALITION; CITIZENS FOR CLEAN AIR; CLEAN AIR COUNCIL; CLEAN AND HEALTHY NEW YORK; CLEAN WATER AND AIR MATTER; COALITION FOR A SAFE ENVIRONMENT; COMITE CIVICO DEL VALLE; COMITÉ DIÁLOGO AMBIENTAL, INC.; COMMUNITY DREAMS; COMMUNITY IN-POWER AND DEVELOPMENT ASSOCIATION; COMMUNITY SCIENCE CENTER; CONSERVATION LAW FOUNDATION MASSACHUSETTS; DEL AMO ACTION COMMITTEE; DESERT CITIZENS AGAINST POLLUTION; DIESEL HEALTH PROJECT; DOWNWINDERS AT

RISK; EAST YARD COMMUNITIES FOR ENVIRONMENTAL JUSTICE; 48217 COMMUNITY AND ENVIRONMENTAL HEALTH ORGANIZATION; FARMWORKER ASSOCIATION OF FLORIDA; INSTITUTE OF NEUROTOXICOLOGY &NEUROLOGICAL DISORDERS; JESUS PEOPLE AGAINST POLLUTION; KENTUCKY ENVIRONMENTAL FOUNDATION; LABADIE ENVIRONMENTAL ORGANIZATION;MARTINEZ ENVIRONMENTAL GROUP;MIDWEST COALITION FOR RESPONSIBLE INVESTMENT;MOSSVILLE ENVIRONMENTAL ACTION NOW; NATURAL RESOURCES DEFENSE COUNCIL; NEIGHBORS FOR CLEAN AIR; NEW MEXICO ENVIRONMENTAL LAW CENTER; NORTH CAROLINA COASTAL FEDERATION; OHIO VALLEY ENVIRONMENTAL COALITION; PENDERWATCH &CONSERVANCY; PESTICIDE ACTION NETWORK NORTH AMERICA; SIERRA CLUB; SOUTHEASTERN NORTH CAROLINA ENVIRONMENTAL JUSTICE COALITION; SOUTHERN APPALACHIAN MOUNTAIN STEWARDS; STEPS COALITION; TEXAS ENVIRONMENTAL JUSTICE ADVOCACY SERVICES; THE CITY PROJECT; THE ORIGINAL UNITED CITIZENS OF SOUTHWEST DETROIT; TRI-VALLEY CARES; WEST END REVITALIZATION ASSOCIATION.

EXAMPLE CLEAN AIR ACT COMMENTS AND PETITIONS PROVIDING ADDITIONAL DETAIL ON THESE ISSUES:

4. Comments on EPA, Petroleum Refinery Sector Risk and Technology Review and New Source Performance Standards; Proposed Rule, 79 Fed. Reg. 36,880 (June 30, 2014), https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2010-0682-0568, Earthjustice submitted these comments on Oct. 28, 2014 on behalf of the following organizations: AIR ALLIANCE HOUSTON, APOSTOLIC FAITH CENTER, CALIFORNIA COMMUNITIES AGAINST TOXICS, CALIFORNIA KIDS IAQ, CLEAN AIR COUNCIL, COALITION FOR A SAFE ENVIRONMENT, COMMUNITY DREAMS, COMMUNITY IN-POWER AND DEVELOPMENT ASSOCIATION, DEL AMO ACTION COMMITTEE, ENVIRONMENT TEXAS, GOOD NEIGHBOR STEERING COMMITTEE (BENICIA), LOUISIANA BUCKET BRIGADE, LOUISIANA ENVIRONMENTAL ACTION NETWORK, LOWER MISSISSIPPI RIVERKEEPER, NATIONAL WILDLIFE FEDERATION, NATURAL RESOURCES DEFENSE COUNCIL, SIERRA CLUB, TEXAS ENVIRONMENTAL JUSTICE ADVOCACY SERVICES, UTAH PHYSICIANS FOR A HEALTHY ENVIRONMENT, EARTHJUSTICE, AND ENVIRONMENTAL INTEGRITY PROJECT; Additional comments raising the need for EPA to update and strengthen its health risk assessment approach to address real-world health risks caused by hazardous air pollution under its Clean Air Act authority were submitted on behalf of over 90 national and community organizations, and the full list is available by request.

5. Petition for Reconsideration of and Petition for New Final Rule for Petroleum Refinery Sector Risk and Technology Review and New Source Performance Standards; Final Rule, Docket ID No. EPA-HQ-OAR-2010-0682, filed on behalf of 11 organizations on

Feb. 1, 2016 (Air Alliance Houston, California Communities Against Toxics, Clean Air Council, Coalition For A Safe Environment, Community In-Power & Development Association, Del Amo Action Committee, Environmental Integrity Project, Louisiana Bucket Brigade, Sierra Club, Texas Environmental Justice Advocacy Services, and Utah Physicians for a Healthy Environment).

6. Petition for Reconsideration of National Emissions Standards for Hazardous Air Pollutant Emissions From Secondary Lead Smelting, 77 Fed. Reg. 556 (Jan. 5, 2012), Dkt. ID No. EPA-HQ-OAR-2011-0344, filed on March 5, 2012, by Earthjustice on behalf of: California Communities Against Toxics, Frisco Unleaded, Missouri Coalition for the Environment Foundation, Sierra Club, and Natural Resources Defense Council.

EXAMPLE FIFRA COMMENTS:

7. Farmworker and Conservation Comments on Seven Organophosphate Pesticides: Chlorpyrifos-methyl (EPA-HQ-OPP-2010-0119), Dicrotophos (EPA-HQ-OPP-2008-0440), Dimethoate (EPA-HQ-OPP-2009-0059), Ethoprop (EPA-HQ-OPP-2008-0560), Profenofos (EPA-HQ-OPP-2008-0345), Terbufos (EPA-HQ-OPP-2008-0119), Tribufos (EPA-HQ-OPP-2008-0883) (Feb. 22, 2016).

8. Comments from the Natural Resources Defense Council (NRDC) on the Draft Pesticide Cumulative Risk Assessment: Framework for Screening Analysis EPA-HQ-OPP-2015-0422, at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2015-0422-0015 (Sept. 28, 2015).

EXAMPLE TSCA COMMENTS:

9. Comments from Earthjustice, Natural Resources Defense Council and Washington Toxics Coalition on Problem Formulation and Initial Assessment Documents for Three Flame Retardant Clusters (November 18, 2015) Docket IDs: EPA-HQ-OPPT-2015-0068, EPA–HQ–OPPT-2015-0081 and EPA-HQ-OPPT-2014-0730, http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2015-0068-0013

10. Earthjustice et al., Farmworker and Conservation Comments on Chlorpyrifos Revised Human Health Risk Assessment (April 30, 2015), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0848 (Comments were filed by Earthjustice on behalf of: Farmworker Justice, Natural Resources Defense Council, Pesticide Action Network, California Rural Legal Assistance Foundation, Farm Labor Organizing Committee, Pineros y Campesinos Unidos del Noroeste, and United Farm Workers).

Attachment 10

ORD Docket
Environmental Protection Agency
Mailcode: 28221T
1200 Pennsylvania Ave., NW
Washington, DC 20460

Submitted online via Regulations.gov
Docket ID: EPA-HQ-ORD-2015-0684

Re: Draft Guidelines for Human Exposure Assessment

March 22, 2016

Improved risk assessment practices at the Environmental Protection Agency (EPA) have the potential to drive policy decisions that would alleviate many of the threats to children's health from environmental exposures. EPA's risk assessment practices, including exposure assessment, need substantial updates to reflect current science and ensure that EPA fully evaluates, and then addresses, the real-world risks to children and communities. It is positive that EPA is updating the Guidelines for Human Exposure Assessment and we urge EPA to complete these important updates this year.

There is increasing evidence that environmental exposures are jeopardizing the health and well-being of children across the country. Preventing these exposures can result in significant decreases in diseases which take an extraordinary toll on our communities:

- Asthma – reducing toxic exposures could alleviate 1 in 3 cases of asthma requiring medical attention[1];
- Childhood Cancers – 10-20% of the 3 most common childhood cancers can be prevented by reducing environmental hazards[1];
- Neurobehavioral Disorders (Autism, ADHD, Intellectual Disability) – an estimated 10% can be prevented by reducing toxic exposures. In California, this was estimated to equal 1800 children each year[1];
- Healthier kids equal significant cost savings
    - California estimate = $254 million annually and $10 to $13 billion over the lifetime of children born within a single year[1]
    - US estimate = $76.6 Billion in 2008[2].

But from the impacts of pesticides in agricultural communities to air toxics from industrial sources in overburdened communities, EPA's risk assessments have failed to properly address the vulnerability of the developing fetus, infant and child, thus likely contributing to an increasing burden of disease.

With the proposed revisions and updates to EPA's Guidelines for Exposure Assessment, EPA has the opportunity to correct and strengthen outdated and scientifically unsupported practices that lead to

[1] California Environmental Health Tracking Program & Public Health Institute, 2015. Costs of Environmental Health Conditions in California Children. Available at: http://www.phi.org/uploads/files/2015ROI_CEHTP.pdf.
[2] Trasande, L. & Liu, Y., 2011. Reducing The Staggering Costs Of Environmental Disease In Children, Estimated At $76.6 Billion In 2008. Health Affairs, 30(5), pp.863–870.

underestimations of risk, ultimately hampering the protection of the developing fetus and children from environmental and consumer product exposures. In order to prevent disease and improve health, it is not enough for EPA to simply finalize these draft guidelines; the guidelines must result in changes to the *actual practices* used at EPA to evaluate health threats from environmental exposures. Bridging the gap between these guidelines and how EPA conducts risk assessments is critical in order to see assessments that more accurately and completely account for real-world health risks, leading to informed risk management and public health protections.

Currently, the draft guidance summarizes important principles that are not routinely incorporated into the assessments conducted by EPA programs. EPA programs need clear directives, methods, and deadlines for incorporating the following principles expressed in the draft guidelines into their risk assessment practice:

(1) **Accurate assessment of aggregate exposures.** EPA acknowledges the importance of evaluating aggregate exposures of contaminants of concern that may impact an individual, or community, via multiple pathways of exposure but assessments often fail to accurately assess aggregate exposures. If there are insufficient data to quantify aggregate exposures, a default should be used to account for these exposures. The guidelines need to ensure that when exposures can occur via multiple pathways (i.e. inhalation and oral), the combined exposure is included in any risk analysis, from the start. Exposures add up, and different exposures may add up to an unsafe level—that is the fundamental premise behind an aggregate assessment, so each risk from one route individually must be considered together in context with all other exposures, and all types of carcinogenic risks must be, at least, added together. This is important for children in agricultural communities, for example, who may be exposed to pesticides from food, water, and off-target drift from fields. It is also critical for children who breathe air near major air toxics sources like refineries, and also drink the breast milk of their mothers who breathe such air, and play on playgrounds nearby, ingesting soil that is contaminated with persistent bioaccumulative toxicants deposited from those refineries' air emissions.

(2) **Accounting for cumulative exposures and effects.** EPA acknowledges that there are additional significant health threats for individuals and communities facing: multiple sources of contaminants; multiple contaminants that together pose a larger health threat because they act through a common pathway or impact similar health endpoints; and the combined impact of contaminant exposure with social stressors. EPA should use default factors to account for the known additional risk coming from these types of exposures where they cannot be more explicitly quantified. These health threats often fall disproportionately on disadvantaged communities where there are more sources of chemicals and greater levels of stress. The guidelines need to provide clear methods to factor these health threats into existing risk assessment protocols, starting with an interim measure until EPA completes full new cumulative risk guidelines. Scammell et al. describe how tools including indexes, maps, and combined approaches can provide an important first step towards evaluating background exposures and delineating the cumulative context for an assessment[3]. EPA should also use available data to quantitatively inform variability and vulnerability factors in risk assessments.

[3] Scammell, M.K., Montague, P. & Raffensperger, C., 2014. Tools for Addressing Cumulative Impacts on Human Health and the Environment. Environmental Justice, 7(4), pp.102–109.

(3) **Consideration of vulnerable groups and populations of concern.** EPA acknowledges the need to consider differential exposure profiles based on life-stage and population characteristics, such as ethnicity, dietary preferences, socioeconomic status, or cultural practices. Although updates have been made to the Exposure Factors handbook to provide additional values to account for unique exposures to children and the developing fetus, including placental transfer, breastmilk and object-to-mouth ingestion, considering these routes of exposure has not yet been incorporated into risk assessments performed by many of the EPA programs. Another example of inadequately accounting for exposures to populations of concern is the consideration of dietary intake of bioaccumulative chemicals, which would be much higher for indigenous and some low-income communities that rely on subsistence fishing or traditional foods such as marine mammals.

(4) **Use of accurate exposure models.** EPA discusses the importance of the rigorous evaluation, and validation, of exposure models and algorithms (including traditional and high-throughput models and algorithms) to ensure that there is sufficient predictive capacity to meet the objectives of the risk assessment. EPA programs must be directed to use the best-available methods and to reject the use of models and algorithms that do not meet the criteria described in the guidance document and are found not to align with observational or experimental data.

The following issues are not adequately addressed in the draft guidelines and revisions should be made to incorporate:

(5) **The science on early-life vulnerability.** These guidelines must incorporate the science documenting that early-life exposures present greater risks to the developing fetus and child due to increased susceptibility and vulnerability. Age-dependent adjustment factors should be used for <u>all</u> carcinogens, not only those that act by a mutagenic mode of action. Adjustment factors should also be used to account for increased susceptibility to carcinogens due to prenatal exposures, which the draft guidelines currently do not cover. For chronic non-cancer risks, increased susceptibility of children (including prenatally) should be accounted for through use of child-specific reference values or additional uncertainty/ safety factors where reference values are not available. Scientific findings over the last decade clearly indicate that the prenatal period is a particular window of susceptibility to multiple adverse health outcomes in addition to cancer, including neurodevelopmental and respiratory effects[4, 5]. These need to be accounted for in the guidelines.

(6) **A systematic literature review as a key first step in planning and scoping.** EPA's exposure assessments should be informed by the body of scientific evidence. It is important that the literature review use elements of a systematic review process in order to transparently conduct a comprehensive literature search, document and evaluate evidence. Systematic review methods for chemical assessments have been developed and implemented through various case studies by the National Toxicology Program (NTP) Office of Health Assessment and Translation

[4] Grandjean, P.; Landrigan, P. J., Neurobehavioural effects of developmental toxicity. 701 Lancet Neurol. 2014, 13, (3), 330-338.

[5] Pinkerton, K.E. & Joad, J.P., 2000. The mammalian respiratory system and critical windows of exposure for children's health. Environmental health perspectives, 108 Suppl , pp.457–62.

(OHAT), the EPA Integrated Risk Information System (IRIS) program, the University of California San Francisco, and others. [6]

To protect people from unsafe exposures to toxicants in the environment and consumer products, EPA needs to finalize the draft exposure guidelines in 2016, release and then implement a plan to transform risk assessment practice according to these guidelines. This will be a critical piece of larger risk assessment reforms that are needed to more comprehensively address early life vulnerabilities and move towards the practices recommended in the National Academies Report *Science and Decisions*[7]. Bringing these guidelines up to date with current science is a critical step towards ensuring safer, healthier communities where children can live, learn and play.

Thank you for the opportunity to comment on this guideline document. We look forward to seeing EPA ensure that families are protected from toxic chemical exposures in their homes, workplaces and communities.

Sincerely,

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(individual signers on next page)

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[6] Rooney AA, Boyles AL, Wolfe MS, Bucher JR, Thayer KA. Systematic review and evidence integration for literature-based environmental health science assessments. Environ Health Perspect . 2014 Jul;122(7):711–8.
Thayer KA, Wolfe MS, Rooney AA, Boyles AL, Bucher JR, Birnbaum LS. Intersection of systematic review methodology with the NIH reproducibility initiative. Environ Health Perspect. 2014 Jul;122(7):A176–7.
Birnbaum LS, Thayer KA, Bucher JR, Wolfe MS. Implementing systematic review at the National Toxicology Program: status and next steps. Environ Health Perspect. 2013 Apr;121(4):A108–9.
Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. Environ Health Perspect. 2014 Oct;122(10):1007–14.

[7] National Research Council, 2009. Science and Decisions: Advancing Risk Assessment, Washington, D.C.: National Academies Press.

The views expressed in this editorial are the opinion of the individuals who are listed below and DO NOT imply an endorsement or support for these opinions by any organizations to which they are affiliated.

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Attachment 11

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

National Emission Standards for Hazardous Air Pollutants: Coal- And Oil-Fired Electric Utility Steam Generating Units—Reconsideration of Supplemental Finding and Residual Risk And Technology Review	)	**Docket No. EPA-HQ-OAR-2018-0794**
84 Fed. Reg. 2670 (Feb. 7, 2019)	)	

COMMENTS OF CHESAPEAKE CLIMATE ACTION NETWORK, CLEAN AIR TASK FORCE, EARTHJUSTICE, ENVIRONMENTAL INTEGRITY PROJECT, AND SIERRA CLUB ON PROPOSED RESIDUAL RISK AND TECHNOLOGY REVIEW

BACKGROUND

In its proposed residual risk and technology review (RTR) for coal- and oil-fired electric generating units (EGUs), EPA declares that the risks from this category are "acceptable" and that its existing standards already provide an ample margin of safety. 84 Fed. Reg. 2670 (February 7, 2019). EPA further declares it has identified no developments in the course of its technology review. *Id.* On the basis of those claims, EPA proposes to find that "no revisions are warranted." *Id.*

As explained in more detail below, both EPA's risk review and its technology review are deeply flawed. EPA's refusal to revise the emission standards for EGUs is unlawful and arbitrary.

I. EPA'S REFUSAL TO SET STRONGER STANDARDS UNDER CLEAN AIR ACT § 112(f) IS UNLAWFUL AND ARBITRARY.

Under § 7412(f)(2), EPA must: (1) prevent all unacceptable health risks; and (2) assure an "ample margin of safety to protect public health" and "prevent . . . an adverse environmental effect."[1] As the D.C. Circuit has recognized, the "aspirational goal" of this provision includes reducing lifetime cancer risk to the most-exposed person to be one-in-one million or lower.[2] As EPA recognizes, this provision directs EPA to "protect[] the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1-in-1 million" and "limit[] to no higher than approximately 1-in-10 thousand [i.e., 100-in-1 million] the estimated risk that a person living near a plant would have if he or she were exposed to the maximum pollutant concentrations for 70 years."[3]

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[1] *Id.* § 7412(f)(2)(A).
[2] *NRDC v. EPA*, 529 F.3d 1077, 1082 (D.C. Cir. 2008) (interpreting 42 U.S.C. § 7412(f)(2)).
[3] 79 Fed. Reg. at 36,885 (quoting Benzene Rule, 54 Fed. Reg. 38,044-45 (Sept. 14, 1989)).

EPA's proposal does remotely meet these requirements. As shown below, EPA chooses – apparently deliberately – to simply ignore the vast majority of the emissions of organic hazardous air pollutants (HAPs) from EGUs. As a result, EPA grossly and blatantly understates the risks that EGUs' organic HAP emissions present.

Compounding that error, which in itself renders the agency's proposal hopelessly arbitrary and unlawful, EPA understates the risks even from the limited set of pollutants it chose to consider.

A. EPA Grossly Understates EGUs' Organic HAP Emissions.

EPA's risk assessment and its rule both rest on the remarkable claim that the entire power plant category emits less than 3 tons per year (tpy) of organic HAPS. 84 Fed. Reg. at 2689. As shown by multiple sources, including data in EPA's own record, that claim is wildly inaccurate.

EPA reached its claim that power plants emit less than 3 tons per year of organic hazardous air pollutants by, first, choosing to ignore the vast majority of organic hazardous air pollutants that power plants emit. As EPA admits, it considered only the following 16 organic hazardous air pollutants:

1. Formaldehyde;
2. Naphthalene;
3. 2-Methylnaphthalene (a kind of polycyclic organic matter, or "POM");
4. Phenanthrene (a kind of POM);
5. 1,2,3,4,6,7,8-Heptachlorodibenzodioxin (a kind of dioxins/furans);
6. Octachlorodibenzo-p-Dioxin (a kind of dioxins/furans);
7. 2,3,7,8-Tetrachlorodibenzofuran (a kind of dioxins/furans);
8. 1,2,3,4,6,7,8-Heptachlorodibenzofuran (a kind of dioxins/furans);
9. Octochlorodibenzofuran (a king of dioxins/furans);
10. 3,3',4,4'-TCB (PCB-77) (a kind of polychlorinated biphenyls, or "PCBs");
11. 2,3',4,4'5-PeCB (PCB-118) (a kind of PCBs);
12. 2,3,4,4',5-PeCB (PCB-114) (a kind of PCBs);
13. 2,3,3',4,4'-PECB (PCB 105) (a kind of PCBs);
14. 2,3',4,4'5,5'-HxCB (PCB-167) (a kind of PCBs);
15. 2,3,3',4,4',5-HxCB (PCBs-156) (a kind of PCBs); and,
16. 2,3,3',4,4',4-HxCB (PCBs-157) (a kind of PCBs).

Residual Risk Assessment for Coal- and Oil-Fired EGU Source Category in Support of the 2019 Risk and Technology Review Proposed Rule ("RRA"), Attachment 1, Development of the RTR Risk Modeling Dataset for the Coal- and Oil-Fired EGU Source Category ("Risk Modeling Memo") at 4-5. Speaking in the ordinary sense, EPA really considered only 5 organic hazardous air pollutants, formaldehyde, naphthalene, POM, dioxins/furans, and PCBs. Apart from formaldehyde and naphthalene, all of the 16 pollutants above are either dioxins/furans, POM, or PCBs.

As EPA is well aware, however, power plants emit many other organic hazardous air pollutants as well. The study by the Electric Power Research Institute (EPRI) that EPA states it

used in preparing the RTR, 84 Fed. Reg. at 2685, shows that power plants emit a host of other organic hazardous air pollutants, including:

1. 1,1-Dichloroethane;
2. 1,2,4-Trichlorobenzene;
3. 1,2-Dibromoethane;
4. 1,4-Dichlorobenezene;
5. 5-methylchrysene;
6. Acetaldehyde;
7. Acrolein;
8. B(a)P equiv.
9. Benzene;
10. Benzyl-chloride;
11. Bis(2-Ethylhexyl)phthalate;
12. Carbon disulfide;
13. Chloroform;
14. Iso-phorone;
15. m/p-Xylene;
16. Methyl chloroform;
17. Methylene chloride;
18. n-Hexane;
19. Phenol;
20. Proprionaldehyde;
21. Tetrachloroethylene;
22. Toluene;
23. Vinyl acetate; and
24. 2,4-Dinitrotoluene

EPRI, June 8, 2018, Hazardous Air Pollutants (HAPs) Emission Estimates and Inhalation Human Health Risk Assessment for U.S. Coal-Fired Electric Generating Units: 2017 Base Year Post-MATS Evaluation ("EPRI Inhalation Study") at Appendix G. Indeed, EPA has plant specific emissions information for all of these hazardous air pollutants. *Id.*

The National Emissions Inventory (NEI), which EPA also claims to have relied on, 84 Fed. Reg. at 2686, shows that power plants emit the following organic hazardous air pollutants:

1. Acetaldehyde
2. Acetophenone
3. Acrolein
4. Benzene
5. Benzyl chloride
6. Bis(2-ethylhexyl)phthalate
7. Bromoform
8. Carbon disulfide
9. 2-Chloroacetophenone
10. Chlorobenzene
11. Chloroform
12. Cumene
13. Cyanide
14. 2,4-Dinitrotoluene
15. Dimethyl sulfate
16. Ethyl benzene
17. Ethyl chloride
18. Ethylene dichloride
19. Ethylene dibromide
20. Formaldehyde

21. Hexane
22. Isophorone
23. Methyl bromide
24. Methyl chloride
25. Methyl ethyl ketone
26. Methyl hydrazine
27. Methyl methacrylate
28. Methyl tert butyl ether
29. Methylene chloride
30. Phenol
31. Propionaldehyde
32. Tetrachloroethane
33. Toluene
34. 1,1,1-Trichloroethane
35. Styrene
36. Xylenes
37. Vinyl acetate

Plainly then, by considering only EGU's emissions of formaldehyde, naphthalene, POM, dioxins/furans, and PCBs, EPA chooses to ignore the vast majority of HAPs that EGUs that EGUs emit.

EPA also understates the quantity of organic HAP emissions by claiming they emit less than 3 tons per year, 84 Fed. Reg. at 2689, and account for less than 1 percent of EGUs total HAP emissions, RRA at 5. Before showing how inaccurate those claims are, it is worth devoting some attention to the method by which EPA reached such an absurd claim.

First, as noted above, EPA considered only five of the more than 30 organic HAPs EGUs emit, formaldehyde, naphthalene, POM, PCBs, and dioxins/furans. EPA's 3 tpy figure is a purported estimate of just one of those pollutants, formaldehyde. RRA at 38 (Table 1). EPA claims the emissions of the rest of the organic HAPs it considered are less than 0.2 tons per year. *Id.*

Second, despite having emissions data for organic HAPs – including in the very data source materials it claims to have used in preparing the proposed RTR – EPA chose to ignore those data and rely, instead, on an analysis of what it describes as "representative detection levels" (RDLs). EPA, Development of Representative Detection Levels of Certain Organic HAP, July, 2018 ("RDL Memo"). For formaldehyde, EPA acknowledged that the RDLs it received in response to its 2010 information collection request ("ICR") varied by more than 4 orders of magnitude, from approximately .0002 parts per million (ppm) to approximately 5.0 ppm. *Id.* at 2-3. EPA states that it chose to use the "second lowest" of these, .000384 ppm. *Id.* at 2. For the other organic HAPs it considered, EPA states its RDLs are "based on" different sources, including the MATs ICR and the ICRs for industrial boilers and coke ovens. EPA does not explain how they are based on these data. Significantly, EPA's approach to using RDLs to estimate emissions departs sharply from the approach EPA that has used in its previous rulemakings for EGUs and other categories and that it has represented as accurate in litigation. In that context, EPA did not use the "second lowest" RDL – an approach that would have led to much more stringent emission standards – but a number equal three times the arithmetic mean of the RDLs it had. *See* EPA, National Emission Standards for Hazardous Air Pollutants (NESHAP) Maximum Achievable Control Technology (MACT) Floor Analysis for Coal- and Oil-fired Electric Utility Steam Generating Units for Final Rule, December, 2016 ("2011 Floor Memo"). By using one approach to generate a high number for the purpose of setting lenient emission standards and another approach to generate a low number for the purpose of determining residual risk, EPA acts arbitrarily. By doing so without any explanation, EPA makes the arbitrariness of its conflicting approaches egregious.

Regardless of its approach, EPA's so-called estimates of EGUs' organic HAP emissions plainly understate these emissions. As shown in the table and attached report from Ranajit Sahu, Phd., an analysis of EPA's own AP-42 factors for coal combustion and the most recent year coal burned in US coal EGUs from reporting by utilities to the Department of Energy, Energy Information Administration (EIA) numbers for the amount of coal consumed by EGUs in 2018, EGUs actually emit almost 3,000 tons of organic hazardous air pollutants each year. *See* Attachment 1, Sahu, Underestimation of Organic HAP Emissions from Coal-Fired Boilers by EPA.

Pollutant	Emission Factor (lb/ton coal burned)	Rating	Coal Used In 2018 (EIA Table 7.3b) (tons/year)	Emissions (2018) (tons/year)
Acetaldehyde	5.7E-04	C	633015526	180.4
Acetophenone	1.5E-05	D	633015526	4.7
Acrolein	2.9E-04	D	633015526	91.8
Benzene	1.3E-03	A	633015526	411.5
Benzyl chloride	7.0E-04	D	633015526	221.6
Bis(2-ethylhexyl)phthalate	7.3E-05	D	633015526	23.1
Bromoform	3.9E-05	E	633015526	12.3
Carbon disulfide	1.3E-04	D	633015526	41.1
2-Chloroacetophenone	7.0E-06	E	633015526	2.2
Chlorobenzene	2.2E-05	D	633015526	7.0
Chloroform	5.9E-05	D	633015526	18.7
Cumene	5.3E-06	E	633015526	1.7
Cyanide	2.5E-03	D	633015526	791.3
2,4-Dinitrotoluene	2.8E-07	D	633015526	0.1
Dimethyl sulfate	4.8E-05	E	633015526	15.2
Ethyl benzene	9.4E-05	D	633015526	29.8
Ethyl chloride	4.2E-05	D	633015526	13.3
Ethylene dichloride	4.0E-05	E	633015526	12.7
Ethylene dibromide	1.2E-06	E	633015526	0.4
Formaldehyde	2.4E-04	A	633015526	76.0
Hexane	6.7E-05	D	633015526	21.2
Isophorone	5.8E-04	D	633015526	183.6
Methyl bromide	1.6E-04	D	633015526	50.6
Methyl chloride	5.3E-04	D	633015526	167.7
Methyl ethyl ketone	3.9E-04	D	633015526	123.4
Methyl hydrazine	1.7E-04	E	633015526	53.8
Methyl methacrylate	2.0E-05	E	633015526	6.3
Methyl tert butyl ether	3.5E-05	E	633015526	11.1
Methylene chloride	2.9E-04	D	633015526	91.8
Phenol	1.6E-05	D	633015526	5.1

Propionaldehyde	3.8E-04	D	633015526	120.3
Tetrachloroethane	4.3E-05	D	633015526	13.6
Toluene	2.4E-04	A	633015526	76.0
1,1,1-Trichloroethane	2.0E-05	E	633015526	6.3
Styrene	2.5E-05	D	633015526	7.9
Xylenes	3.7E-05	C	633015526	11.7
Vinyl acetate	7.6E-06	E	633015526	2.4
Sum (All Above)	**9.2E-03**			**2907.6**
SUM (A-rated only)				**563.4**
SUM (C-rated only)				**192.1**

Data from the National Emissions Inventory (NEI) and the EPRI Inhalation Report, both of which EPA claims to have used in preparing the proposed RTR, confirm that EPA's 3 tpy figure for organic HAPs is wildly inaccurate. The NEI data indicate that, in 2014, organic HAP emissions from EGUs were over 3400 tons. *See* Attachment 1.

Table 2 - Organic HAP from 2014 NEI		
Organic HAP	**Emissions (lb/year)**	**Emissions (tons/year)**
Cyanide	1907742	954
Benzene	773003	387
Benzyl Chloride	491297	246
Isophorone	433072	217
Methyl Chloride	411648	206
Acetaldehyde	396199	198
Propionaldehyde	271559	136
Methylene Chloride	246643	123
Acrolein	230872	115
Methanol	204464	102
Formaldehyde	199745	100
Toluene	192148	96
Methylhydrazine	138346	69
Methyl Bromide	121648	61
Xylenes (Mixed Isomers)	114798	57
Carbon Disulfide	97596	49
Ethyl Benzene	91075	46
Bis(2-Ethylhexyl)Phthalate	65960	33
Hexane	49329	25
Chloroform	44344	22
Dimethyl Sulfate	38049	19
Ethyl Chloride	34703	17
Bromoform	31308	16

Ethylene Dichloride	31100	16
Tetrachloroethylene	30870	15
Styrene	30377	15
Methyl Tert-Butyl Ether	27592	14
Chlorobenzene	18610	9
Phenol	18472	9
Methyl Methacrylate	15961	8
Acetophenone	13758	7
Naphthalene	13353	7
Methyl Isobutyl Ketone	10599	5
Acrylonitrile	9532	5
Biphenyl	7288	4
Vinyl Acetate	6421	3
Allyl Chloride	6283	3
Methyl Chloroform	5616	3
2-Chloroacetophenone	5600	3
Phenanthrene	5024	3
Cumene	4190	2
Dibenzofuran	3559	2
2,4-Dinitrotoluene	3374	2
Ethylene Dibromide	2892	1
1,2,4-Trichlorobenzene	1935	1
Methyl Iodide	1922	1
Nitrobenzene	1794	1
Benzidine	1778	1
1,4-Dichlorobenzene	1732	1
PAH/POM - Unspecified	1665	1
o-Cresol	1538	1
Acenaphthene	1105	1
Dimethyl Phthalate	1074	1
p-Cresol	1050	1
Vinyl Chloride	911	0.456
Fluorene	826	0.413
Vinylidene Chloride	776	0.388
Fluoranthene	776	0.388
Dibutyl Phthalate	774	0.387
Ethylidene Dichloride	723	0.362
m-Xylene	710	0.355
1,3-Dichloropropene	666	0.333
Chrysene	617	0.309
Carbon Tetrachloride	599	0.299
1,1,2-Trichloroethane	594	0.297
Benzo[a]Pyrene	501	0.251
Propylene Dichloride	403	0.201
Phthalic Anhydride	392	0.196

Benz[a]Anthracene	358	0.179
Trichloroethylene	344	0.172
Acetonitrile	323	0.161
o-Xylene	215	0.107
m-Cresol	201	0.101
Pyrene	180	0.090
Acenaphthylene	135	0.068
Benzo[g,h,i,]Perylene	124	0.062
Carbonyl Sulfide	118	0.059
Anthracene	114	0.057
1,1,2,2-Tetrachloroethane	73	0.036
Hexachlorobenzene	72	0.036
N-Nitrosodimethylamine	54	0.027
Indeno[1,2,3-c,d]Pyrene	30	0.015
1,3-Butadiene	26	0.013
Dibenzo[a,e]Pyrene	15	0.007
Chloroacetic Acid	12	0.006
5-Methylchrysene	10	0.005
2,4-Dinitrophenol	10	0.005
Pentachloronitrobenzene	8	0.004
Cresol/Cresylic Acid (Mixed Isomers)	8	0.004
2,2,4-Trimethylpentane	7	0.004
Benzofluoranthenes	5	0.003
N-Nitrosomorpholine	4	0.002
Trifluralin	4	0.002
Pentachlorophenol	4	0.002
Quinoline	4	0.002
Hexachloroethane	4	0.002
1,2-Dibromo-3-Chloropropane	4	0.002
2-Methylnaphthalene	3	0.002
2,4,6-Trichlorophenol	3	0.002
2,4,5-Trichlorophenol	3	0.001
Hydroquinone	3	0.001
2-Chloronaphthalene	3	0.001
o-Anisidine	3	0.001
Dichloroethyl Ether	2	0.001
4-Nitrobiphenyl	2	0.001
3,3'-Dimethoxybenzidine	2	0.001
p-Xylene	2	0.001
o-Toluidine	2	0.001
4,4'-Methylenedianiline	2	0.001
1,2-Epoxybutane	1	0.001
Aniline	1	0.001
N,N-Dimethylaniline	1	0.001

4-Dimethylaminoazobenzene	1	0.001
Benzo[b]Fluoranthene	1	0.001
4-Aminobiphenyl	1	0.0004
3,3'-Dimethylbenzidine	1	0.0004
4-Nitrophenol	1	0.0003
Dibenzo[a,h]Anthracene	0.43	0.0002
Polychlorinated Biphenyls	0.34	0.0002
Ethyl Acrylate	0.29	0.0001
Vinyl Bromide	0.22	0.0001
Dibenzo[a,j]Acridine	0.16	0.0001
Benzo[k]Fluoranthene	0.15	0.0001
Dibenz[a,h]acridine	0.03	0.00002
Benzo[e]Pyrene	0.03	0.00002
		3442

It bears emphasis that EPA's estimate is inaccurate even for the HAPs EPA claims to have considered. For example, whereas EPA claims formaldehyde emissions are less than 3 tpy, the AP-42 emissions data indicate formaldehyde emissions are 76 tons per year.

Many of the organic HAPs that EPA either chose to ignore or grossly underestimated cause cancer and other serious adverse health effects. The following is a summary of the health impacts of some of the hazardous air pollutant compounds emitted by power plants.

Benzene Human exposure to benzene has been associated with a range of acute and long-term adverse health effects and diseases, including cancer and adverse hematological, reproductive and developmental effects. [4] Benzene is a known carcinogen; long term exposure can cause leukemia.[5] Inhalation of high doses of benzene may impact the central nervous system leading to drowsiness, dizziness, irregular heartbeat, nausea, headaches, and depression.[6] Female workers experiencing high exposure levels over the course of many months experienced reproductive impacts, such as a decrease in the size of their ovaries. In animal studies, breathing benzene was associated with developmental effects such as low birth weight, delayed bone formation, and bone marrow damage.[7]

Toluene California's list of chemicals known to cause cancer or reproductive toxicity includes toluene as a developmental toxicant.[8] Similar to many organic solvents, toluene acts as a

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[4] CARB, Report to the Scientific Review Panel on Benzene, Prepared by the Staffs of The Air Resources Board and The Department of Health Services, November 27, 1984, http://www.arb.ca.gov/toxics/id/summary/benzene.pdf.

[5] Chronic Toxicity Summary: Benzene, http://www.oehha.org/air/chronic_rels/pdf/71432.pdf

[6] World Health Organization, Exposure to Benzene: A Major Public Health Concern, http://www.who.int/ipcs/features/benzene.pdf.

[7] Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Benzene,* U.S. Department of Health and Human Services, August 2007.

[8] California EPA Office of Environmental Health Hazard Assessment, 'Chemicals Known to the State to Cause Cancer or Reproductive Toxicity', 2013, http://oehha.ca.gov/prop65/prop65_list/files/P65single052413.pdf (accessed June 2013)

respiratory tract irritant, particularly at high air concentrations.[9] For this reason, it can be especially harmful to people with asthma. A ubiquitous air pollutant, exposure to toluene constitutes a serious health concern as it has negative impacts on the central nervous system. Exposure to toluene can cause headaches, impaired reasoning, memory loss, nausea, impaired speech, hearing, and vision, amongst other health effects.[10] Long term exposure may damage the liver and kidneys.[11]

Ethylbenzene Ethylbenzene has been recently classified as a possible human carcinogen by the International Agency for Research on Cancer ("IARC")[12], and has been associated with a number of adverse health outcomes. Breathing high levels can cause dizziness as well as throat and eye irritation; chronic, low-level exposure over several months to years can result in kidney damage as well as hearing loss.[13]

Xylene[14] Short term exposure to xylene may result in a number of adverse human health effects including irritation of the skin, eyes, nose and throat; difficulty breathing; damage to the lungs; impaired memory; and possible damage to the liver and kidneys. Long term exposure may affect the nervous system presenting symptoms such as headaches, lack of muscle coordination, dizziness, confusion, and loss of balance.[15] More serious long term health effects include memory impairment, red and white blood cell abnormalities, abnormal heartbeat (in laboratory workers), liver damage, mutagenesis (mutations of genes), reproductive system effects, and death due to respiratory failure.[16]

Polycyclic aromatic hydrocarbons (PAHs also described as Polycyclic Organic Matter, or POM) are a group of over 100 different chemicals that are formed during incomplete

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[9] Agency for Toxic Substances and Disease Registry, *Toluene Toxicity*: *Case Studies in Environmental Medicine*, U.S. Department of Health and Human Services, Division of Toxicology and Environmental Medicine, February 2001, http://www.atsdr.cdc.gov/hec/csem/toluene/docs/toluene.pdf (accessed June, 2013)

[10] *Id.*

[11] National Institute for Occupational Safety and Health, 'Toluene', *NIOSH Pocket Guide to Chemical Hazards*, 2010, http://www.cdc.gov/niosh/npg/npgd0619.html (accessed June 2013)

[12] Henderson, Leigh, David Brusick, Flora Ratpan, and Gauke Veenstra, 'A Review of the Genotoxicity of Ethylbenzene', *Mutation Research/Reviews in Mutation Research,* 635 (2007), 81-89 <doi:10.1016/j.mrrev.2007.03.001>

[13] Agency of Toxic Substances and Disease Registry, *Toxicological Profile for Ethylbenzene*, *ToxFAQs*, 2010, http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=382&tid=66 (accessed June 2013)

[14] Also known as dimethyl benzene

[15] Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Xylene,* U.S. Department of Health and Human Services, August 2007.

[16] Zoveidavianpoor, M., A. Samsuri, and S. R. Shadizadeh, 'The Clean Up of Asphaltene Deposits in Oil Wells', *Energy Sources, Part A: Recovery, Utilization, and Environmental Effects*, 35 (2013), 22–31 <doi:10.1080/15567036.2011.619630>

combustion.[17,18,19] Infants and children are *especially* susceptible to the hazards of PAHs, a class of known human mutagens, carcinogens, and developmental toxicants found in diesel exhaust.[20] Greater lifetime cancer risks result from exposure to carcinogens at a young age. These substances are known to cross the placenta to harm the unborn fetus, contributing to fetal mortality, increased cancer risk, and birth defects.[21] Prenatal exposure to PAHs may also be a risk factor for the early development of asthma-related symptoms and can adversely affect children's cognitive development, with implications for diminished school performance.[22] Exposure of children to PAHs at levels measured in polluted areas can also adversely affect IQ.[23] Low molecular weight PAHs can form quinones, which exert pulmonary oxidative stress and have a potent negative affect on the immune system.[24]

Cyanide exposure at high levels swiftly harms the brain and heart, beginning with rapid breathing, followed by convulsions, and loss of consciousness, and can even cause coma and death.[25] More commonly, even low level exposure to hydrogen cyanide is associated with breathing difficulties, chest pain, vomiting, headaches, and enlargement of the thyroid gland.[26]

Naphthalene, a known carcinogen, also has respiratory impacts, ocular effects such as cataracts and retinal damage, and impacts to the hematological systems.[27]

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[17] Salmon A.G. and Meehan T. Potential Impact of Environmental Exposures to Polycyclic Organic Material (POM) on Children's Health, California Office of Environmental Health Hazard Assessment (OEHHA). http://www.oehha.ca.gov/public_info/public/kids/pdf/PAHs%20on%20Children's%20Health.pdf

[18] Agency for Toxic Substances and Disease Registry, Public Health Statement for Polycyclic Aromatic Hydrocarbons (PAHs). August 1995. http://www.atsdr.cdc.gov/PHS/PHS.asp?id=120&tid=25

[19] Perera FP. DNA Damage from Polycyclic Aromatic Hydrocarbons Measured by Benzo[a]pyrene-DNA Adducts in Mothers and Newborns from Northern Manhattan, The World Trade Center Area, Poland, and ChinaCancer Epidemiol Biomarkers Prev 2005;14(3):709–14.

[20] Salmon A.G. and Meehan T. "Potential Impact of Environmental Exposures to Polycyclic Organic Material (POM) on Children's Health," California Office of Environmental Health Hazard Assessment (OEHHA). http://www.oehha.ca.gov/public_info/public/kids/pdf/PAHs%20on%20Children's%20Health.pdf.

[21] Perera FP. "DNA Damage from Polycyclic Aromatic Hydrocarbons Measured by Benzo[a]pyrene-DNA Adducts in Mothers and Newborns from Northern Manhattan, The World Trade Center Area, Poland, and China," *Cancer Epidemiology Biomarkers & Prevention* 14, no. 3 (2005):709–14.

[22] Perera FP, Rauh V, Tsai WY, Kinney P, Camann D, et al. "Effects of transplacental exposure to environmental pollutants on birth outcomes in amultiethnic population," *Environmental Health Perspective* 111 (2003): 201–205. Perera FP et. al. "Effect of Prenatal Exposure to Airborne Polycyclic Aromatic Hydrocarbons on Neurodevelopment in the First 3 Years of Life among Inner-City Children," *Environmental Health Perspective* 114 (2006):1287–1292.

[23] Perera, FP et. al. "Prenatal Airborne Polycyclic Aromatic Hydrocarbon Exposure and Child IQ at Age 5 Years," *Pediatrics* 124 (2009):e195–e202.

[24] Bolton, J., Trush, M.A., Penning, T.M., Dryhurst, G., & Monks, T.J. (2000). Role of Quinones in Toxicology. Chemical Research in Toxicology, 13(3), 135–160. doi: 10.1021/tx99; Ikeda, A., Vu, K.K.-T., Lim, D., Tyner, T.R., Krishnan, V.V., & Hasson, A.L. (2012). An Investigation of the Use of Urinary Quinones as Environmental Biomarkers for Exposure to Ambient Particle-Borne Pollutants. Science of the Total Environment (submitted).

[25] ATSDR, ToxFaqs, http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=71&tid=19

[26] *Id.*

[27] CalEPA, Air Toxics Hotspots, Adoption of a Unit Risk Value for Naphthalene, 2004. http://www.oehha.ca.gov/air/hot_spots/pdf/naphth080304.pdf

1,3-butadiene causes inflammation of nasal tissues, changes to lung, heart, and reproductive tissues, neurological effects, and blood changes; it is a known carcinogen associated with cancers of the blood and lymphatic system, and it may also cause birth defects according to animal studies.[28]

Formaldehyde is a known carcinogen that can cause asthma or asthma-like symptoms, neurological effects, increased risk of allergies, and Eczema and changes in lung function at exposure levels from 0.6 to 1.9 ppm.[29]

Acetaldehyde is carcinogenic, mutagenic (or genotoxic) and may cause reproductive and developmental harm based on animal studies.[30]

Both by failing to even consider most of the organic HAPs that EGUs emit and by grossly understating emissions of the few organic HAPs it did consider, EPA vastly understates the risk of cancer and other adverse health effects that EGUs still present. Even if EPA does not believe the emission estimates derived from the AP-42 factors, from the NEI data, and from the EPRI study are correct, the agency's emissions estimate – and therefore its risk estimates – would still be unlawful arbitrary and capricious. EPA cannot dispute that EGUs emit organic HAPs that its risk assessment does not consider. The Clean Air Act requires EPA to evaluate the full risk from EGU's emissions, not the risk from a subset of those emissions. EPA's proposed RTR is unlawful and arbitrary both because it ignores the majority of HAPs emitted by EGUs and because EPA offers no explanation for ignoring these HAPs despite having several data sources showing that EGUs emit them. EPA must withdraw the RTR and issue a new one based on an accurate calculation of the risks presented by emissions of all the HAPs that EGUs emit.

B. EPA Underestimates Emissions of The HAPS It Considered.

1. EPA's Use of So-Called "Actual" Emissions Data Is Unlawful and Arbitrary.

For the HAPs included in its risk analysis as well, EPA understates EGUs' emissions. First, although EPA claims to be basing its assessment of inhalation risks on "allowable" emission numbers, the agency also provides so-called "actual" emission numbers and may be basing its risk assessment on them. EPA appears to have used only so-called "actual" emission numbers to assess acute risks and multipathway risks.

Any estimate based on so-called "actual" emission numbers is unlawful and arbitrary for several reasons. First, many of these numbers do not reflect actual emissions at all. As EPA itself states, "[o]ther sources of data that were used … included EPA-developed emission factors and emission factor-based ratios, EPA-developed representative detection limit (RDL) values, the 2014 National Emissions Inventory (NEI), and the June 2018 2018 EPRI technical report on HAP emissions from coal fired EGUs." RRA, Appendix 1 at 7.

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[28] ATSDR ToxFaqs; http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=458&tid=81
[29] ATSDR ToxFaqs; http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=219&tid=39
[30] CalEPA, 1993 Determination of Acetaldehyde as a TAC. http://www.oehha.ca.gov/air/toxic_contaminants/html/Acetaldehyde.htm

As shown above, EPA's use of RDLs for the purpose of assessing risk is starkly and arbitrarily inconsistent with its use of RDLs to set emission standards. As for estimates based emission factors, which includes both the NEI and EPRI data, EPA's own Inspector General has stated that the use of emission factors, generally, results in inaccurate and unreliable emissions datans data is used to create regional and that "[t]he heavy use of emission factors in the [national emissions inventory] makes the *reliability of the data highly uncertain*. Emission factors can result in emissions data of *questionable reliability* . . . ."[31]

Emission factors underestimate emissions in part because; (1) they incorporate the erroneous assumption that equipment is operating as designed under normal conditions and (2) the emission factors do not account for environmental variables that significantly impact emissions. The tests used to develop emission factors are intentionally conducted on new equipment operating under normal conditions because emission factors are formulas that attempt to estimate long-term average emissions.[32] EPA itself notes that "[p]arameters that can cause short-term fluctuations in emissions are generally avoided in testing and not taken into account in test evaluation."[33] Further, "[s]ources often are tested more frequently when they are new and when they are believed to be operating properly, and *either situation may bias the results*."[34] The incorporation of this erroneous assumption in the development of the emission factors significantly distorts emissions data in two significant ways – emissions generated during upset, SSM events, and increased emissions that result from poor maintenance of equipment are not accounted for in a facility's reported emissions and emissions inventories.

Because emission factors incorporate the assumption that equipment is functioning as designed under normal conditions, emissions produced during SSM events are not accurately represented in reported emissions. The emissions from SSM events can be significant, and industry-filed reports show that for some facilities, releases from SSM events were actually higher than the total annual emissions reported to EPA's Toxics Release Inventory ("TRI") or state emission inventories for the entire facility for the entire year.[35] In 2004, for example, half of the 37 facilities studied had SSM emissions of at least one pollutant that were 25% or more of their reported annual emissions of that pollutant.[36] For 10 of the facilities, SSM emissions of at least one pollutant actually exceeded the annual emissions that each facility reported to the state for that pollutant.[37]

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[31] Office of Inspector Gen., U.S. Envtl. Prot. Agency, EPA Can Improve Emissions Factors Development and Management (No. 2006-P-00017) (Mar. 22, 2006) [hereinafter EPA Can Improve] at 18 *and* Memorandum from Brenda Shine, U.S. Envtl. Prot. Agency, on Potential Low Bias of Reported VOC Emissions from the Petroleum Refining Industry to EPA Docket No. EPA-HQ-OAR-2003-0146 (July 27, 2007) [hereinafter EPA, Potential Low Bias].

[32] EPA, Compilation of Air Pollutant Emission Factors, Vol. 1: Stationary Point and Area Sources, 4-5, *available at* http://www.epa.gov/ttn/chief/ap42/index.html [hereinafter EPA, AP-42 Series].

[33] *Id.*

[34] *Id.* at 2–3. (emphasis added).

[35] Envtl. Integrity Project, Gaming the System: How Off-the-Books Industrial Upset Emissions Cheat the Public Out of Clean Air (Aug. 2004).

[36] *Id.*

[37] *Id.*

Similarly, basing emission factors on this faulty assumption fails to accurately account for increased emissions that result from poor maintenance of equipment. Failing to account for the significant emissions produced during SSM upset events or increased emissions that result from poor equipment maintenance results in grossly inaccurate, unreliable, and biased emissions data.

Further, even where EPA does not use emission factors, the data EPA uses range widely in quality from particulate matter (PM) continuous emissions monitoring systems (CEMS) used for compliance purposes to data gathered intermittently from sorbent traps, to data from a single stack test. RRA, Appendix 1, at 5-8. EPA also used parameter monitoring data, which is linked only indirectly to actual emissions and only based on parameter measurements taken during a single stack test.

Where EPA uses anything less than a continuous and uninterrupted stream of CEMS compliance data, it is providing only a partial picture of EGUs' actual emissions. Where EPA relies on a single stack test, it is providing only a snapshot. Emissions before and after the snapshot or snapshots that EPA provides may be higher, especially given that EGUs have both ample opportunity and incentive to optimize their operations and minimize their emissions for stack tests, which are scheduled well in advance. In these circumstances, EPA itself has consistently taken the position that it needs to account for the variability of sources' emissions during the times other than when the test is being conducted. To do so, in the standard-setting context, EPA has used a 99 percent upper prediction limit (99% UPL) approach. EPA has represented repeatedly to courts and to the public – including in setting the standards for EGUs that it is now reviewing – that this 99% UPL approach yields an estimate of the "average" level of emissions for the sources to which it applies. EPA has argued that it could not use the emissions test without applying the 99% UPL because doing so would fail to account for the higher emission levels that occur when a source is not being tested. Given EPA's prior representations, EPA must apply the same 99% UPL approach now to any so-called "actual" emissions data it chooses to use in the risk assessment process. Failure to do so would be unlawful and arbitrary. Further, EPA's failure to even acknowledge its own prior representations that actual data do not accurately represent sources' performance and that a 99% UPL is necessary to account for variability, and to explain why it is not using the 99% UPL approach in its risk assessment, is arbitrary.

Because all of these sources of data underestimate emissions for the reasons given above, it is unlawful and arbitrary for EPA to rely on them to assess risk. To avoid having the use of these estimates hopeless taint its risk assessment, EPA must assume that all EGUs emit as much as they are allowed to emit at all times. Even then, as explained below, EPA's approach will underestimate emissions.

2. EPA Must Account For The Increased Emissions, And Health Risks, From "Non-Routine" Or Malfunction-Based Emissions, And During Startup And Shutdown Periods, Instead Of Simply Ignoring These Emissions And Risks.

EPA states that it believes the use of so-called "MACT-allowable" emission levels to determine risk levels "is inherently reasonable since that risk reflects the maximum levels

facilities could emit and still comply with national emission standards." 84 Fed. Reg. at 2689. For two obvious reasons, EPA's premise is wrong.

First, EPA ignores that its emission limits to not apply to periods of startup and shutdown. EGUs can and do exceed their emission limits during these periods. Second, EGU can and do exceed their emission limits during malfunctions. The excess hazardous emissions that occur during malfunctions are not "allowable," but that does not make them any less real or any less dangerous to the people who are exposed to them.

a. EPA may not lawfully or rationally fail to account for additional emissions and health risks during upsets and malfunctions.

EPA *must* account for upset emissions in modeling for risk assessments. EPA must also consider whether changes in the existing standards could mitigate the problem and better protect the public with an ample margin of safety. It is not enough simply to point to the availability of enforcement suits by citizens or government entities.

Malfunction events increase emissions and thereby pose increased health risks which EPA must consider. Where control equipment fails for any reason, emissions could be at least 100 times greater than usual (e.g., in the circumstance where a control device has 99% efficiency, such that an uncontrolled release would cause 100 times the usual amount of emissions). Ignoring such emissions is an unlawful and arbitrary example of the problem of ignoring health risk in the agency's assessment. The higher emissions caused by malfunction or upset emissions can accumulate and combine to increase public health impacts and lead to much higher risks for community members than those they face on a daily basis.

Failing to look at the true potential for spikes in emissions over a person's lifetime may underestimate acute risk, cancer risk and the amount of chronic non-cancer risk based on pollutants that persist in the environment, such as nickel and antimony (for the two source categories EPA recognizes emit one or both of those pollutants). Ignoring these emission spikes is equivalent to treating additional health risk caused by exceedances as zero. The Science Advisory Board has criticized EPA's underestimation of maximum short-term emissions, and this rulemaking continues to suffer from the same flaws that SAB identified. EPA knows that there is additional risk from malfunctions and violations, and it has no lawful or scientific basis to ignore this additional risk.

EPA calls its method of calculating acute risk a "worst-case" scenario approach, and it does attempt to account for some variability in assessing health risks as shown by the use of a factor at all. But it does not come close to modeling the actual "worst case" scenario because each such factor is too low, as it is ignoring all malfunctions which exceed the standards. Still, EPA's recognition that it is appropriate to use factors to assess higher emissions shows that the agency could simply use a more accurate factor to account for malfunctions for acute and other types of health risk in order to close the gap and respond appropriately to SAB's criticism of its current method. EPA regularly uses statistical methods and probability factors, which are readily available tools that EPA can also use to assess health risk due to malfunctions in order to set clean air standards.

To create representative factors to assess the health risk from malfunctions, EPA has information available, or can collect information, on EGUs' malfunction and violation histories from the reports required under the prior rule. If EPA needs more refined data regarding these emissions to fulfill its legal obligation, EPA should simply request additional data from sources.

b. EPA may not lawfully or rationally fail to account for additional emissions and health risks during startups and shutdowns.

As explained in more detail below, air pollution from EGUs can be particularly problematic during periods when these facilities are starting up and shutting down, which can occur many times in the course of a year. EPA found that the "average EGU had between 9 and 10 startup events per year during 2011-2012, but data from a small number of EGUs indicated significantly more startup events (e.g., the EGUs with the most startup events had over 100 startup events in 2011 and over 80 in 2012)." Assessment of startup period at coal-fired electric generating units - Revised, EPA-HQ-OAR-2009-0234-20451 at 4 (Nov. 2014) ("Measurability Analysis").[38] As environmental groups have previously pointed out in comments, as coal-fired EGUs are forced into more and more intermittent use by less expensive gas-fired units and renewable energy, the number of startups will likely increase. *See* EPA-HQ-OAR-2009-0234-20427 at 3, Ex. C.

EPA has recognized that EGUs' pollution can be significant during periods of startup and shutdown. In EPA's "SSM SIP call," EPA stated that startup and shutdown emissions have "real-world consequences that adversely affect public health." 80 Fed. Reg. 33,840, 33,850 (June 12, 2015). In a memo that EPA cited in the preamble to that rule, EPA stated that it is "concerned about the amounts of excess emissions that occur during" periods of startup, shutdown, and malfunction. *Id.* at 33,850 n.22; Memorandum: Statutory, Regulatory, and Policy Context for this Rulemaking, EPA-HQ-OAR-2012-0322-0029 at 22 ("Rulemaking Context Memo"). "Available evidence suggests that the amount of extra emissions that occurs during these … periods is potentially large." Rulemaking Context Memo at 23."

By failing to account for EGUs' HAP emissions during startup, EPA unlawfully and arbitrarily ignores risk from EGUs and understates the total risk from this category.

II. EPA UNDERESTIMATES HEALTH RISKS FROM EGUS.

Although EPA states that it is taking a conservative, health-protective approach, and it has made some progress in recent years, the agency still lags well behind the best available, current science to address the real-world health risk for the individual most exposed to the current source categories. EPA must finally act to apply this science in the risk assessment for EGUs and all other health risk rulemakings under the Clean Air Act under § 7412(f)(2).

In particular, EPA has no valid excuse not to follow the recommendations of the National Academy of Sciences and its own Science Advisory Board on the below-discussed key issues

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[38] EPA noted that it may have double-counted some startup events. *Id.* at n.10.

that affect the most-exposed and most vulnerable populations, especially children and environmental justice communities.

California's Office of Health Hazard Assessment ("OEHHA") has addressed most of the scientific developments described below, particularly the explicit consideration of infants and children; EPA has no reasonable basis not to do the same. In particular, OEHHA is now applying final scientific technical support documents to update its Air Toxics Hot Spots Program Guidance Manual (Sept. 2014).[39] Those scientific documents and the new manual provide a clear roadmap that the U.S. EPA can and should use to close major gaps in its consideration of health risks from air toxics sources.

As further explained below, EPA must consider the science, and update and strengthen its risk assessment in, at least, each of the following ways before finalizing the rule:

- Account for individual-level vulnerability in this risk assessment by better incorporating the vulnerability of children, early-life exposures, and the developing fetus into risk assessment methods:
    - Account for increased susceptibility by using age-dependent adjustment factors for all carcinogens, not just known mutagens.
    - Pre-natal susceptibility: Account for increased susceptibility by using a pre-natal adjustment factor for all carcinogens of <u>at least 10X.</u>
    - For chronic non-cancer risk, consult and apply child-specific reference values (such as those created by California EPA scientists), where available.
    - If child-specific reference values are unavailable, consult science on early exposure impacts, and use an additional default factor of <u>at least 10X</u>.
- Account for vulnerability due to residence in a community that is highly exposed, by including factors to account for increased vulnerability based on demographic differences, as part of the risk assessment. EPA also must fully integrate the findings of its environmental justice analyses into this risk assessment and rulemaking, and set stronger pollution limits to provide environmental justice.
- Assess the cumulative burden of exposures to multiple pollutants and sources via multiple pathways:
    - Assess and aggregate exposure from multiple pathways – including by adding inhalation and non-inhalation-based cancer risks.
    - Include the interaction of multiple pollutants.
    - Account for exposure to multiple sources. Until EPA has a specific mechanism for estimating total exposures, a default or uncertainty factor of at

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[39] *See* Air Toxics Hot Spots Program Guidance Manual (SRP Draft) (Sept. 2014), http://oehha.ca.gov/air/hot_spots/riskguidancedraft2014.html. Although this manual is a draft, the scientific determinations it implements are all <u>final, peer-reviewed</u> documents, which all went through public notice and comment. As OEHHA explains, "the draft Guidance Manual combines the critical information from the three [Technical Support Documents, finalized in 2008, 2009, and 2012] into a guidance manual for the preparation of health risk assessments." *Id.* Each of these final Technical Support Documents are attached in the Appendix, although EPA has them before the agency in other rulemaking dockets as well.

least 10X should be used to provide overburdened communities with the protection they need now.

- Account for cumulative impacts of multiple exposures and vulnerabilities by shifting the level of risk which triggers policy action.
    - Reduce EPA's benchmark of what it considers acceptable lifetime cancer risk instead of relying on the outdated upper limit of 100-in-a-million.
    - Use a Margin of Exposure ("MOE") framework for non-cancer impacts and adjust the target MOE according to known vulnerability factors.
- In the face of increasing evidence calling into question the assumption of a safe or acceptable level of exposure, EPA should also consider changing its approach to risk assessment to support reducing risks to the lowest possible level, to protect public health, rather than suggesting that there is always a safe or acceptable level. As EPA itself has recognized, there are many uncertainties suggesting its risk assessment is an underestimate and only addresses part of the picture.

EPA has no reasoned explanation for not applying the current science to address each of the above problems with its current risk assessment. And, as shown below, EPA has no valid basis for ignoring the science from experts such as the National Academy of Sciences, Science Advisory Board, and other expert regulators, such as California EPA's Office of Health Hazard Assessment (OEHHA). EPA must direct its staff to apply the best scientific evidence tools currently available on risk assessment.

It would be both unlawful under § 7412(f)(2) for EPA to ignore the health risks outlined above, and arbitrary and capricious for EPA to avoid applying the best available science here. It also would be unacceptable and unjust for EPA to ignore the current scientific and regulatory tools available for communities bombarded by toxic air pollution from the current source categories and many others. If EPA wishes to act on its stated commitment to environmental justice, it will finally start using the science available now to address these impacts and risks, while also working to continue to update its risk assessment approaches.

A. EPA's Assessment of Health Risks at the Census Block Centroid Violates the Act's Requirement to Protect "the Most-Exposed Individual" And Is Arbitrary.

As part of the residual risk assessment for each source category, EPA unlawfully and arbitrarily fails to assess the health risks for "the individual most exposed to emissions" from each of the three source categories as § 7412(f)(2) requires. Instead, EPA has chosen an arbitrary point, a census-block centroid, without demonstrating that this is equivalent to the person "most exposed." 84 Fed. Reg. at 2690. As EPA's Science Advisory Board explained in a 2018 report, EPA's ad hoc attempt to assess health risks to the most-exposed person is not

scientifically justified.[40] EPA's failure to meet this core statutory requirement renders the proposed rule unlawful and arbitrary.

EPA's modeling understates cancer and other chronic health risk by assuming that chronic exposure to hazardous air pollutants from this source occurs at the census block centroid and *not* at the facility fence or property line, even though people do live in those locations. According to the risk assessment document, EPA used concentrations at the census block centroid as "as a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block." 84 Fed. Reg. at 2690. For these risks from HAP emissions, no effort was made to move receptor points closer to the facility to assess chronic or cancer risk, even in those instances where local residents live nearer to a facility than the geographic centroid of the census block. This conflicts with the recommendation of the SAB, which has urged EPA to consider "specific locations of residences."[41]

Census block centroids are insufficient as a matter of science and do not satisfy EPA's duty to assess health risks and protect the "most exposed" individual as required by § 7412(f)(2). EPA's current modeling approach understates cancer and other chronic health risks by assuming that chronic exposure to hazardous air pollutants from this source occurs at the census block centroid and *not* at the facility fence or property line, even though people often do live or spend significant time at or near those locations. For risks from HAP emissions, no scientific effort has been made to move receptor points closer to the facility to assess chronic or cancer risk, even in those instances where local residents live nearer to a facility than the geographic centroid of the census block. This conflicts with the recommendation of the Science Advisory Board, which has urged EPA to consider "specific locations of residences."[42]

Even in its most recent (2018) review, the SAB has found that EPA's report "does not provide enough information about the tool, especially regarding criteria that would determine the number and placement of new receptors."[43] Like the SAB panel, Commenters are concerned that EPA's method is not scientific or lawful, would not be reproducible, and that application would vary should a different risk assessor conduct modeling on an individual facility. It is imperative that the EPA has verification metrics in place to ensure that it assesses health risks based on the actual or likely locations of specific receptors representative of those living near the facility and/or who are the people most exposed to a source or source category.

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[40] SAB, "Review of EPA's Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis" (April 25, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/ea5d9a9b55cc319285256cbd005a472e/325bb44f95bdfe218525827b00708c90/$FILE/Final%20Draft%20RTR%20Panel%20Report%2025Apr18.pdf.

[41] SAB May 2010 at 4, *supra* n.93.

[42] SAB, "Review of EPA's draft entitled, 'Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing" (May 7, 2010), https://yosemite.epa.gov/sab/sabproduct.nsf/0/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf.

[43] SAB, "Review of EPA's Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis" (April 25, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/ea5d9a9b55cc319285256cbd005a472e/325bb44f95bdfe218525827b00708c90/$FILE/Final%20Draft%20RTR%20Panel%20Report%2025Apr18.pdf.

Taking geographic variation out of the equation fails to properly account for exposure to the "individual most exposed to emissions" as required by section 7412(f)(2)(A), and fails to provide an accurate accounting of risks. Estimating the annual average concentrations at the area-weighted centers of census blocks blatantly and artificially underestimates the risk estimated for people at the fence-line since the center of a census block is almost always further away from the facility than the fence-line. Census blocks vary greatly in size, especially outside of large urban areas, yet EPA provides no evidence that it reviewed census block size or configuration to consider how concentrations of pollutants might vary within these blocks. Therefore, area-weighted centers of census blocks likely significantly underestimate exposure in some cases. By failing to assess health risks for the most-exposed person (rather than just by the middle of a census block) EPA violates this provision.

EPA's failure to adjust receptor points for residents living on the fence-line is particularly inexcusable given that the HEM-AERMOD system allows for such an adjustment, and that such an adjustment was appropriately made for the estimation of acute health risks.[44] Having recognized that the maximum exposed individual for acute risks is likely present at the fence-line, EPA cannot justify failing to analyze cancer and other chronic health effects in a similar manner.

B. EPA Unlawfully And Arbitrarily Chooses Less Protective Risk Values, And Assigns Zero Risk To Pollutants When It Lacks Risk Information.

EPA admits that it does not have dose-response values for all of the HAPs it considered in its risk assessment. RRA at 54. The agency states that "where we conclude similarity with a HAP for which a dose-response assessment value is available, we use that value as a surrogate for the assessment of the HAP for which no value is available." *Id.* However, EPA also states that some HAPs were simply not included in its quantitative risk assessment because the agency lacked dose-response values for them and, apparently, did not believe any other HAPs were similar enough to use as surrogates. *Id.* EPA does not say which HAPs there are but, EPA's failure to assess the risk for each of the HAPs that EGUs emit renders its RTR unlawful and arbitrary. If EPA assigns a zero risk to any of the HAPs EGUs emit, its assessment of the risk from EGUs is unlawful and arbitrary. If there is anything EPA knows about HAPs, it is that the risk of exposure to them is not zero.

EPA must stop treating various types of risk as zero when the science shows risk is present. Just because EPA has not yet developed a risk function for a pollutant, type of exposure, or type of risk, does not mean risk does not exist and can be ignored.[45] As the NAS explained, EPA should develop "explicitly stated defaults to take the place of implicit or missing defaults," and "[k]ey priorities should be development of default approaches to support risk estimation for chemicals lacking chemical-specific information to characterize individual susceptibility to cancer . . . and to develop a dose-response relationship."[46]

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[44] 83 Fed. Reg. at 46,273 (stating that EPA evaluated acute exposures and risks "at the point of highest off-site exposure to assess the potential risk to the maximally exposed individual," *i.e.*, not just the census block centroids).
[45] *See, e.g.*, National Research Council, National Academy of Sciences, "Science and Decisions: Advancing Risk Assessment" at 203-04, 207 (2009) ("NAS 2009"), http://www.nap.edu/catalog.php?record_id=12209.
[46] *Id*. at 207.

If EPA cannot or does not wish to follow the NAS recommendation to use defaults then, at minimum, it must engage in the interim in a qualitative assessment of the additional, missing risks, and account for them in its analysis. It can have no valid or reasonable basis for failing to attempt to account in any way for all risks known to be present in some amount, due to the existence of HAP emissions.

There are many HAPs that EPA claimed to consider in its risk assessment for which the agency did not provide any dose-response number for cancer. In the list of HAPs EPA considered, the following pollutants lack any such number (known as a "unit risk estimate" or URE). RRA at 38.

TABLE 3.1-1 SUMMARY OF EMISSIONS FROM THE COAL- AND OIL-FIRED EGU SOURCE CATEGORY AND DOSE- RESPONSE VALUES USED IN THE RESIDUAL RISK ASSESSMENT

HAP	Emissions (tpy)	Number of Facilities Reporting HAP (322 facilities in data set)	Prioritized Inhalation Dose-Response Value Identified by OAQPS			PB-HAP Oral Benchmark Values for Cancer (1/(mg/kg/d)) and/or Noncancer (mg/kg/d)[a]
			Unit Risk Estimate for Cancer (1/(µg/m^3))	Reference Concentration for Noncancer (mg/m^3)	Health Benchmark Values for Acute Noncancer (mg/m^3)	
Hydrochloric Acid	2,797	322		0.02	2.1 (REL)	
Hydrofluoric Acid	2,034	322		0.014	0.24 (REL)	
Selenium Compounds	68	322		0.02		
Manganese Compounds	46	322		0.0003		
Nickel Compounds	39	322	0.00048	0.00009	e	
Chromium Compounds						
Chromium (III) Compounds	38	322				
Chromium (VI) Compounds	5	322	0.012	0.0001		
Lead Compounds	6	322		0.00015[d]		
Cobalt Compounds	6	322		0.0001		
Arsenic Compounds	5	322	0.0043	0.000015	0.0002 (REL)	1.5 (cancer)
Antimony Compounds	4	322		0.0002		
Mercury Compounds						
Mercury (elemental)	3	322		0.0003	0.0006 (REL)	c
Gaseous Divalent Mercury	0.6	322		0.0003		0.0001 (noncancer)

Particulate Divalent Mercury	0.04	322		0.0003		0.0001 (noncancer)
Formaldehyde	3	322	0.000013	0.0098	0.055 (REL)	
Cadmium Compounds	0.8	322	0.0018	0.00001	0.1 (AEGL-1 (1-hr))	0.001 (noncancer)
Naphthalene	0.7	322	0.000034	0.003		
Beryllium Compounds	0.4	322	0.0024	0.00002	0.025 (ERPG-2)	
Polycyclic Organic Matter						
Phenanthrene	0.1	322				b
2-methylnaphthalene	0.03	322	0.000048			0.05 (cancer)
Polychlorinated Biphenyls						
Pentachlorobiphenyl	0.004	322	0.0001			
Hexachlorobiphenyl	0.002	322	0.0001			
Dioxins/Furans						
1,2,3,4,6,7,8,9-octachlorodibenzo-p-dioxin	0.001	322	0.0099	0.00013		45 (cancer)
1,2,3,4,6,7,8,9-octachlorodibenzofuran	0.0003	322	0.0099	0.00013		45 (cancer)
1,2,3,4,6,7,8-heptachlorodibenzofuran	0.0003	322	0.33	0.000004		1500 (cancer)
1,2,3,4,6,7,8-heptachlorodibenzo-p-dioxin	0.0001	322	0.33	0.000004		1500 (cancer)
2,3,7,8-tetrachlorodibenzofuran	0.0001	322	3.3	0.0000004		15000 (cancer)

For the HAPs for which EPA has no URE, EPA apparently assumed that the cancer risk is zero. EPA cannot assume that a pollutant is not carcinogenic simply because it has not determined whether or not that pollutant causes cancer. *Sierra Club v. EPA*, 895 F.3d 1, 10-11 (D.C. Cir. 2018). Indeed, *Sierra Club* expressly rejects EPA's claims that hydrogen chloride, hydrogen fluoride "pose no cancer risk." *Id.* at 11. Yet EPA once again chooses to assign these very HAPs a zero cancer risk. RRA at 38. EPA persistence in arbitrarily assigning zero risk to pollutants when it has no basis for doing so is especially arbitrary in light of its decision to rush the EGU RTR out. EPA did not need to issue the EGU RTR before gathering the information it needs to promulgate a rational and supportable rule. The only apparent reason EPA had for this action is precisely to avoid gathering or considering the data that would undermine its predetermined decision to avoid strengthening the standards.

EPA also lacks dose-response numbers for non-cancer from some of the HAPs it claims to have considered. RRA at 38. For example, EPA provides no non-cancer risk number for polycyclic organic matter, *id.*, even though is well known that POM causes many serious non-

cancer health harms, including birth defects,[47] asthma-related symptoms for babies and young children, diminished cognitive development with implications for diminished school performance,[48] lowered IQ,[49] and a weakened immune system.[50] By pretending the non-cancer risk from POM is zero, despite strong evidence to the contrary, EPA unlawfully and arbitrarily understates the risks that EGUs present. Moreover, the mere fact that EPA currently lacks information on whether a pollutant presents non-cancer risks, does not mean the non-cancer risk from pollutant is zero. By pretending the non-cancer risk from HAPs for which it lacks a non-cancer dose-response value is zero when it has not shown that to be true, EPA acts unreasonably and arbitrarily. *Sierra Club*, 895 F.3d at 10-12.

Similarly, EPA lacks dose-response values for acute risks. RRA at 38. EPA states its RTR "includes emissions of 7 HAP with relevant and available quantitative acute dose response values." *Id.* at 37. EPA does not and cannot claim, however, that those "7 HAP" are the only HAPs emitted by EGUs that present acute risks. EPA's record shows that there are acute risks from HAPs that are emitted by EGUs but that the agency did not consider at all in its risk assessment. RRA, Appendix 8. For example, the record shows that many of the organic HAPs EPA did not consider at all present acute risks. *Id.* Moreover, the mere fact that EPA currently lacks information on whether a pollutant presents acute risks, does not mean the acute risk from pollutant is zero. By pretending the acute risk from HAPs for which it lacks an acute dose-response value is zero when it has not shown that to be true, EPA acts unreasonably and arbitrarily. *Sierra Club*, 895 F.3d at 10-12.

Even where EPA does have dose-response values, EPA has arbitrarily chosen low values to present the risk from EGUs as lower than it actually is. For example, EPA states it chose to use the ASTDR MRL for manganese instead of its own reference concentration from IRIS. RRA at 27. The ASTDR MRL (.0003 mg/m^3) is more than an order of magnitude less protective than the IRIS RfC (.00005 mg/m^3). Although EPA describes the former as "updated," the agency does not say why it believes the updates – which the agency does not discuss in any detail – makes this far less protective number more accurate. As EPA is well aware, many so-called updates merely reflect the ability of industry lobbyists to overcome sound scientific judgment. To issue a non-arbitrary risk assessment, EPA must do more than simply claim the less protective number it prefers is updated and, therefore, more appropriate. Making EPA's choice of the weaker number even more arbitrary is the agency's failure to even acknowledge that there is another dose-

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[47] Perera FP. "DNA Damage from Polycyclic Aromatic Hydrocarbons Measured by Benzo[a]pyrene-DNA Adducts in Mothers and Newborns from Northern Manhattan, The World Trade Center Area, Poland, and China," *Cancer Epidemiology Biomarkers & Prevention* 14, no. 3 (2005):709–14.

[48] Perera FP, Rauh V, Tsai WY, Kinney P, Camann D, et al. "Effects of transplacental exposure to environmental pollutants on birth outcomes in amultiethnic population," *Environmental Health Perspective* 111 (2003): 201–205. Perera FP et. al. "Effect of Prenatal Exposure to Airborne Polycyclic Aromatic Hydrocarbons on Neurodevelopment in the First 3 Years of Life among Inner-City Children," *Environmental Health Perspective* 114 (2006):1287–1292.

[49] Perera, FP et. al. "Prenatal Airborne Polycyclic Aromatic Hydrocarbon Exposure and Child IQ at Age 5 Years," *Pediatrics* 124 (2009):e195–e202.

[50] Bolton, J., Trush, M.A., Penning, T.M., Dryhurst, G., & Monks, T.J. (2000). Role of Quinones in Toxicology. Chemical Research in Toxicology, 13(3), 135–160. doi: 10.1021/tx99; Ikeda, A., Vu, K.K.-T., Lim, D., Tyner, T.R., Krishnan, V.V., & Hasson, A.L. (2012). An Investigation of the Use of Urinary Quinones as Environmental Biomarkers for Exposure to Ambient Particle-Borne Pollutants. Science of the Total Environment (submitted).

response figure that is also more protective than the ATSDR number, California EPA's RfC (.00009 mg/m^3). EPA claims the California EPA numbers are a source of its dose-response information. RRA at 25-27. By choosing the less protective ATSDR number over the California EPA RfC without explaining why or even acknowledging the existence of that RfC, EPA acts arbitrarily. To the extent, EPA simply gives the ATSDR number a higher "priority" than those from the California EPA without explaining why it is doing so in this situation, *id.* at 25, the agency's approach has already been held to unreasonable and arbitrary. *Sierra Club*, 895 F.3d at 11-12.

For mercury, EPA used its own RfC of .0003 mg/m^3, again ignoring California EPA's RfC which is ten times more protective (.00003 mg/m^3). EPA provides no explanation for this choice and does not even recognize the existence of the more protective number, rendering its decision arbitrary. To the extent, EPA simply gives its own numbers a higher "priority" than those from the California EPA, *id.* at 25, the agency's approach has already been held to unreasonable and arbitrary. *Sierra Club*, 895 F.3d at 11-12.

EPA admits that it lacks dose-response values "[f]or certain HAP." RRA at 27. Among these are acrolein, glycol ethers, and carbonyl sulfide. For each of these HAPs, EPA claimed it used some other source of does response data. RRA at 27-30. It is difficult to understand what EPA means by its statements about these HAPs. None of them is among the HAPs that EPA even claims to have even considered in its risk assessment. RRA at 38-39; Risk Modeling Memo at 4-5.

EPA did not provide public notice of all HAPs for which it is aware of cancer, chronic non-cancer, acute, or multipathway risk, for which it did not evaluate such risk. This is a violation of notice and comment because it prevents Commenters from having a meaningful opportunity to present data to EPA that may be useful in EPA's evaluation of the risk from pollutants for which EPA is currently treating a risk as zero.

It is unlawful under § 7412(f)(2), arbitrary, and capricious for EPA not to assess risk at all from any HAP, because it ignores risks EPA knows exist and which led Congress to list that pollutant under § 7412(b)(1), and conflicts with scientific evidence before the agency. Just as *National Lime Association*, 233 F.3d at 642, requires EPA to set emission limits for all HAPs, EPA must assess the health risk for all listed HAPs. EPA may not, as it stated here, just write off the amount of a highly dangerous pollutant even if EPA believes it is "not emitted in appreciable quantities (0.001 tpy)," (notwithstanding its underestimation of emissions).[51] Pollutants like PCBs are highly toxic and persistent in the environment, creating reservoirs of future exposure by contaminating soil and dust and fish that people will eventually eat. EPA cannot write-off the long-term and multi-pathway impacts that such toxic chemicals can have when they are emitted pollutants that the Act requires EPA to regulate.

Where there is no reference value for a pollutant, EPA may not simply *ignore* health risks associated with these pollutants completely in its analysis by hiding behind uncertainty. Section 7412 requires EPA to address and regulate all emitted HAPs. In fact, an understatement of risk for pollutants that are excluded from the analysis is *certain* because EPA has performed no

[51] 79 Fed. Reg. at 36,936.

quantitative assessment of health risk for those pollutants *at all*. The absence of a reference value means that EPA does not know by how much it is *underestimating* risk to human health, but it does know that its assessment is an underestimation.

As the NAS explained, it is a problem that "agents that have not been examined sufficiently in epidemiologic or toxicologic studies are insufficiently included in or even excluded from risk assessments" by EPA.[52] Many chemicals have no cancer slope factor, RfD, or RfC.[53] It is not appropriate to treat such compounds "as though they pose no risk that should be subject to regulation."[54] The NAS has recommended that EPA develop "explicit defaults to use in place of missing defaults," including for its "untested-chemical assumption," *i.e.*, that a chemical with no reference value poses no risk.[55] In the absence of an available reference dose, EPA must, at minimum, add an uncertainty factor to account for the additional risk that a HAP likely causes, until such time as EPA does have a reference value to use. Using a protective uncertainty factor – developed based on the best available science – would allow EPA to satisfy its legal duty under section 7412(f)(2) to prevent unacceptable health risk, and ensure an "ample margin of safety to protect public health."[56] The NAS has described an approach EPA can use to account for this risk, and explained that this approach "is based on the notion that for virtually all chemicals it is possible to say *something* about the uncertainty distribution regarding dose-response relationships."[57] For example, EPA can use information on chemical structure, available toxicologic tests and model or experimental data, and data on similar chemicals that have been well-studied.[58]

Section 7412(f)(2) of the CAA creates a critical duty and opportunity for EPA to conduct a comprehensive and protective analysis of risk to public health and the environment. In view of this, it is a serious problem for EPA's analysis that some pollutants continue to have no reference values.[59] Over twenty years after the Clean Air Act was amended, sufficient studies for some pollutants have not been conducted to calculate reference doses, reference concentrations, or potency values. Moreover, the Integrated Risk Information System ("IRIS") review process has been bogged down for many pollutants as the Government Accountability Office recently documented.[60] As the Center for Progressive Reform ("CPR") has recognized, EPA should

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[52] NAS 2009, *supra* note 45, at 193.
[53] *Id*. at 203.
[54] *Id.* at 193.
[55] *Id.* at 203.
[56] 42 U.S.C. § 7412(f)(2).
[57] NAS 2009, *supra* note 45, at 203 (emphasis added).
[58] *Id.* at 204.
[59] *See, e.g.*, 79 Fed. Reg. at 36,936, 36,897.
[60] U.S. Gov't Accountability Office, GAO-12-42, Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program 17-18 (2011).

prevent the delay in this process from undermining its residual risk analysis for source categories under review.[61]

For pollutants currently under IRIS assessment, EPA must use the best available scientific information from the IRIS review during current rulemakings.[62] At minimum, EPA must account for the lack of reference values or the lack of an up-to-date final IRIS assessment rather than just allowing another important rulemaking to go by without any consideration of health risk due to such pollutants.

C. EPA MUST RECOGNIZE THAT CHRONIC (NON-CANCER) RISK-CAUSING POLLUTANTS HAVE NO SAFE LEVEL OF EXPOSURE.

NAS recommends that cancer and chronic non-cancer risk assessment use the same approach in order to address the fact that very low levels of non-carcinogen exposures can pose health risks.[63]

The use of reference doses ("RfDs") for dose-response risk assessment of chronic non-cancer health effects may significantly underestimate risk according to NAS:

> For these health effects, risk assessments focus on defining the reference dose (RfD) or reference concentration (RfC), which is defined as a dose "likely to be without an appreciable risk of deleterious effects" over a lifetime of exposure. In actual fact, these levels may pose appreciable risks.[64]

For this reason, EPA should follow the NAS recommendation to use similar approaches for chronic non-cancer as for cancer risk assessment, which assumes deleterious health effects for any amount of exposure.

Traditional toxicology risk assessment is a method developed for engineering but is very poor for assessing the biological complexities of human health. Most government and industry scientists that study environmental contaminates are not physicians, but rather toxicologists. In

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[61] *See* Rena Steinzor *et al*., *Setting Priorities for IRIS: 47 Chemicals that Should Move to the Head of the Risk-Assessment Line*, Ctr. For Progressive Reform (Dec. 2010), (http://www.progressivereform.org/articles/IRIS_Priorities_1010.pdf. CPR's analysis of IRIS offers a critical expose of these problems. *EPA's IRIS: A Database With Blind Spots*, Ctr. For Progressive Reform, http://www.progressivereform.org/iris.cfm (last visited June 27, 2013). *See also* Gov't Accountability Office, GAO-11-278, "High Risk Series: An Update" (2011); Gov't Accountability Office, GAO-09-774T, http://www.gao.gov/new.items/d11278.pdf; Gov't Accountability Office, "EPA Chemical Assessments: Process Reforms Offer the Potential to Address Key Problems" (2009); Gov't Accountability Office, GAO-08-743T, http://www.gao.gov/new.items/d09774t.pdf; Gov't Accountability Office, "Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals" (2008); Gov't Accountability Office, GAO-08-440, 29, (2008), http://www.gao.gov/new.items/d08743t.pdf; Gov't Accountability Office, "Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System" (2008), http://www.gao.gov/new.items/d08440.pdf.

[62] Integrated Risk Information System (IRIS); Announcement of 2012 Program, 77 Fed. Reg. 26,751 (May 7, 2012).

[63] NAS 2009, *supra* note 45, at 265-266.

[64] NRDC Issue Paper, Strengthening Toxic Chemical Risk Assessments to Protect Human Health at 10 (Feb. 2012), http://www.nrdc.org/health/files/strengthening-toxic-chemical-risk-assessments-report.pdf.

recent years the medical community has increasingly parted ways with toxicologists regarding the health consequences of environmental and chemical toxins. For 400 years the foundation of toxicology has been the concept of "the dose makes the poison," which is a presumption that health effects are related to dose, and that a dose can be found for virtually all chemicals where no effect is found. As reassuring as that thought may be, it no longer holds up to scientific scrutiny.

Medical scientists are now pointing out two important contradictions to this pillar of toxicology. The greatest public health threat of chemicals is for fetal exposure and the dose may be less important than the timing, *i.e.*, does the exposure occur during a critical window of embryonic development? The second contradiction is the idea that the smaller the dose, the less effect. Medicine is now discovering that for some toxic chemicals, the clinical effect can actually increase as the chemical concentration decreases and that there is no safe level of exposure.

Prominent medical societies are now publicly disputing the assumption of safe levels of exposure for toxic agents like endocrine disruptors. PAHs, for example, are now known to act as endocrine disruptors. A 2009 statement by the Endocrine Society, the largest organization of internal medicine physicians that specialize in endocrine and hormonal diseases, made this statement regarding endocrine disruptors and their potential harm to fetal development:

> Even infinitesimally low levels of exposure indeed, any level of exposure at all, may cause endocrine or reproductive abnormalities, particularly if exposure occurs during a critical developmental window. Surprisingly, low doses may even exert more potent effects than higher doses.[65]

The extraordinary vulnerability of in utero development makes reducing EGU emissions a public health an urgent matter. This risk was specifically addressed by a recent joint public statement by the American College of Obstetricians and Gynecologists and the American Society for Reproductive Medicine. The position statement included this:

> Reducing exposure to toxic environmental agents is a critical area of intervention for obstetricians, gynecologists, and other reproductive health care professionals. Patient exposure to toxic environmental chemicals and other stressors is ubiquitous, and preconception and prenatal exposure to toxic environmental agents can have a profound and lasting effect on reproductive health across the life course. Prenatal exposure to certain chemicals has been documented to increase the risk of cancer in childhood...[we] join leading scientists and other clinical practitioners in calling for timely action to identify and reduce exposure to toxic

[65] Endocrine Society, Scientific Statements, https://www.endocrine.org/endocrine-press/scientific-statements.

environmental agents while addressing the consequences of such exposure.[66]

A recent panel of twelve national endocrine disruptor specialists recently wrote a review of the medical literature and made this comment: "[for] every chemical that we looked at that we could find a low-dose cutoff, if it had been studied at low doses it had an effect at low doses."[67]

Finally, a report published in The New England Journal of Medicine, regarding the toxicity of volatilized compounds from oil made these important statements illustrating the risk from small exposure to toxic agents.

- "Mutagenic effects theoretically can result from a single molecular DNA alteration. Regulatory prudence has led to the use of "one-hit models" for mutagenic end points, particularly cancer, in which every molecule of a carcinogen is presumed to pose a risk."

- "Pregnant women should particularly avoid dermal contact with oil and should avoid areas with visible oil contamination or odors."[68]

The medical community's growing recognition of this science illustrates the exquisite sensitivity that the developing fetus has to toxic agents at extremely small doses, and the fact that EPA needs to evaluate non-cancer chronic risk similarly to cancer risk: in recognizing that there is no safe level of human exposure.

D. TO ASSESS THE RISK TO THE MOST EXPOSED PERSON, EPA MUST ACCOUNT FOR INDIVIDUAL-LEVEL VULNERABILITY AND VARIABILITY.

EPA is legally required under § 7412(f)(2) to assess the health risks to the "individual most exposed" to EGU emissions. 42 U.S.C. § 7412(f)(2). EPA's failure to account for vulnerability and variability based on the current science, particularly the science addressing early-life and socioeconomic factors in the risk related to exposure, has led EPA to underestimate the health risks from EGUs to the most-exposed individuals.

First, the National Academy of Sciences ("NAS") reports and other new scientific and policy developments direct that EPA must better account for vulnerability and variability.[69] In particular, the science is now clear that "children are not 'little adults'" when it comes to toxic

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[66] American College of Obstetricians and Gynecologists Committee on Health Care for Underserved Women, American Society for Reproductive Medicine Practice Committee, Committee Opinion No. 575, Exposure to Toxic Environmental Agents (Oct. 2013), http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Exposure-to-Toxic-Environmental-Agents.

[67] Vandenberg L, et al. Hormones and endocrine-disrupting chemicals: low-dose effects and nonmonotonic dose responses. Endocrine Rev; doi:10.1210/er.2011-1050 [online 14 Mar 2012].

[68] Goldstein B, Osofsky H, Lichtveld M. The Gulf Oil Spill N Engl J Med 2011; 364:1334-1348April 7, 2011.

[69] NAS 2009, *supra* note 45.

chemicals.[70] They are both susceptible to greater harm from exposure to toxic chemicals, because they are still growing and developing, *and* they are exposed to such chemicals at a greater rate than adults because of age-specific behaviors and physiological characteristics.

Second, EPA must also better account for other types of human variability because some people exposed to the same amount of a pollutant experience greater health risk due to other factors, such as genetics and baseline health status. Socioeconomic status has been shown to act as a proxy for other types of human variability to chemical risk that EPA has not adequately addressed in its draft risk assessment for the EGUs rule.[71]

This section discusses key ways in which EPA must better address both the greater risk to children (including from early-in-life exposure to toxic chemicals), and other important types of human variability. Summarized at the end of this document are the currently available scientific and policy developments on children's health and environmental justice that illustrate the need for updates to EPA's risk assessment approach.

1. Children's Risk and Early-Life Exposures

a. Cancer: Account for increased early life susceptibility by using age-dependent adjustment factors for all carcinogens.

EPA's cancer risk assessment for EGUs does not adequately account for early-life exposure or the greater risk to and susceptibility of children. EPA must follow the science and account for increased early-life susceptibility by applying age-dependent adjustment factors for *all carcinogens* emitted by a source category.

EPA has restricted its application of age-dependent adjustment factors, as discussed in the 2005 *Guidelines* and *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*, to those HAPs included in EPA's list of carcinogens that act by a mutagenic mode of action.[72] EPA therefore has not applied age-dependent adjustment factors to assess cancer risk from all of the carcinogens emitted by EGUs. The NAS recognized this as a "missing" default in EPA's approach that it should address and account for.[73]

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[70] National Research Council, "Pesticides in the Diets of Infants and Children" at 3 (1993).
[71] Draft Risk Assessment, EPA-HQ-OAR-2010-0682-0225.
[72] *Id.* at 29-30; *See* EPA, "Guidelines for Carcinogen Risk Assessment," EPA/630/P-03/001F, at 1-19 to 1-20 (Mar. 2005), http://www.epa.gov/raf/publications/pdfs/CANCER_GUIDELINES_FINAL_3-25-05.PDF; EPA, "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens," EPA/630/R-03/003F (2005), http://www.epa.gov/raf/publications/pdfs/childrens_supplement_final.pdf.
[73] NAS 2009, *supra* note 45, at 196 (Tbl. 6-3 - Examples of "Missing" Defaults in EPA "Default" Dose-Response Assessments).

EPA must follow the science showing the need to use age-dependent adjustment factors for all carcinogens.[74] Because OEHHA has provided robust scientific support for this approach, using these factors to assess cancer risk for all carcinogens would be consistent with the NAS recommendations. As the NAS explained in 2009: "EPA needs methods for explicitly considering in cancer risk assessment . . . chemicals that do not meet the threshold of evidence that the agency is considering for judging whether a chemical has a mutagenic mode of action . . . . Special attention should be given to hormonally active compounds and genotoxic chemicals that do not meet the threshold of evidence requirements."[75]

The 2005 Guidelines recognized that updates would be needed if more data become available.[76] Now that such data are available, including from the NAS and OEHHA, to follow even EPA's own guidelines, the agency must update its approach and implement age-dependent adjustment factors for all carcinogens.[77]

b. Cancer: Pre-natal susceptibility: Account for increased susceptibility to pre-natal exposures by using pre-natal adjustment factors for all carcinogens.

EPA's risk assessment also does not take into account increased susceptibility to carcinogens due to pre-natal exposures, even for known-to-be mutagenic carcinogens.[78]

The 2005 Supplemental Guidance recognized the scientific findings of increased susceptibility to carcinogens resulting from pre-natal exposure, but did not develop adjustment factors to account for increased cancer risk resulting from pre-natal exposures.[79] For example, EPA recognized that "[e]xposures that are of concern extend from conception through adolescence and also include pre-conception exposures of both parents."[80] The NAS identified the lack of accounting for "*in utero* periods" of exposure as a major omission in EPA's 2005 cancer guidelines.[81]

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[74] Cal. EPA, OEHHA, "Technical Support Document for Cancer Potency Factors: Methodologies for Derivation, Listing of Available Values, and Adjustments to Allow for Early Life Stage Exposures" 3-4, 50-51 (May 2009), http://www.oehha.ca.gov/air/hot_spots/2009/TSDCancerPotency.pdf, and http://oehha.ca.gov/air/hot_spots/tsd052909.html.

[75] NAS 2009, *supra* note 45, at 112 (ch. 4) (describing the fact that "*in utero* periods and nonmutagenic chemicals were not covered" by EPA's 2005 guidelines, as significant omissions).

[76] *See* EPA, 2005 Supp. Guidance at 21, 31 ("EPA expects to expand this Supplemental Guidance to specifically address modes of action other than mutagenicity when sufficient data are available and analyzed.").

[77] Cal. EPA, OEHHA, TSD for Cancer Potency Factors, *supra* note 74. EPA should also update the 2005 Guidelines to fully reflect current science as described in OEHHA's 2009 review of the scientific literature on increased susceptibility to carcinogens from early life exposures

[78] Draft Risk Assessment (-0225) at 29 (noting that EPA applied factors only to known mutagens to account for "children aged 0-1" but not younger than that).

[79] EPA, 2005 Supp. Guidance at 4-5, 14 & tbl. 1a (A-1) (discussing research on human and animal cancer risks from prenatal exposure).

[80] EPA 2005 Guidelines for Carcinogen Risk Assessment, EPA/630/P-03/001F, at 1-16.

[81] NAS 2009, *supra* note 45, at 112-13; *see also id.* at 112, 196 (noting that it is a "missing" default that EPA recognizes in utero carcinogenic activity, but fails to take account of it or calculate any risk for it as "EPA treats the prenatal period as devoid of sensitivity to carcinogenicity").

OEHHA conducted its own review of the scientific literature to account for pre-natal susceptibility and exposures, which EPA should also consult and use.[82] It has also developed methods and adjustment factors to account for pre-natal susceptibility and exposures that EPA should use.[83] In its risk assessment guidelines and risk assessment manual, OEHHA includes procedures for exposure assessment during fetal development, which EPA should evaluate.[84] OEHHA specifically discusses the use of a 10X adjustment factor for cancer risk to account for pre-natal (third trimester) to age 2 exposures, and EPA should consider using this same factor.[85]

EPA should consult the science OEHHA has used to develop this well-supported factor, and should then use at least a 10X adjustment factor for all carcinogens to assess health risk due to pre-natal exposure.

As EPA's rules are insufficient to protect humans at the critical stage of embryonic development, they simply are failing to protect public health. Exposure to toxic agents in the intrauterine stage of life has one of the most important impacts on life long health, and can be irreversible.

c. Chronic non-cancer risk: EPA must consult and apply child-specific reference values, where available.

Most of EPA's IRIS toxicity threshold values (reference concentrations and reference doses) used for chronic non-cancer risk assessment do not incorporate the latest science on increased susceptibility of children.[86] EPA needs to account for early exposure and the greater risk to and susceptibility of children in its risk assessment, including for nickel, cadmium, manganese and lead. EPA has recognized these are emitted by EGUs.

OEHHA child-specific health values include reference doses for cadmium, manganese, nickel, and pentachlorophenol, and a benchmark for lead.[87] OEHHA has generated these child-specific reference values based on the latest science to take into account children's greater exposure and greater vulnerability.

Until the IRIS values fully account for the increased risk caused by early-life exposure to

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[82] *See* Cal. EPA, OEHHA, "Technical Support," *supra* note 74, App. J: "In Utero and Early Life Susceptibility to Carcinogens: The Derivation of Age-at-Exposure Sensitivity Measures" – conducted by OEHHA's Reproductive and Cancer Hazard Assessment Branch," .http://oehha.ca.gov/air/hot_spots/2009/AppendixJEarly.pdf.

[83] *Id.* App. J at 7-8 & tbl. 1.

[84] *See* Cal. EPA, *Air Toxics Hot Spots Program Risk Assessment Guidelines: Technical Support Document for Exposure Assessment and Stochastic Analysis* at 1-6 to 1-7 (Aug. 27, 2012) ("OEHHA 2012 Guidelines"), http://www.oehha.ca.gov/air/hot_spots/tsd082712.html.

[85] *See id.*; 2014 Air Toxics Hot Spots Program Guidance Manual, *supra* note 39, at 2.

[86] OEHHA has explained why child-specific reference doses or values are needed and provided a list of chemicals. *See, e.g.*, Cal. EPA, OEHHA, "Prioritization of Toxic Air Contaminants - Children's Environmental Health Protection Act" (Oct. 2001), http://oehha.ca.gov/air/toxic_contaminants/pdf_zip/SB25%20TAC%20prioritization.pdf; Cal. EPA, OEHHA, "Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code 901(g): Identification of Potential Chemical Contaminants of Concern at California School Sites, Final Report" (June 2002), http://oehha.ca.gov/public_info/public/kids/pdf/ChildHealthreport60702.pdf.

[87] A full list, with links to each scientific determination document, is available here: OEHHA, Table of all child-chRDs Finalized to Date (last updated 06/22/09), http://oehha.ca.gov/public_info/public/kids/chrdtable.html.

an emitted pollutant, EPA should use the OEHHA child-specific reference doses or benchmarks available to assess chronic non-cancer health risk from ingestion for certain pollutants. EPA should also assess such risk from inhalation by using standard methods to translate these values into child-specific reference concentrations to assess inhalation-based risk.

d. Chronic non-cancer risk: Where child-specific reference values are unavailable, EPA must consult science on early exposure impacts and use an additional default or uncertainty factor.

The increased susceptibility of children, while known to exist, has not been quantified for many toxic chemicals. Until EPA has child-specific or child-based reference values available for a given pollutant, EPA should apply a default or uncertainty factor of at least 10 to account for increased risk from early-life exposures for non-cancer risk in this rulemaking and other risk assessments.

This would be consistent with the NAS recommendation on the need for EPA to use default factors to account for greater risk,[88] with the science developed and considered by OEHHA, and with the 10X factor enacted by Congress in the Food Quality Protection Act. Specifically, as the SAB report explained:

> California EPA/OEHHA has determined that inhalation dosimetry for children is sufficiently different from adults to warrant a full 10-fold intra-individual pharmacokinetic uncertainty factor (i.e., an extra 3-fold PK uncertainty for children relative to the IRIS method) as a default approach. In setting non-cancer reference exposure levels (RELs), Cal EPA/OEHHA also considers that children may be outliers in terms of chemical susceptibility and on a case-specific basis adds a children's pharmacodynamic factor of 3-fold, making the inhalation risk for children as much as 10 times greater than adults.[89]

In addition, Congress has recognized this science in its unanimous vote on toxics legislation passed in 1996 – the Food Quality Protection Act ("FQPA") – in which Congress found the need to use, and enacted, a Ten-fold Margin of Safety, or "10X factor." Specifically, the Act provides that "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and

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[88] NAS 2009, *supra* note 45, at 190-93, 203.

[89] Cal. EPA, OEHHA, "Technical Support Document for Cancer Potency Factors: Methodologies for Derivation, Listing of Available Values, and Adjustments to Allow for Early Life Stage Exposures" 3-4, 50-51 (May 2009), http://www.oehha.ca.gov/air/hot_spots/2009/TSDCancerPotency.pdf, and http://oehha.ca.gov/air/hot_spots/tsd052909.html.

toxicity to infants and children."[90] Congress's recognition of the need to use this default factor provides a model that EPA should consider and incorporate into its residual risk assessment.

It would be appropriate and within EPA's authority under Clean Air Act section 7412(f)(2) to determine that EPA must similarly use a children's ten-fold margin of safety factor here, to fulfill the Clean Air Act's "margin of safety" requirement.[91] In doing so, EPA may rely directly on the science itself, and also on the unanimous guidance from Congress, provided in the FQPA, that the existing evidence of increased harm requires significant action to protect children from toxic exposure.

Further, the child-specific reference doses that OEHHA has created for some pollutants provide support for the use of an additional ten-fold Margin of Safety Factor. EPA's current reference values are generally one order of magnitude less protective (*i.e.*, larger) than the values that California has recognized as needed to protect children, based on the currently available science and a specific assessment of research relevant to early life exposures.

As further discussed in Part II.C, EPA can have no valid basis for ignoring science showing that pollutants other than carcinogens also can cause substantial harm even at low doses if exposure occurs *in utero* and during the early windows of vulnerability.

E. Account For Increased Vulnerability Based On Demographic Differences, As Part Of The Risk Assessment.

The NAS report also identified significant flaws in EPA's assessment of individual variability in risk assessments, like the EGUs rule, that could result in significant underestimation of risk, including in regard to socioeconomic differences. In particular, EPA must fully account for the fact that people can be more vulnerable to toxic pollution due to various physiological, societal, demographic, and exposure history differences, and can therefore experience greater health risk from the same amount of a toxic chemical exposure.[92] As the NAS has observed, performing risk assessment that is meaningful for communities that already face a significant amount of pollution and for communities concerned about environmental justice "requires an ability to evaluate multiple agents or stressors simultaneously—to consider exposures not in isolation but in the context of other community exposures and risk factors."[93]

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[90] 21 U.S.C. § 346a(b)(2)(C) (requiring that, in establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, "for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied" to protect infants and children).

[91] 42 U.S.C. § 7412(f)(2).

[92] *See, e.g.*, NAS 2009, *supra* note 45, at 135-39, 145-51 (explaining that "[h]ow the population responds to chemical insults depends on individual responses, which vary among individuals"; and "[i]f the sensitive people constitute a distinct group either because of their numbers or because of identifiable characteristics—such as ethnicity, genetic polymorphism, functional or health status, or disease—they should be considered for separate treatment in the overall risk assessment"); *id.* at 112 (noting that EPA's guidelines do not address variability due to factors "such as age, ethnic group, socioeconomic status, or other attributes," and explaining that "there is a need for a nonzero default to address the variation in the population expected in the absence of chemical-specific data"); *see also id*. at 134 (discussing various factors and recommending that "much more emphasis needs to be placed on describing the ranges of susceptibility and risk"); *see also id.* at 177-82, 196.

[93] *Id*. at 214-15.

Addressing this issue is particularly important for EPA because of the need to consider and address environmental justice as mandated by Executive Order 12898.

As explained in the declaration of Amy B. Rosenstein (Attachment 2, "[a]s acknowledged by EPA in the Air Toxics Rule, evidence points to the increased susceptibility of minority and lower-income communities to environmental exposures, including ambient air pollution and industrial emissions,[94] including complex mixtures of environmental air pollutants.[95] Minority and low-income communities incur disproportionate exposures to environmental contaminants, as well as being more susceptible than the general population to the effects of such exposures "because of limited understanding of environmental hazards, disenfranchisement from the political process, and socioeconomic factors such as poor nutrition, stress, and lack of adequate health care…, and …substandard housing and resource-poor communities…."[96]

EPA has assessed the demographics of the areas surrounding the existing regulated power plants, and found that individuals living within three miles of a coal-fired power plant were 48 percent more likely to be members of a racial minority, and 31 percent more likely to be living below the poverty line, than the national average. 77 Fed. Reg. 9304, 9445 (Feb. 12, 2015).24. As acknowledged by EPA in the Air Toxics Rule, evidence points to the increased susceptibility of minority and lower-income communities to environmental exposures, including ambient air pollution and industrial emissions,[97] including complex mixtures of environmental air pollutants.[98] Minority and low-income communities incur disproportionate exposures to

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[94] Bell ML, Zanobetti A, Dominici F, Evidence on vulnerability and susceptibility to Health Risks associated with short-term exposure to particulate matter: A systematic review and meta-analysis, 178 Am. J. Epidemiology 865 (2013) (available at http://aje.oxfordjournals.org/content/early/2013/07/24/aje.kwt090.full.pdf+html); Jerrett M, Burnett R, Brook J, Kanaroglou P, Giovis C, Finkelstein N, et al., Do socioeconomic characteristics modify the short term association between air pollution and mortality? Evidence from a zonal time series in Hamilton. Canada. 58 J. Epidemiol. Community Health 31 (2004) (available at http://jech.bmj.com/content/58/1/31.full.pdf+html); Krewski D, Jerrett M, Burnett RT, Ma R, Hughes E, Shi Y et al., Extended Follow-Up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality, 140 Respiratory Rep. Health Effects

[95] Carter-Pokras O, Zambrana RE, Poppell CF, Logie LA, Guerrero-Preston R, The environmental health of Latino children, 21 J. Pediatric Health Care 307 (2007) (available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2967224/pdf/nihms-244430.pdf).

[96] *Id.* (citing Institute of Medicine, Toward environmental justice: Research, education, and health policy needs, Washington, D.C. (1999) (available at http://www.nap.edu/read/6034/chapter/1).

[97] Bell ML, Zanobetti A, Dominici F, Evidence on vulnerability and susceptibility to Health Risks associated with short-term exposure to particulate matter: A systematic review and meta-analysis, 178 Am. J. Epidemiology 865 (2013) (available at http://aje.oxfordjournals.org/content/early/2013/07/24/aje.kwt090.full.pdf+html); Jerrett M, Burnett R, Brook J, Kanaroglou P, Giovis C, Finkelstein N, et al., Do socioeconomic characteristics modify the short term association between air pollution and mortality? Evidence from a zonal time series in Hamilton. Canada. 58 J. Epidemiol. Community Health 31 (2004) (available at http://jech.bmj.com/content/58/1/31.full.pdf+html); Krewski D, Jerrett M, Burnett RT, Ma R, Hughes E, Shi Y et al., Extended Follow-Up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality, 140 Respiratory Rep. Health Effects Inst. 114 (2009) (available through: http://pubs.healtheffects.org/).

98 Carter-Pokras O, Zambrana RE, Poppell CF, Logie LA, Guerrero-Preston R, The environmental health of Latino children, 21 J. Pediatric Health Care 307 (2007) (available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2967224/pdf/nihms-

environmental contaminants, as well as being more susceptible than the general population to the effects of such exposures "because of limited understanding of environmental hazards, disenfranchisement from the political process, and socioeconomic factors such as poor nutrition, stress, and lack of adequate health care…, and …substandard housing and resource-poor communities….[99]"

Because EGUs affect communities that are disproportionately minority or lower income, EPA cannot ignore this greater risk in its assessment. As a key starting point, EPA must assess the greater health risk based on socioeconomic status found in epidemiological research studies.[100] As the NAS recognized, "there is growing epidemiologic evidence of interactions between environmental stressors and place-based and individual-based psychosocial stressors, driven in part by the spatial and demographic concordance between physical and chemical environmental exposures and socioeconomic stressors," and there is also a growing field of information on social epidemiology, which addresses the relationship between social factors and disease in human populations.[101] Data describing these factors are available from the Center for Disease Control's Environmental Public Health Tracking ("EPHT") Program, the U.S. Agency for Toxic Substances and Disease Registry, state and local health agencies, and academic researchers,[102] and EPA must consider and use such information in its risk assessment.

Further, EPA must recognize and evaluate the need to consider socioeconomic factors not only as part of an environmental justice analysis, but also as part of EPA's consideration of both vulnerability and variability, as core elements of the risk assessment itself. EPA has been assessing the demographics of affected communities, pursuant to CAA § 7412(f) and the Environmental Justice Executive Order 12898.[103] This is necessary and important to continue. However, in addition to looking at the demographic census data on race, ethnicity, poverty level, and similar factors, EPA must also assess the starting point or baseline overall health status of the affected individuals and communities using the best available data at a local and national level, including the baseline cancer levels, respiratory problems, and health problems associated with the toxic chemicals emitted by a source category. Doing so would be consistent with the 1999 Residual Risk Report.[104] It would also follow EPA's own statements in the 2014 Second Integrated Urban Air Toxics Report that more work is needed to reduce excess cancer risks in

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244430.pdf).

99 Id. (citing Institute of Medicine, Toward environmental justice: Research, education, and health policy needs, Washington, D.C. (1999) (available at http://www.nap.edu/read/6034/chapter/1).

[100] NAS 2009, *supra* note 45, at 109-10 & tbl. 4-1 (describing the need to consider increased susceptibility due to prior and concurrent exposures; and to "social and economic factors"); *id.* at 220-21 (describing ways to assess cumulative risk including by consideration of "epidemiologic concepts" and information, and by considering "what the burden of disease is in the context of simultaneous exposure to a number of stressors"); *id.* at 230 (discussing the role of epidemiology and surveillance data).

[101] *Id*. at 230-33.

[102] *Id*. at 232 (describing data available on health status, and patterns of diseases and exposures).

[103] Exec. Order 12898, "Federal Actions To Address Environmental Justice," *supra*.

[104] U.S. EPA, "Residual Risk Report to Congress" at 42, 67 (Mar. 1999), EPA-453/R-99-00 (discussing factor of "overall health" and recognizing the need to consider sensitive subpopulations that "consist of a specific set of individuals who are particularly susceptible to adverse health effects because of physiological (e.g., age, gender, pre-existing conditions), socioeconomic (e.g., nutrition), or demographic variables, or significantly greater levels of exposure," based on various demographic factors).

urban areas that continue to face elevated risks.[105]

Further, EPA has significant research available on which it must draw to incorporate "overall health" into its risk assessment. For example, the American Lung Association has published research showing that African Americans are at a much higher risk of lung cancer than white Americans, and that African-American men have a 37 percent higher risk of lung cancer than white men.[106] EPA must consider this type of health information as part of the EGUs risk assessment.

Thus far, EPA has failed to adequately assess human variability, particularly the increased vulnerability of different socioeconomic groups, or to incorporate the information gained from the environmental justice analysis into its risk assessment. In this rulemaking, EPA has recognized that there are disproportionate impacts, *e.g.*, on African Americans, Latinos, and low income people (living below the poverty level). But EPA also has not considered the existing health burden at all in local EGU communities, or the greater vulnerability to toxic air pollution of the particular demographic groups EPA acknowledges are exposed. This is unlawful because it means EPA has not fully evaluated the risks as required by § 7412(f)(2). And it is arbitrary because EPA can have no rational basis for ignoring this information, or the fact that it shows additional risk beyond that estimated by EPA here.

As the NAS discussed, "EPA should compile relevant data related to socioeconomic status (SES), which may serve as a proxy for numerous individual risk factors . . . and may be a more direct measure of vulnerability than could reasonably be assembled by looking at all relevant individual risk factors."[107] EPA should follow the NAS recommendations and science to review and address these risk factors in the EGUs risk assessment.

In addition, or in the alternative, EPA should simply use a default factor to account for socioeconomic and other community-based stressors, just as it does to account for intrinsic biological factors.[108] For example, it traditionally uses a factor of 100 to account for the use of animal studies, when translating such studies to assess human impacts. The Food Quality Protection Act directed EPA to use a factor of at least 10 to account for *in utero* exposure. California's Office of Environmental Health Hazard Assessment uses a similar factor to account for in utero exposure. EPA also uses age-dependent adjustment factors in other contexts. EPA should do the same to account for increased vulnerability based on socioeconomic factors or the presence of multiple sources to which a community is exposed.

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[105] Second Integrated Urban Air Toxics Report, at xiv.

[106] Am. Lung Ass'n, "Too Many Cases, Too Many Deaths: Lung Cancer in African Americans" at 1 (2010), http://www.lungusa.org/assets/documents/publications/lung-disease-data/ala-lung-cancer-in-african.pdf (explaining higher risk to African Americans even though primary factor for lung cancer, *i.e.*, cigarette smoke exposure, is lower than for whites); *see also* State of Lung Disease in Diverse Communities: 2010, available at www.LungUSA.org.

[107] NAS 2009, *supra* note 45, at 226 (citing O'Neill *et al*. (2003)).

[108] Rachel Morello-Frosch, Zuk, Jerrett, Shamasunder & Kyle, *Understanding The Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, 30(5) Health Affairs 879, 881 nn.24-26 (2011) (citing sources).

F. To Assess The Risk To The Most-Exposed Person, EPA Must Assess The Cumulative Burden Of Exposures To Multiple Pollutants And Sources Via Multiple Pathways.

1. EPA's Multipathway Risk Assessment Is Incomplete and Underestimates Risk.

EPA admits that it performed a multipathway risk assessment for only some of the HAPs that are emitted by EGUs and harm people's health through multiple pathways. Specifically, EPA considered only arsenic, dioxins, POM, cadmium, and mercury. RRA at 43. EPA did not consider hexachlorobenzene, hexachlorocyclohexane, lead compounds, and PCBs, even though EPA admits these are all persistent and bioaccumulative HAPs. *Id.* at 17. In addition, EPA did not consider nickel, manganese, hexavalent chromium and other HAPs that persist in the environment and contaminate water, soil and food. For lead, EPA states it compared emissions to the National Ambient Air Quality Standards for lead (0.15 $\mu g/m^3$) rather than performing a multipathway assessment. RRA at 45.

EPA provides little if any rationale for refusing to consider the multipathway risks presented by many of the persistent and bioaccumulative HAPs that EGUs emit. The agency states that, for these HAPs, "the model has not been parameterized such that it can be used for that purpose." 84 Fed. Reg. at 2697. In some cases, EPA states, "we may not have appropriate multipathway models that allow us to predict the concentration of that pollutant." *Id.* EPA "acknowledges that other HAP beyond those we are evaluating may have the potential to cause adverse effects" and states it may evaluate those HAPs "in the future." *Id.* It bears emphasis that EPA chose to rush its RTR for EGUs out early and, therefore, chose to proceed without data that is plainly and undisputedly relevant to its risk determination. It cannot plausibly use lack of data or fully developed models as an excuse. EPA's failure to consider all the persistent and bioaccumulative HAPs that EGUs in its RTR for EGUs means that its risk assessment understates actual risk and that its decision not to set more protective standards is unlawful and arbitrary.

To do a multipathway risk assessment for the HAPs it considered, first, EPA used a Tier 1 screening analysis. Even with its artificially lowered risks, EPA initially found that 307 of the 322 facilities it considered exceeded the screening thresholds it used for cadmium, dioxins and furans, mercury, and/or POM. *Id.* at 42-43.

EPA then performed what it called a Tier 2 analysis. *Id.* at 43. EPA found 199 EGUs exceeded the Tier 2. *Id.* EPA then chose to evaluate only a "selected set" of the facilities that exceeded its Tier 2, screen in a third "Tier 3" screening. Specifically, although EPA found that 199 EGUs exceeded the Tier 2 screening levels, the agency conducted Tier 3 screening only 6 of these plants. EPA provides no reason for assuming that the other 199 EGUs do not pose risks higher than those presented by the 6 plants it chose to screen under Tier 3. EPA apparently just assumed that almost 200 EGUs that exceeded Tier 2 screening levels did not need to be evaluated further despite having exceeded its Tier 2 screening value.

EPA assessed two EGUs that had cancer screening values greater than 100 in and four facilities that had non cancer screening values for mercury that were greater or equal to 20. *Id.*

Based on its Tier 3 screening, EPA claims the highest cancer screening value is 50 and the highest non-cancer value (for mercury) is 9. *Id.*

According to EPA's method, this means that at least one facility may have cancer risk from arsenic, or from a combination of arsenic, dioxins and POM, of 50-in-1-million, 50 times the threshold. *Id.*

a. EPA must assess the non-inhalation-based risk created by EGUs' emissions of all persistent and all bioaccumulative pollutants.

EPA's choice to continue assessing only certain contaminants that bioaccumulate is not supported by the 2004 Guidance which states that "multipathway risk assessment may be appropriate generally when air toxics that persist and which also *may* bioaccumulate and/or biomagnify are present in releases."[109] This guidance does not direct that the multipathway assessment be limited to only those contaminants listed as PB-HAPs, let alone a subset of those HAPs, but that is what EPA did. By excluding persistent and bioaccumulative HAPs from its analysis, EPA underestimates risks from HAPs. The 2004 guidance document recognized deposition of *persistent* HAPs as a source of soil contamination presenting a potentially significant route of exposure, particularly for children.[110]

Hexachlorobenzene, hexachlorocyclohexane, lead compounds, PCBs, nickel, manganese, hexavalent chromium are all persistent and bioaccumulative HAPs. Air emissions of these compounds therefore present a risk to nearby communities via dermal, ingestion, and other non-inhalation pathways that are currently not being considered in the residual risk assessment. For extensive documentation on the rationale for multipathway analysis for these compounds and multipathway exposure parameters, please review the OEHHA 2012 Guidelines for Exposure Assessment.[111]

In addition to other metals listed by OEHHA, manganese is a pollutant to which children have particular exposure and vulnerability, and there is evidence that it can pose a multipathway risk due to elevated levels in soils around major emission sources.[112] Naphthalene is a PAH and as such must be considered in the POM category which is listed as a PB HAP. Naphthalene has been demonstrated to be persistent and to bioaccumulate in biota, particularly shellfish.[113]

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[109] *Id.*, Part III, Ch. 14 "Human Health Risk Assessment: Multipathway," at 14-1(emphasis added).
[110] *Id.* ch. 20.
[111] *Id.* App. E.
[112] *See, e.g.*, ATSDR, "Draft Toxicological Profile for Manganese" at 12 (Sept. 2012) ("Manganese concentrations in soil may be elevated when the soil is in close proximity to a mining source or industry using manganese and may therefore pose a risk of excess exposure to children who ingest contaminated soil.") http://www.atsdr.cdc.gov/ToxProfiles/tp151.pdf ; *see also* Cal. EPA, OEHHA, "Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code Section 901(g): Child-Specific Reference Doses (chRDs) for School Site Risk Assessment: Manganese and Pentachlorophenol," at 10 (June 2006) (discussing science showing that manganese can accumulate in the brain and showing that ingestion of high levels of manganese is associated with harm).
[113] R. Yender *et al.*, NOAA, "Managing Seafood Safety after an Oil Spill," (Nov. 2002).

Therefore, in this risk assessment, EPA must assess multipathway (*i.e.*, non-inhalation) risk for *all* metals and *all* other pollutants with a persistent or bioaccumulative impact, as OEHHA has recognized is appropriate based on the science. California OEHHA has recommended a multipathway assessment for metals based on scientific research.[114] EPA should consider and apply this science in its risk assessment. EPA simply may not assume that the ingestion and other multipathway risks are zero for persistent pollutants when science shows otherwise. The failure to assess multipathway risk from exposure to all PB-HAPs, both individually and cumulatively, results in an underestimate of the health risks of HAP emissions.

b. EPA must perform multipathway assessment for all pathways of exposure, including those that particularly affect children.

EPA should recognize that the science shows *additional pathways* that it has not addressed for certain pollutants, for which it does recognize the need for a multipathway assessment. For example, OEHHA has recognized that soil ingestion, dermal exposure to contaminated soil, and breast milk consumption are all "mandatory exposure pathways" that must be evaluated for residential receptors.[115] EPA should evaluate the research on various pathways of toxic exposure discussed by OEHHA.

In particular, science shows that EPA has been relying on outdated estimates of incidental soil ingestion exposures and EPA must update these values to ensure that it considers the urban child scenario in its multipathway risk assessment.[116] Risk assessment of exposure to soil contaminants should evaluate both direct exposure, hand-to-mouth, and indirect, object-to-mouth exposure. Indirect hand-to-mouth activity is the exposure from young children who touch an object or food with soil contaminated hands and then put that object or food into their mouths. Published studies show that there is noticeable indirect hand-to-mouth activity in infants and children. In fact, one study found that, on average, a toddler will touch an object and then put that object into his or her mouth 15 times in one hour. At the high end of the study's distribution (90th percentile), that rate rises to 66 times per hour.[117] This same study found a statistically significant positive correlation between the frequency of object or food in mouth activity and

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[114] OEHAA 2012 Guidelines, Appendix E, at E-5, E-10 to E-12, http://oehha.ca.gov/air/hot_spots/SRP/index.html.

[115] OEHHA Risk Assessment Manual, *supra* note 39, at 8-10; OEHHA 2012 Guidelines, *supra* note 84, App. E, at E-12, tbl. E3.

[116] As an additional problem, California's lead in soil standard is more stringent than EPA's due to more recent science on the harm of lead exposure. EPA has recognized that its standard is based on out-dated information about lead, that previously assumed children's blood-lead levels below 10.0 ug/dL was safe. EPA now admits that number is not protective, but has not updated its soil standard. *See, e.g.*, "EPA fails to revise key lead-poisoning hazard standards," USA Today (Mar. 10, 2013), http://www.usatoday.com/story/news/nation/2013/03/10/epa-has-not-revised-lead-hazard-standards-for-dust-and-soil/1971209 ("The EPA has not revised key hazard standards that protect children from lead poisoning since 2001, despite science showing harms at far lower levels of exposure than previously believed."); Children's Health Advisory Protection Comm., Letter to Administrator Jackson Regarding Childhood Lead Poisoning (Mar. 29, 2012), http://yosemite.epa.gov/ochp/ochpweb.nsf/content/chpac_childhood_lead_poison_letter.htm.

[117] Ko, S., Schaefer *et al*., *Relationships of Video Assessments of Touching and Mouthing Behaviors During Outdoor Play in Urban Residential Yards to Parental Perceptions of Child Behaviors and Blood Lead Levels*, 17 J. of Exposure Science and Environ. Epidemiology 47 (2007).

blood lead levels. The 2011 update to EPA's Exposure Factors Handbook includes more recent studies and estimates of hand-to-mouth behavior, which must be used to assess risks from exposures to contaminated soils.[118]

c. EPA must perform a multipathway assessment for all pathways of exposure, including those that particularly affect children.

EPA must assess multipathway risk based on "allowable" emissions, not just the so-called "actual" emissions, which are likely underestimated. EPA assessed the "allowable" emissions number for inhalation, and has given no reasonable basis not to do the same for multipathway risk.

EPA has recognized greater amounts of inhalation-risk pollutants, but has not recognized or assessed the full potential for persistent and bioaccumulative emissions by failing to assess the potential for greater amounts of other PB-HAP emissions. Intermittent or short spikes of PB-HAPs can represent a significant health risk because the contaminants stay in the environment and small amounts can accumulate into larger amounts over time. For this reason, EPA's analysis likely underestimates the health risks from multipathway routes of exposure.

d. EPA must account for the aggregate impact of inhalation and multipathway cancer and chronic non-cancer risk by adding each type of similar risk together for all pollutants.

The purpose of the multipathway assessment is to allow EPA to look overall at a person's exposure – not just inhalation, and not just other exposure pathways, in isolation. To do so, EPA must add inhalation and multipathway risk. Failing to add up each type of risk in order to come up with a *total* cancer risk number and a *total* non-cancer number, and then (as further discussed below), a *cumulative* burden metric makes EPA's overall risk assessment incomplete.

In performing a cumulative risk assessment, the NAS suggests the consideration of chemical and non-chemical stressors and how these stressors work in concert to promote adverse health outcomes.[119]

e. EPA cannot ignore the risks to subsistence fishers who eat fish from the Great Lakes and other large waterbodies.

In conducting its multipathway analysis, EPA states, it did not consider the risks to people who fish in "[v]ery large lakes and bays" including "the Great Lakes, the Great Salt Lake, Lake Okeechobee, Lake Ponchartrain, Lake Champlain, Green Bay, and Galveston Bay." RRA at 20 n.7. As EPA is well aware many people fish in these water bodies, including people in subsistence fishing communities. As EPA is also well aware, these water bodies and the fish that live in them are badly contaminated by, among other things, the HAPs that EPA purported to consider in its multipathway risk assessment. By simply ignoring the risk to fishers in the water

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[118] EPA, Exposure Factors Handbook, 2011 Edition (http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252).
[119] NAS 2009, *supra* note 45, at 9-10, 219-223.

bodies it excluded from its multipathway assessment, EPA unlawfully and arbitrarily understates the risks that EGUs present.

G. EPA's risk assessment and determinations are unlawful, arbitrary and capricious because EPA has not followed its own policy and guidelines in summing cancer risks to assess the cancer risk to the individual most-exposed.

EPA found an inhalation-based cancer risk of 10-in-1 million and a multipathway risk of 50-in-1 million. RRA at 6. Adding risks together yields a total risk of 60-in-1 million. Given that EPA completely failed to even consider the risks posed by the vast majority of EGUs' organic HAP emissions, many of which are cancer drivers, and that EPA substantially understated the risks from those organic HAP emissions it did consider, the total cancer risk from EGUs is likely above EPA's presumptive acceptability threshold of 100-in-1 million.[120] Yet EPA did not sum these cancer risks, and as a result it did not recognize that the total cancer risk is above the agency's "presumptive limit of acceptability."

There is scientific consensus that carcinogens have no safe level of human exposure and EPA has long recognized this. *See, e.g.*, *NRDC v. EPA*, 824 F.2d 1211, 1215 (D.C. Cir. 1987) (citing 50 Fed. Reg. 46,880, 46,896 (Nov. 13, 1985)). Congress acknowledged this as part of the need to protect public health from cancer-causing air pollution in enacting the 1990 Clean Air Act Amendments.[121]

It is also a basic scientific principle that additional exposure to carcinogens causes additional cancer risk, such that the cancer risks are additive.[122] That is, the more carcinogens a person is exposed to, the greater their risk of cancer over their lifetime, and cancer risks should be summed together.

EPA has codified that scientific principle in its own guidelines.[123] EPA's action not to sum these risks and thus recognize that the total cancer risk was indeed higher than

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[120] See 80 Fed. Reg. at 75,187 (calling 100-in-1 million "the presumptive limit of acceptability"); 79 Fed. Reg. at 36,899 ("an MIR [maximum individual lifetime cancer risk] of approximately one in 10 thousand [*i.e.*, 100-in-1 million] should ordinarily be the upper end of the range of acceptability.").

[121] See S. Rep. No. 101-228, at 175, *reprinted in* 1990 U.S.C.C.A.N. 3385, 3560 ("Federal Government health policy since the mid-1950s has been premised on the principle that there is no safe level of exposure to a carcinogen").

[122] See, e.g., Cal. EPA OEHHA, Risk Assessment Guidance Manual at 1-5, 2-4, 8-12 (finalized Mar. 6, 2015) ("Cancer risks from all carcinogens addressed in the HRA [health risk assessment] are added."); "Cancer risks from different substances are treated additively in risk assessment generally, and in the Hot Spots Program in part because many carcinogens act through the common mechanism of DNA damage.").

[123] *See, e.g.*, FRRA at 34, EPA-HQ-OAR-2010-0682-0800 ("To combine risks across multiple carcinogens, our assessments use the mixtures guidelines' [37,38] default assumption of additivity of effects, and combine risks by summing them using the independence formula in the mixtures guidelines.") (citing EPA, Guidelines for the Health Risk Assessment of Chemical Mixtures, EPA-630-R-98-002 (1986); EPA, Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures at 73, 125 & A-9, EPA-630/R-00-002 (2000)).

"approximately 100-in-1 million" contradicts peer-reviewed science and the agency's own guidelines, and thus is arbitrary and capricious within the meaning of the Clean Air Act.

EPA's attempt to explain why it did not add the multipathway and inhalation cancer risks together, to reach a total of at least 60-in-1 million from routine cancer-causing emissions, is arbitrary and capricious. EPA claims it performed a "reined site-specific multipathway assessment." RRA at 44. In previous "refined" assessments, EPA has summed the inhalation and multipathway assessment results (e.g., secondary lead smelters)." Nowhere in the proposed RTR does EPA explain why its purportedly "refined" assessment for EGUs is substantially less refined than the refined assessment it used for lead smelters. In particular, EPA does not say why it did not sum inhalation and multipathway risks here, even though its prior practice indicates that summing these risks can be done and should be done.

EPA also has not demonstrated that the most-exposed person, whom the Act directs EPA to consider, 42 U.S.C. § 7412(f), would not experience a high enough inhalation or multipathway risk to tip over the 100-in-1 million benchmark EPA uses. Just by summing the inhalation and multipathway risks it considered, EPA would reach 60-in-one-million, and consideration of the substantial risks EPA chose to ignore – not least EGU's vast emissions of carcinogenic organic HAPs – could easily tip the cancer risk to the most exposed person over 100-in-1-million, the level of risk even EPA acknowledges to be unacceptable.

EPA's risk determinations – *i.e.*, that risk is "acceptable" and that no additional residual risk standards are required to reduce the risk driver HAPs – are unlawful, arbitrary and capricious under § 7412(f). EPA has failed to provide a reasoned explanation not to sum cancer risks as described above and as its guidelines require.

1. EPA Must Assess the Combined Impact of Multiple Pollutants.

a. Assess the combined total of each type of risk for multiple pollutants, not just some risks.

In the EGUs risk assessment, EPA only assesses the combined impact of cancer risk and chronic non-cancer risk that operates on the same target organ. These are important and consistent with existing science. In addition, however, EPA should apply the same scientific principles to recognize that it also must combine and look at the whole picture of all other kinds of risk from multiple pollutants.

In particular, EPA must assess the total and synergistic cancer risk and total chronic non-cancer risk for different pollutants. For example, as OEHHA found, "[t]he potential neurotoxicity of arsenic in children, possibly in combination with other environmental agents, is also a concern. Studies in mice[124] indicate combined effects of lead and arsenic on the central nervous system that were not observed with either metal alone."[125]

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[124] Meija *et al.*, (1997)

[125] Cal. EPA, OEHHA, "Prioritization of Toxic Air Contaminants - Children's Environmental Health Protection Act, Arsenic and Arsenic Compounds" at Arsenic-2 (Part II) (Oct. 2001).

In addition, EPA should apply these same principles to create a mechanism for assessing the total acute risk to chemical mixtures, such as the target organ specific hazard index ("TOSHI") for chronic risk, that aggregates the acute impacts on the same organ systems for all pollutants. EPA recognizes that for the noncancer risk, some TOSHI values may be underestimated (RRA at 35). The TOSHI largely underestimates risk by calculating the hazard index based on risk driven by a specific organ system as opposed to aggregating risk across all organ systems. The human body does not distinguish risk based on the highest risk driver to a particular organ system – risk is distributed across organ systems with pollutants affecting multiple organs or organ systems at once.

b. Assess the total cumulative risk burden from all pollutants.

EPA must create a metric to assess the total and cumulative risk burden, rather than only looking at each type of risk in a discrete, separate way.[126] EPA should be integrating its assessments and performing a "comprehensive risk assessment" as the NAS has emphasized.[127] After first assessing the total cancer, chronic non-cancer, and acute risks, for both inhalation and multipathway exposure, EPA also must create a metric to assess the total bundle of risks.[128] EPA must aggregate health risk for each pollutant, and each type of health risk, to create a cumulative risk determination for the individual "most exposed" to emissions as the Act requires.[129]

Unless and until EPA creates a combined health risk metric, it is unclear how it can make an ample margin of safety determination that is based on the full picture of health risk for a source category and that can be compared to other source categories. EPA must assess the full cumulative burden for public health. By failing to perform a full, cumulative risk assessment, EPA fails to gather the information needed to assess whether the risk to public health is acceptable under CAA § 7412(f)(2).

2. EPA Must Account for Multiple Sources.

EPA must assess and account for the cumulative impact and risk caused by exposure to multiple source categories' toxic air emissions. In many communities containing EGUs, there are many other nearby sources of toxic air emissions within the 3, 5, 10, and the full 50 km radius of EPA's residual risk assessment. Such exposures increase the vulnerability of a community to new and additional toxic air emissions, as discussed above. Further, EPA's own analysis recognizes that EGUs create disproportionate health risk for minority and lower income communities. This problem is exacerbated even more by the fact that EGUs and other toxic air

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[126] *See, e.g.*, NAS 2009, *supra* note 45, at 177 ("The underlying scientific and risk-management considerations point to the need for unification of cancer and noncancer approaches in which chemicals are put into a common analytic framework regardless of type of outcome.").

[127] *Id.* at 131; *see also id.* at 132-33 (discussing related issues).

[128] Cal. EPA, OEHHA, "Cumulative Impacts," *supra* at 19-21, 25 (describing total "pollution burden" as sum of exposures, public health effects, and environmental effects); EPA, "Concepts, Methods and Data Sources," *supra*, at 4-42 to 4-46.

[129] 42 U.S.C. § 7412(f)(2).

sources are concentrated in minority and lower income communities, creating a serious environmental justice problem.[130]

Therefore, in addition to performing a cumulative assessment from EGUs alone, EPA also must perform a cumulative analysis that considers source categories' individual impact and risk with that of other sources to which people are exposed.[131] EPA has acknowledged the importance of addressing multiple source exposures, by stating that it "understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility," and that it is "interested in placing source category and facility-wide HAP risks in the context of total HAP risks from all sources combined in the vicinity of each source."[132] And, EPA has also recognized this need in its recent risk report.[133] Yet, so far EPA has failed to follow through on this.

EPA has not proposed any changes to the emission standards based on the combined exposure to emissions from EGUs and other sources. Although EPA has calculated what it calls "facility-wide" risk for different sources collocated at the same address, RRA at 42, it has not used that number to set standards, and it has ignored different sources in close proximity.

In addition, EPA has provided no information at all on how it reached the "facility-wide" risk number. For example, EPA does not state what other sources it considered as collocated. It just provides the numbers in the record, without any way for the public to evaluate or comment meaningfully. This is a violation of the Clean Air Act's notice and comment requirements. 42 U.S.C. § 7607(d).

EPA's failure to assess the combined, cumulative impact on health risk from multiple pollution source categories conflicts with the recommendation from the Scientific Advisory Board that in May 2010 urged EPA to incorporate cumulative risk into its residual risk analysis. The SAB stated that "RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area."[134]

To perform a cumulative risk or impact analysis, EPA should combine current baseline emissions, exposures, and health impacts in addition to those of the specific source category EPA is reviewing. The NAS explained the need for "[i]ncorporation of background additivity to

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[130] *See, e.g.*, Cal. EPA, OEHHA, "Cumulative Impacts," *supra*.

[131] We support EPA's recognition of the need to assess whether the maximum exposed individual is exposed to emissions from more than one source *within* each source category. We also appreciate that EPA has considered facility-wide risk in some way in this rulemaking. However, those assessments offer only part of the picture. And, even on both of these issues, EPA has provided very little information about what it included in such assessments, as discussed elsewhere in these comments. EPA just states numbers found for facility-wide risk, without explaining where those numbers came from, how they were calculated, or what emission sources they cover.

[132] 79 Fed. Reg. at 36,900.

[133] U.S. EPA, "Concepts, Methods and Data Sources," *supra,* at xxxii (defining a cumulative risk assessment as including "aggregate exposures by multiple pathways, media and routes over time, plus combined exposures to multiple contaminants from multiple sources").

[134] SAB May 2010, at ii, 10.

account for . . . [a]dditional sources of exposure to the same chemical or to similarly acting chemicals (including endogenous sources). . . ."[135] As part of this analysis, EPA should aggregate or add the emissions for the most-exposed communities coming from: (1) the source category (including all individual sources within it); (2) facility-wide risk from collocated sources outside of this category; and (3) all other sources of toxic air pollution in the area. Virtually all of the existing federal air toxics standards (under section 7412(d)) require periodic testing and monitoring, and this is something EPA must ensure is included in all rules as it updates them. Using these data, EPA can aggregate the community's exposure and assess the full health threats faced by the affected community, including from the source under review.

Moreover, toxicology assessments typically ignore the impact of toxic exposures to genetics and epigenetics and the evidence that many adverse health impacts from environmental exposures, like chemicals in air pollution, can in fact be passed on to subsequent generations. This scientific evidence illustrates an additional dimension of the long-term harm that can occur in communities that have been and continue to be exposed to toxic air pollution over time.[136]

EPA must also consider the research that has already occurred to assess health risk from toxic air pollution in urban communities nationwide.[137] EPA should also draw on the OEHHA cumulative assessment approach.[138] EPA should consult with OEHHA and investigate the scientific approach it is using to address cumulative impacts, and consider and apply a similar science-based approach in this residual risk assessment.

Further, the NAS has recommended that EPA evaluate "background exposures and vulnerability factors," as well as use "epidemiologic and toxicologic evidence" in its risk assessments.[139] Rather than separating an environmental justice analysis and considerations of inequality from the risk assessment, considering these factors as part of the cumulative risk

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[135] NAS 2009, *supra* note 45, at 180 (explaining that this may require the use of default factors).

[136] *See, e.g.*, Bruner-Tran, KL and KG Osteen. 2010. Developmental exposure to TCDD reduces fertility and negatively affects pregnancy outcomes across multiple generations. Reproductive Toxicology http://dx.doi.org/10.1016/j.reprotox.2010.10.003; Baccarelli A. Breathe deeply into your genes!: genetic variants and air pollution effects, Am J Respir Crit Care Med. 2009 Mar 15;179(6):431-2; Rubesa J, Rybara R, Prinosilovaa P, Veznika Z, et al. Genetic polymorphisms influence the susceptibility of men to sperm DNA damage associated with exposure to air pollution. Mutation Research 683 (2010) 9–15; Rubes J, Selevan S, Evenson D, Zudova D, Vozdova M, Zudova Z, Robbins W, Perreault S. Episodic air pollution is associated with increased DNA fragmentation in human sperm without other changes in semen quality. Human Reproduction Vol.20, No.10 pp. 2776–2783, 2005 doi:10.1093/humrep/dei122. Advance Access publication June 24, 2005; Sánchez-Guerra M, Pelallo-Martínez N, Díaz-Barriga F, Rothenberg SJ, Hernández-Cadena L, Faugeron S, Oropeza-Hernández LF, Guaderrama-Díaz M, Quintanilla-Vega B. Environmental polycyclic aromatic hydrocarbon (PAH) exposure and DNA damage in Mexican children. Mutat Res. 2011 Dec 17. [Epub ahead of print]

[137] *See, e.g.*, Rachel Morello-Frosch & Bill M. Jesdale, Envtl. Health Perspectives, *Separate and Unequal: Residential Segregation and Estimated Cancer Risks Associated with Ambient Air Toxics in U.S. Metropolitan Areas*, 114(3) Envtl. Health Perspectives 386 (2006) (assessing toxic air pollution cancer risk for 309 metropolitan areas encompassing 45,710 tracts); "National Air Toxics Program: The Integrated Urban Strategy," 64 Fed. Reg. 38,706, 38,738 (July 19, 1999).

[138] *See, e.g.*, Cal. EPA, "Cumulative Impacts," *supra*.

[139] NAS 2009, *supra* note 45, at 221-23 (discussing Menzie et al. 2007 model); *id.* at 230 (discussing the role of epidemiology and surveillance data).

assessment – because of the increased vulnerability created (as also discussed in Part I.E above) – would be a more effective, meaningful, and scientific approach.

In assessing a source category's emission contributions in affected communities and considering whether these contributions cause the most-exposed people to experience an unacceptable level of public health risk when combined with the existing baseline from past emissions, other HAP emissions, and the community's health status, EPA can describe and manage uncertainties, as it does and other federal agencies do for many other analyses.[140] Uncertainties do not justify failing to assess and address the severe cumulative harm and risk to local communities from air toxics sources. Rather, there is no excuse for treating an unknown amount of additional risk as a missing default, to use the NAS term.

As a scientific and policy matter, where there is exposure to air toxic emissions beyond the individual source category, the level of total risk that is occurring, including the baseline health risk and the risk from other sources, is greater. Thus, the total risk that is unacceptable for the most-exposed person must in fact be lower for each source category that person is exposed to, because it combines with other risks to create a *total* risk from all regulated source categories which must be minimized. Looking at a source category's contribution of risk in isolation is equivalent to ignoring the facts and pretending other health risks are not occurring. EPA may not decide that it is okay for a person to be exposed at a higher level simply because they live in a community where they are exposed to multiple sources of air pollution. That is the opposite of what EPA is required to do – protect the people in local communities who are most exposed and most vulnerable to air pollution. It also conflicts with EPA's own commitment to consider and provide environmental justice to overburdened communities.

At minimum, until EPA develops a data-driven approach to comprehensively model cumulative risk or impacts from multiple sources, EPA must not treat multiple source exposure as a missing default, or ignored amount of health risk. EPA must incorporate an explicit default or uncertainty factor to adjust the degree to which each individual source category is contributing to the total risk experienced by the most-exposed individuals. For example, wherever there is evidence that the source category is contributing pollutants on top of a history of other exposures or is contributing pollutants in addition to other source categories, the "unacceptable" level of cancer, non-cancer chronic, and acute risk from the source category must be adjusted downward

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[140] *See, e.g.*, 42 U.S.C. §§ 7475(a)(3), 7503(a)(1) (requiring a localized, cumulative assessment of whether or not a new or modified source's additional emissions will cause an attainment area to deteriorate, or will make it difficult for a nonattainment area to make progress toward achieving the national ambient air quality standards); *New York v. EPA*, 443 F.3d 880, 883 n.1 (D.C. Cir. 2006) (citing *New York v. EPA*, 413 F.3d 3, 11-14 (D.C. Cir. 2005)); *see also* 40 C.F.R. § 1508.27(b)(7) (requiring a consideration of "[w]hether the action is related to other actions with individually insignificant but cumulatively significant impacts. Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts"); *see also* 40 C.F.R. § 1508.7; *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 930 (9th Cir. 2008) (applying 16 U.S.C. § 1536(a)(2) to enforce the Endangered Species Act duty to ensure against jeopardy which includes the requirement to assess a newly proposed action in the context of all other impacts, and determine whether or not the specific action will "tip a species from a state of precarious survival into a state of likely extinction," or, where baseline conditions already jeopardize a species, whether it will "deepen[] the jeopardy by causing additional harm").

based on the number of other facilities contributing HAP exposure risks (such that no single source category could consume all of it, when the most-exposed person is exposed to many other source categories). ***For a source category in an area with up to 10 other HAP-emitting facilities, this default or uncertainty factor should equal at least 10, consistent with the common scientific use of this factor for other kinds of vulnerability.***[141]

III. BY RELYING ON THE LEAD NAAQS ALONE, EPA FAILS TO SATISFY § 7412(F)(2) REQUIREMENTS TO ENSURE NO "UNACCEPTABLE" HEALTH RISKS FROM LEAD AND TO ESTABLISH STANDARDS THAT PROVIDE AN "AMPLE MARGIN OF SAFETY TO PROTECT PUBLIC HEALTH" FROM LEAD.

A. EPA Has Failed to Assess Health Risks From Lead as Required by § 7412(f)(2) Based on Current Science, and Thus Has Failed to Lawfully or Rationally Support Its Determination that Health Risks Due to Lead Emissions from Cement Kilns Are "Acceptable."

The NEI data indicate that EGUs emitted 41 tons of lead in 2014. Even assuming that number has been reduced by 81 percent, the percentage by which EPA claims non-Hg metals were reduced between 2010 and 2017, EGUs still emit approximately 8 tons, or 1600 pounds, of lead each year. As described above, lead has no safe level of human exposure, and is particularly harmful to children and the developing fetus. Yet EPA assigns a health risk value of zero to lead emissions from these sources.

Concerning the health risks caused by lead, EPA considered only the 2008 Lead National Ambient Air Quality Standards ("NAAQs"). EPA performed no § 7412(f)(2) health risk assessment for lead – it simply assessed compliance with a different standard. As EPA states in the Risk Assessment:

> In evaluating the potential multipathway risks from emissions of lead compounds, rather than developing a screening emission rate for them, we compared maximum estimated chronic atmospheric concentrations with the current National Ambient Air Quality Standard (NAAQS) for lead. Values below the NAAQS were considered to have a low potential for multipathway risks.[142]

EPA, Centers for Disease Control and Prevention ("CDC"), California EPA, and the American Academy of Pediatrics ("AAP") acknowledge that no safe level of lead has been identified.[143] By solely relying on the NAAQS, EPA has failed to evaluate the different health

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[141] For areas with more facilities, which cause an even greater level of health risk combined, the UF should be adjusted accordingly, *i.e.*, 11-20 facilities would result in an UF of 20, and more than 20 would result in an UF of 100, so the source category's contribution is no higher than 1/100 of the threshold.

[142] RRA at 22.

[143] EPA, Basic Information about Lead in Drinking Water (last updated Aug. 21, 2017), https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water; CDC, Lead (last updated Aug. 21, 2017), https://www.cdc.gov/nceh/lead/ ; American Academy of Pediatrics (AAP). With No Amount of Lead Exposure Safe for Children, American Academy of Pediatrics Calls For Stricter Regulations (June

risks from lead – i.e., inhalation (risks from breathing) and multipathway (risks from other types of exposure). EPA's own past approach under section 112 shows that it has interpreted this provision as requiring it to consider all elements of risk created by a pollutant. EPA has recognized the need to assess cancer risk, chronic non-cancer risk, acute risk, and multipathway risk for all pollutants except for lead. EPA failed to assess either inhalation and multipathway risk for lead in the way it has recognized the need to do for other pollutants. It did not come up with any chronic non-cancer value, for example, based on lead emissions. Nor did EPA combine the lead-based risk with other target-organ-specific hazards from other chemicals emitted by cement kilns that target the brain and neurological system. EPA must do an actual health risk assessment that considers the real-world health threats from lead-exposure due to cement kilns' emissions rather than only relying on the NAAQS. As EPA has acknowledged, there is no safe level of exposure to lead emissions. Yet, in light of this, EPA has failed to assess all potential risks from lead independently or together, to determine whether the cumulative health risk burden from lead (and other neurotoxicants) is, acceptable.

EPA's reliance on the NAAQS fails to satisfy the agency's legal responsibility to assess the cumulative impacts of lead emissions from multiple facilities in the EGU source category under section 112(f)(2). If a single source is allowed to emit as much as can occur without that single source's emissions violating the NAAQS, then – unless it is the sole lead-emitting source in the area, that source has significant potential to cause a NAAQS exceedance when its emissions are combined with other sources' lead emissions. Therefore, even under EPA's analysis, it is unclear how a NAAQS-based 112(f) emission standard would ensure a NAAQS-level of protection in the real world because an individual source's emissions, combined with other sources of lead could cause the NAAQS to be exceeded.

EPA's residual risk assessment has not accounted for background levels of lead – found in homes, soils and waterways. Lead found in such environmental media may increase blood lead levels in pregnant women, infants, children and others who come in contact with dust in homes and soils around the home. Considering the harm that lead causes in the human body, any additional allowable lead emissions are unacceptable.

In regard to lead emissions, EPA may not merely rely on the lead NAAQS to decide what is "acceptable" risk under § 7412(f)(2). EPA must address and incorporate the best currently available information on children's exposure. The Children's Health Protection Advisory Committee's ("CHPAC") recommended lowering the lead NAAQS to 0.02µg/m^3 [144] from the current EPA NAAQS level of 0.15 µg/m^3. The CDC has now recognized that there is no safe level of exposure, and has replaced the now-outdated 10 µg/dL standard with a recognition that action is required at the reference level of 5 µg/dL.[145] California's health benchmark for lead

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20, 2016), https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/With-No-Amount-of-Lead-Exposure-Safe-for-Children,-American-Academy-of-Pediatrics-Calls-For-Stricter-Regulations.aspx.

[144] Letter from Dr. Melanie A. Marty, Chair, Children's Health Protection Advisory Comm., to Administrator Stephen L. Johnson, (June 16, 2008), http://www2.epa.gov/sites/production/files/2014-05/documents/61608.pdf.

[145] CDC, What Do Parents Need to Know to Protect Their Children? (last updated May 17, 2017), http://www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm

shows EPA should look at a blood-lead level change of 1.0 µg/dL as the level at which measurable neurological harm, illustrated by a correlating loss of 1 IQ point, can occur. [146]

In order for this risk assessment to be considered protective of human health, with an ample margin of safety, EPA should fully evaluate lead risks posed to the fetus, infants and children (utilizing the Integrated Exposure Uptake Biokinetic ("IEUBK") model for infants and children and the Adult Lead Methodology ("ALM") for the fetus). Furthermore, the results of such evaluations should be numeric and should be included in additional tables. It is not adequate or acceptable to simply not evaluate lead in the multipathway screening because "results of this analysis estimate that the NAAQS for lead would not be exceeded by any facility", thus this was not further evaluated.[147]

For the reasons listed above, EPA should also update the residual risk assessment to include available data on testing of lead in soil and waterways and evaluate the potential health impacts following the emission of lead from each facility. Additional monitoring should also be required to ensure that lead emitted from the facility is at low enough concentrations such that it does not raise an individual's blood lead level by 1 µg/dL. Finally, this facility, and many others, have emitted lead for many years. Background levels of lead in soil need to be taken into account when considering the potential for a child's blood lead level to increase due to the emission levels for each facility EPA has allowed and is proposing to continue to allow, as new lead going into the air (and thus the soil and water) in communities that have had longstanding lead emissions under EPA's standards for years.

Because EPA simply replicates its determination on the lead NAAQS in its proposed residual risk determination, EPA has not met the legal standard of section 7412(f)(2). The Clean Air Act sets different tests for these rules to meet (e.g., "ample margin of safety to protect public health" v. "adequate margin of safety to protect public health) and EPA cannot substitute one for the other. The residual risk standards are designed to do more than just replicate other statutory protections, such as those provided by the NAAQS. If Congress had intended EPA simply to replicate the NAAQS, or some other different Clean Air Act requirement, in its section 7412(f)(2) residual risk rulemaking, the section 7412(f)(2) requirement would become redundant for any hazardous air pollutant that also has any relationship to any other regulated pollutant. If there were any ambiguity on this question, statutory construction requires a reading of section 7412(f)(2) that preserves its independent value and meaning.

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[146] See OEHHA, J. Carlisle et al., Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code Section 901(g): Child-Specific Benchmark Change in Blood Lead Concentration for School Site Risk Assessment, Final Report at 1 (Apr. 2007) (explaining that this blood-lead level increase may occur from a daily intake of 6 µg of ingested soluble lead or 5 µg of inhaled lead), https://oehha.ca.gov/media/downloads/crnr/pbhgv041307.pdf.; see also CalEPA, Prioritization of Toxic Air Contaminants Under the Children's Environmental Health Protection Act at 25-26 (Oct. 2001) ("Lead is in Tier 1 because it is a developmental neurotoxin. The increased susceptibility of infants and children is well established and the neurological effects are extremely prolonged. In addition, lead is a carcinogen. Although airborne lead exposures have dropped due to removal of lead from gasoline, airborne lead exposures still occur as a result of stationary source emissions and reentrainment of soil contaminated with lead. In addition, deposition of airborne lead onto soil, vegetation, and other surfaces results in exposure via ingestion.").

[147] Risk Assessment at 44.

IV. EPA MUST RECOGNIZE THAT THE HEALTH RISKS EGUS CREATE ARE UNACCEPTABLE.

A. EPA Should Recognize That Risk Is Unacceptable Even Where the MIR Is 100-in-1 Million Or Below.

EPA has a longstanding policy of assuming that it is possible to find a safe or acceptable level of cancer and other kinds of health risks. Currently available science debunks this assumption because there is so much uncertainty built into EPA's risk assessment, and because EPA lacks information on so many pollutants. For communities overburdened by pollution, this policy is especially problematic.

As a major example, EPA should recognize that cancer risk from a major industrial source category of toxic air pollution (listed under CAA § 7412) that is 100-in-1 million or less cannot be presumed safe or "acceptable." Since 1990, however, EPA has made this assumption. EPA based this assumption not on scientific information about cancer risk, but on an unusual study of people's perceptions of their own risk from 1988, known as the Survey of Societal Risk (July 1988), to consider various types of health risks at that time.[148] Using a comparison of cancer risk to other kinds of hazards Americans then faced in their daily lives, EPA effectively chose a number out of a hat that it would consider acceptable. EPA looked at an odd collection of risks, such as dangers from driving a car, and found that "the presumptive level established for MIR [maximum individual risk of cancer] of approximately 1 in 10 thousand is within the range for individual risk in the survey, and provides health protection at a level lower than many other risks common 'in the world in which we live.'"[149]

EPA has failed to revisit or update this number for the decades since, even though scientists have made breakthroughs on early-life exposure and children's vulnerability; biomonitoring and other data on adult body burdens of chemicals; the vulnerability of overburdened communities, including socioeconomic disparities; and on ways to analyze and control the impacts of pollutants on human health.

<u>LANDMARKS SINCE 1990</u>

In 1990, the Clean Air Act Amendments required new basic stringency requirements for technology-based control for hazardous air pollutants and added an additional review of residual health risk to ensure protection of communities.[150]

In 1993, the National Research Council published *Pesticides in the Diets of Infants and*

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[148] Benzene Rule Docket No. OAQPS 79-3, Part I, Docket Item X-B-1, EPA Air Docket (cited at Nat'l Emission Standards for Hazardous Air Pollutants; Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants, 53 Fed. Reg. 28,496, at 28,512-13 (July 28, 1988)).

[149] 54 Fed. Reg. 38,044, 38,046 (Sept. 14, 1989) (emphasis added) (quotation omitted).

[150] 42 U.S.C. § 7412, 1990 Amendments.

Children, finding that children are not little adults, and have greater exposures and susceptibility.[151]

In 1994, President Clinton signed Executive Order 12898 on Environmental Justice.[152]

In 1996, Congress enacted the Food Quality Protection Act and the Safe Drinking Water Act amendments, which explicitly require consideration of the susceptibility of children and due to early exposure.[153] This same year, EPA announced a new National Agenda to Protect Children's Health.

In 1997, the President issued the Children's Environmental Health Executive Order (No. 13045) on the need to address risks to children.[154]

In 2000, EPA first published *America's Children and the Environment*, which it has since updated.[155]

In 2006, EPA issued new guidance on protecting children from environmental health risks as part of the rulemaking process.[156] Among other things, this Guide[157] recognized the problem of disproportionate risk to children because they may be more sensitive to pollution and exposed at a higher rate than adults because of their developmental stage. This Guide also recognized the need "to think in terms of the broad range of early life, pre-natal and post-natal, environmental exposures that may affect the incidence of disease or alter development."[158]

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[151] Nat'l Research Council, "Pesticides in the Diets of Infants and Children" (1993); *see also* Hugh A. Barton *et al.*, *Assessing Susceptibility from Early-Life Exposure to Carcinogens,* 113(9) Envtl. Health Perspectives 1125 (2005); Dale Hattis *et al.*, *Age-Related Differences in Susceptibility to Carcinogenesis: a Quantitative Analysis of Empirical Animal Bioassay Data*, 112(11) Envtl. Health Perspectives 1152 (2004).
[152] Exec. Order No. 12898, 3 C.F.R. 859 (1995), *reprinted as amended in* 42 U.S.C. § 4321 (1998).
[153] 21 U.S.C. § 346a(b)(2)(C) (requiring that, in taking certain actions on pesticides "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure *shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children*") (emphasis added); 42 U.S.C. § 300g-1(b)(1)(C) (requiring that, in selecting unregulated contaminants for consideration, EPA "shall take into consideration, among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as *infants, children, pregnant women*, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population") (emphasis added); *id.* § 300j-18(a)(1) (requiring EPA to "identify groups within the general population that may be at greater risk than the general population of adverse health effects from exposure to contaminants in drinking water. The study shall examine whether and to what degree *infants, children, pregnant women*, the elderly, individuals with a history of serious illness, or other subpopulations that can be identified and characterized are likely to experience elevated health risks, including risks of cancer, from contaminants in drinking water. . . .") (emphasis added).
[154] Exec. Order 13045, 62 Fed. Reg. 19,885 (Apr. 21, 1997).
[155] U.S. EPA, "American's Children and the Env't" (3d ed. 2013), http://www.epa.gov/opeedweb/children/publications/index.html.
[156] U.S. EPA, "Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children" (2006), http://yosemite.epa.gov/ochp/ochpweb.nsf/content/ADPguide.htm/$File/EPA_ADP_Guide_508.pdf.
[157] *Id.* at 8.
[158] *Id.*

In 2008, EPA updated the Child-Specific Exposure Factors Handbook.[159]

In 2008 and 2009, the major National Academy of Sciences reports – *Science and Decisions: Advancing Risk Assessment* ("NAS 2009"), and *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (2008) – were released, re-emphasizing the importance of addressing real-world risk to children and cumulative health risk.

In 2009, EPA Administrator Jackson declared environmental justice and children's health priorities.[160]

In 2010, EPA Administrator Jackson issued *EPA's Action Development Process: Interim Guidance on Considering Environmental Justice During the Development of an Action*.[161]

In 2011, EPA Administrator Jackson announced Plan EJ 2014 including rulemaking and science goals to finally achieve the goals of the 1994 Environmental Justice Executive Order.[162] EPA continues to work to issue guidance that will advance these goals.

In addition, in recent years, EPA's Children's Health Protection Advisory Committee has recommended addressing the developmental origins of adult disease that come from childhood exposure to air pollution and other environmental contaminants.[163] Similarly, the Committee has recommended that EPA incorporate a more robust analysis of childhood and pre-natal exposure to environmental contaminants into its risk assessment method.[164]

The Science Advisory Board has also urged EPA to address the greater risk to children from hazardous air pollution.[165] As the SAB further explained: "California's Office of

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[159] U.S. EPA, Child-Specific Exposure Factors Handbook (2008).
[160] http://www.epa.gov/compliance/ej/plan-ej/index.html.
[161] U.S. EPA, "EPA's Action Development Process: Interim Guidance on Considering Environmental Justice During the Development of an Action" (2010). http://www.epa.gov/compliance/ej/resources/policy/ejrulemaking.html.
[162] Plan EJ 2014, U.S. EPA, http://www.epa.gov/compliance/ej/plan-ej/index.html.
[163] U.S. EPA, *Report of the Task Group of the Children's Health Protection Advisory Comm. on America's Children & the Env't*, 3d Ed. (2010), http://yosemite.epa.gov/ochp/ochpweb.nsf/content/ACETask.htm/$file/ACE%20Task%20Group%20Report.pdf.
[164] Letter from Pamela Shubat, Chair, Children's Health Protection Advocacy Council,CHPAC to Lisa Jackson, Administrator, U.S. EPA, (Oct. 21, 2010) ("CHPAC recommends that EPA staff scientists participating in the upcoming discussions bring the concern of early life stage exposure and sensitivity to the conversations that will take place concerning optimizing risk assessment practice."), http://yosemite.epa.gov/ochp/ochpweb.nsf/content/CHPAC_NRC_Report.htm.
[165] U.S. EPA, Sci. Advisory Bd., Review of EPA's draft entitled, "Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing," EPA-SAB-10-007 (May 2010), at 7 (stating that "an overarching concern with the Agency's chronic inhalation exposure estimates is that children's exposures do not appear to have been adequately addressed"); *see also id.* at 34 n.13 ("In particular is the question of whether the interindividual variability factor for non-carcinogens and the standard cancer unit risk derivation adequately covers children. If it does not, it is a potentially significant uncertainty given the greater intake rate of children via inhalation and sensitivity to carcinogens and other toxicants.").

Environmental Health Hazard Assessment (OEHHA) has very recently updated its methodology in ways that could affect the development of RfC and URE (unit risk estimate) values. EPA should examine these developments to make sure that the RTR process adequately covers children's risks."[166]

Finally, during the last decade, OEHHA has also released a number of groundbreaking scientific determinations and protocols to consider and address children's health, early life exposure, and cumulative impacts, which are cited in this document, above, and are all available at http://oehha.ca.gov/. Most recently, these include three final Technical Support Documents on risk assessment and a proposed Risk Assessment Manual (2014).[167]

It is time for EPA scientists and science policymakers to revisit the outdated assumption EPA makes regarding what level of cancer risk triggers policy interventions. EPA's own policy regarding carcinogens recognizes that they have no safe threshold of exposure. EPA has appropriately recognized that cancer risks add up to increase lifetime risk. EPA cannot reconcile what it knows – and does not know – about carcinogens with its outdated presumption that a cancer risk of 100-in-1 million is acceptable.

Importantly, EPA's presumption regarding cancer risk ignores the experience of communities exposed to multiple sources and types of sources of pollution. Even if some level of risk might otherwise be acceptable, that cannot be assumed to be true for communities exposed to more than one source that is causing that level of health risk. EPA has a responsibility to address the science on cumulative impacts and risk and update its assumptions accordingly, to acknowledge that cancer risks below 100-in-1 million cannot be presumed safe.

EPA should also reform how it evaluates chronic and acute hazard indices, in which a risk number below 1 does not result in policy changes or standards. EPA should instead factor in uncertainties and vulnerability factors that adjust the "acceptable level of risk." This is currently done under the FQPA when EPA uses factors to determine a Target Margin of Exposure and risks below this level warrant increased scrutiny and changes to allowable exposures.[168]

In the face of increasing evidence which challenges the assumption of a safe or acceptable level of exposure, EPA should also consider reforming risk assessments to support reducing risks to the lowest possible level, to protect public health, rather than suggesting that there is a safe or acceptable level.

B. EPA Should Decide That The Health Risks Under the Existing EGU Standards Are Unacceptable.

EPA proposes that the health risks it has found are acceptable, but is taking comment on whether it should actually find them to be unacceptable. 84 Fed. Reg. at 2700. EPA appears to base its proposed acceptability determination mainly on the fact that the cancer risks (MIR) from

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[166] *Id.* at 6

[167] *See* OEHHA 2014 Manual and final Technical Support Documents, cited *supra* note 39.

[168] *See, e.g.*, EPA, Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, Proposed Rule, 76 Fed. Reg. 3422, 3427 (Jan. 19, 2011) (explaining use of MOE).

inhalation are below 100-in-1 million, "which is [EPA's] presumptive limit of acceptability." *Id.* This overly narrow view (see below) fails on its own terms.

EPA should also find the current health risks to be unacceptable for all, or any one, of the following reasons:

1. EPA has significantly underestimated the cancer risk from inhalation. If EPA addressed any of the above science outlined on this point, including the fact that it is underestimating the risk from early exposure, it would likely find the inhalation-based cancer risk exceeds even EPA's presumptive limit.

2. EPA has also underestimated the cancer risk from multipathway exposure. If EPA fully assesses multipathway cancer risk and adds that to the inhalation risk, that is also likely to exceed EPA's presumptive limit.

3. EPA should recognize that the combination of cancer, and high chronic non-cancer and acute risks, together, create unacceptable risk, particularly where EPA has underestimated all other kinds of risk as well, as described above.

4. EPA also should decide that it is unjust and inconsistent with the Act's health-protection purpose to allow the high health risks caused by EGUs to fall disproportionately on communities of color and lower income communities who are least equipped to deal with the resulting health effects. Because of that disparity, EPA should recognize that the risks found are unacceptable and set stronger national standards for all exposed Americans.

5. EPA has recognized that the rule likely does not address all emissions, particularly fugitive emissions, and this provides an additional reason to find the current level of health risk unacceptable.

V. EPA MUST PROVIDE AN "AMPLE" MARGIN OF SAFETY.

Regardless of whether EPA thinks the current level of risk from EGUs is "acceptable," EPA must determine whether stronger standards are "required in order to provide an ample margin of safety to protect public health." 42 U.S.C. § 7412(f)(2). Although EPA declares that its existing standards do provide an ample margin of safety to protect public health, 84 Fed. Reg. at 2700, that declaration lacks any record support. It is based entirely on EPA's claim that the remaining risks from EGUs are low, that reductions from "available control options would result in minimal health benefits," and that "no additional measures were identified for reducing HAP emissions" from EGUs. *Id.*

The D.C. Circuit has confirmed that, where the Clean Air Act demands an "ample margin of safety," EPA must provide one. *Sierra Club*, 895 F.3d at 12-13. Even if EPA "is entitled to deference in determining how to include an ample margin of safety," the agency may not refuse to provide any margin of safety at all. *Id.* at 13.

Here, EPA does not identify any "margin of safety" provided by its existing standards, let alone explain how that unidentified margin is "ample." EPA's opinion that the risks from EGUs are low neither identifies an ample margin of safety nor shows that one exists. Nor do EPA's claims about "available control options" and the health benefits they would confer identify the margin of safety identify an ample margin of safety nor show that one exists. When EPA promulgates new and stronger emission standards under § 112(f)(2), such considerations might be relevant in determining how much of a margin of safety EPA provides – i.e., how much stronger those standards must be. When EPA declares that its existing standards do not need to be changed, however, such claims say nothing about whether those standards provide an ample margin of safety.

EPA may not dodge its obligation to ensure that its standards – whether it strengthens them or leaves them the same – provide an ample margin of safety to protect public health. Nor may EPA simply declare they provide an ample margin of safety without saying what the margin of safety is or why it is ample. That is the approach the D.C. Circuit considered and rejected in Sierra Club.

Moreover, even if EPA's argument for declaring there is an ample margin of safety were relevant, they are refuted by the record. First, whether or not EPA thinks the risks from EGUs are acceptable, a cancer risk level of 60-in-1-million or even 50-in-1-million is not "low." 84 Fed. Reg. at 2700. Indeed, EPA does not even say what it means by "low" or why it thinks these numbers are "low."

Second, as explained in detail above, EPA has significantly understated the risk from EGUs by, inter alia, ignoring the vast majority of EGUs' emissions of organic HAPs, many of which are carcinogenic. Without considering the risk from these HAPs, EPA cannot possibly know whether the risks from EGUs are either "low" or "acceptable," let alone claim they provide an "ample margin of safety to protect public health."

Third, there are "additional measures for reducing HAP emissions," and they would confer health benefits. Most obviously, EPA could set limits to reduce EGUs' organic HAP emissions instead of pretending these emissions do not exist. EPA's existing standards for EGUs require only a work practice, consisting of periodic tune-ups for organic HAP emissions, and the agency provides no record evidence showing that this work practice has reduced EGUs' organic HAP emissions at all, let alone by any signicicant amount. If EPA reduced EGUs' emissions of benzene, formaldehyde, naphthalene, POM, dioxins, and other organic HAPs, it would reduce the health risks that EGUs create.

EPA's failure to even consider these points renders unlawful and arbitrary the agency's claim to have provided an ample margin of safety and the agency's refusal to set stronger limits for the pollutants that are covered by the existing EGU standards and new limits to control organic HAPs.

VI. EPA HAS UNDERESTIMATED ECOLOGICAL RISK.

EPA has correctly recognized that it is legally required to perform an environmental or ecological risk assessment in this rulemaking, under § 7412(f)(2), in order to "prevent ... an

adverse environmental effect."[169] As the SAB has stated: "The assumption that ecological receptors will be protected if human health is protected is incorrect."[170] In addition to inhalation risk for wildlife and air impacts to plants, chemicals that are persistent in the environment or bioaccumulative in living tissue will remain or increase over time, particularly in areas of high emissions. Accordingly, any additional exposure from current activities would thus be added to a background that is likely unsafe already for wildlife and other environmental resources. EPA must perform an appropriate ecological assessment, however, and Commenters are concerned that EPA has not adequately examined environmental, wildlife, and other ecological risks, including region-specific impacts to wildlife, including federally listed species under the Endangered Species Act, and aquatic resources in rivers and estuaries from EGU emissions as EPA's materials appear to apply a "one size fits all" assessment without regard to region-specific science.

In this risk assessment, EPA is legally required to assess impacts to endangered and threatened species, and yet EPA's assessment includes no discussion of potentially affected species, much less any evaluation of the risks they face. EPA also says nothing at all about ESA consultation, which provides further evidence that it has not considered or addressed its duty to prevent adverse environmental effects, as recognized by the D.C. Circuit.[171] EPA must assess potential endangered and threatened species.

Even after implementation of the MATs rule, EGUs continue to emit persistent and bioaccumulative pollutants into the environment. Because EPA chose to promulgate only a tune-up work practice requirement for organic HAPs rather than numeric emission standards, EGUs' emissions of persistent and bioaccumulative organic HAPs – including not only dioxins, PCBs and POM, but also hexachlorobenzene, hexachlorocyclohexane,– continue at approximately the same levels as before the MATs rule was promulgated.

EPA also makes clear that it did not consider any of the impacts of EGU emissions on the great water bodies, including the Great Lakes. As EPA is well aware, these water bodies are subject to fish consumption advisories for persistent and bioaccumulative HAPs that EGUs emit. EGUs continued emissions of these pollutants prolongs and increases this problem. Yet EPA does not even consider it.

As EPA is also aware, top predators in the aquatic food are threatened by the accumulation of persistent and bioaccumulative HAPs in their bodies, eggs, breast milk, and offspring. For example, Orcas already carry an extremely heavy body burden of toxins (PCBs, lead, mercury), likely coming from their primary food sources (primarily salmon for the resident pods, mammals like seals for the transients), and possibly from sediment/ambient levels.[172] Orcas are listed as endangered under the Endangered Species Act. Puget Sound

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[169] 42 U.S.C. § 7412(f)(2).
[170] SAB May 2010, *supra* note **Error! Bookmark not defined.**, at 48.
[171] *See Sierra Club v. EPA*, 353 F.3d at 992 (ESA consultation part of the section 7412(f)(2) rulemaking).
[172] NOAA Fisheries, Killer Whale (Orcinus orca), http://www.nmfs.noaa.gov/pr/species/mammals/cetaceans/killerwhale.htm (updated June 25, 2014).

Chinook salmon, the primary food for resident orcas, are themselves listed as threatened.[173] In addition to Chinook, many other salmon species inhabit the Sound and its tributaries.

Recent research suggests that PAHs in streams are creating big problems for salmon. Coho salmon are dying within hours of entering streams in the Puget Sound region to spawn. The same research is showing that salmon eggs and fry are deformed and do not hatch when exposed to water in these streams. Current research by the National Oceanic and Atmospheric Administration ("NOAA") concerns stormwater runoff and PAHs.[174] While stormwater is plainly an issue, the research is relevant and important here in that it points out regional species' sensitivity to PAH emissions from any source and it highlights a mistaken assumption EPA made in its risk assessment. In EPA's assessment, it appears to look only at lakes (and the extent to which EPA focused on any Washington waters is not clear). Plainly for at least some of the pollutants, stream species might also be affected. Concentrating only on mountain lakes is not giving EPA the full picture for impacts to salmon and orcas.

The latest studies about mercury in Olympic National Park are here and EPA must consider these and other similar scientific research in this rulemaking in order to fulfill its legal duty to evaluate the adverse environmental effect of EGUs' pollution under § 7412(f)(2):

- http://pubs.usgs.gov/of/2014/1051/pdf/ofr2014-1051.pdf
- http://www.kitsapsun.com/news/local-news/environment/study-reveals-mercury-laced-fish-in-olympic
- The WACAP study features lakes in Olympic and Mt. Rainer national parks and clearly shows mercury deposition to be a problem:
  - http://www.nature.nps.gov/air/studies/air_toxics/wacap.cfm
  - http://www.nature.nps.gov/air/studies/air_toxics/docs/2008FinalReport/WACAP_Report_Vol_I_Main_Chapters/5_Chapter_2_WACAP_Rpt_Vol_I.pdf
- *See also*, http://www.sfnps.org/download_product/1834/0

VII. EPA MUST REVISE ITS STANDARDS UNDER § 7412(d)(6).

A. EPA Must Set Numeric Emission Standards For Organic HAPs.

Section 112(d)(6) requires EPA to review its emission standards for EGUs and "revise [them] as necessary (taking into account developments in practices, processes and control technologies)." 42 U.S.C. § 7412(d)(6). When EPA promulgated its standards for EGUs, the

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[173] NOAA, Endangered and Threatened Species; Threatened Status for Three Chinook Salmon Evolutionarily Significant Units (ESUs) in Washington and Oregon, and Endangered Status for One Chinook Salmon ESU in Washington, 64 Fed. Reg. 14,308 (Mar. 24, 1999).

[174] *See* NOAA Northwest Fisheries Science Center, Polycyclic aromatic hydrocarbons, http://www.nwfsc.noaa.gov/research/divisions/efs/ecotox/pah.cfm and NOAA Northwest Fisheries Science Center, Stormwater science: ecological impacts, http://www.nwfsc.noaa.gov/research/divisions/efs/ecotox/ecoimpacts.cfm and publications cited there.

agency set work practice requirements for organic HAPs rather than numeric emission standards. To do so, EPA invoked § 112(h), which allows EPA to set work practice requirements instead of numeric emission limits "if it is not feasible in the judgment of the Administrator to prescribe or enforce" a numeric emission limit. 42 U.S.C. § 7412(h)(1). Section 112(h)(2) then defines "not feasible to prescribe or enforce an emission standard" to "mean[] any situation in which the Administrator determines that— … (B) the application of measurement technology to a particular class of sources is not practicable due to technological or economic limitations." *Id.* § 7412(h)(2). EPA states: "Work practice standards were established because most of the organic HAP emissions data for EGUs obtained from the 2010 information collection request (ICR) test results were at or below the detection levels of the prescribed test methods, even when long duration (~8 hour) test runs were required. Therefore, the EPA considered it impracticable to require measurements of organic HAP emissions from these units." EPA-HQ-OAR-2018-0794-0015, Technology Review for Coal- and Oil-Fired EGU Source Category ("Technology Review") at 11.

Regardless of what might be true for the "most of the organic HAP emissions data," *id.* the data sources EPA used for the proposed RTR now show that measurement of many organic HAPs is "practicable." 42 U.S.C. § 7412(h)(2). In fact, it is already being done. Therefore, it is feasible to prescribe an enforce numeric emission limits for many of the organic HAPs that EGUs emit – perhaps even for all of them. Because the Clean Air Act permits EPA to set work practice requirements instead of numeric emission limits only if it is "not feasible" to prescribe or enforce a numeric emission limit, 42 U.S.C. § 7412(h)(1), it is now "necessary" to revise the emission standards for EGUs to include numeric emission limits for all the organic HAPs for which measurement is practicable.

In addition, the evidence that measurement of organic HAPs is practicable is a "development" that EPA must "tak[e] into account in its § 112(d)(6) analysis.

The EPRI report provides emission factors for "a selected subset" of the organic HAPs that EGUs emit. Inhalation Report at 4-21. Each emission factor is rated from A to E "based on the percentage of detected values in the data set used to calculate the factor and the number of sites used to develop the factor as described in Appendix B." *Id.* An A rating means that more than 50 percent of the test results were above detection limits and at least 30 sites were used. *Id.* at 4-22 (Table 4-13, note a). A B rating means between 10 and 50 percent of test results were above detection limits and at least 20 sites were used. *Id.* A C rating means that between 5 and 10 percent of test results were above detection limits and at least 5 sites were used. *Id.* A D rating means that at least some results were above detection levels at some sites. *Id.*

EPRI provides A, B, C, or D ratings for 27 organic HAPs. *Id.* Because it is now demonstrably "practicable" to measure emissions of these HAPs, it is unlawful to have work practice requirements rather than numeric emission limits for them. 42 U.S.C. § 7412(h)(2). Accordingly, it is "necessary" under § 112(d)(6) for EPA to revise its emission standards for EGUs by setting numeric limits for these numeric HAPs.

Plainly, for some pollutants, it is simply untrue that a "significant majority" of test data are below detection levels, 77 Fed. Reg. at 9369. For those, EPRI assigns an A rating, at least half the data are above detection levels and for those EPRI assigns a B rating between 10 and 50 percent of test results are above detection levels.

More to the point, the test under the Clean Air Act is that the measurement of emissions be "practicable," 42 U.S.C. § 7412(h)(2). The EPRI data show that it is practicable to measure emissions of at least the subset of organic HAPs EPRI chose to report on. That some emission test results may be below detection levels does not show otherwise, it merely indicates that: (1) some sources that conducted testing used less sensitive testing or analysis methods with higher detection levels; and/or (2) some sources had emissions below detection levels. Neither of those possibilities even suggests that measurement of the emissions of these pollutants is not practicable. Even a measurement showing emissions for a HAP are below detection levels is plainly a measurement, and it can be used to prescribe and enforce emission standards. Further, EPA's own analysis for formaldehyde confirms that detection levels vary widely from one test to another. As noted above, detection levels for formaldehyde varied by four orders of magnitude, from approximately .0002 ppm to more than 5.0 ppm. RDL Memo at 3. That shows it is practicable to measure formaldehyde at levels far lower than the detection levels used by some sources, and the same is equally true for other organic HAPs.

Because the EPRI report does not provide emission factors or ratings for all of the organic HAPs that EGUs emit, it is possible that there are some for which emissions measurement is actually not "practicable" and for which work practices, therefore, remain permissible. Even if true, that does not mean EPA may refrain from setting numeric limits for the organic HAP that are measurable. It is well established that EPA must set emission limits for each HAP a category emits. *See National Lime Ass'n v. EPA*, 233 F.3d 625, 634 (D.C. Cir. 2000). EPA not dodge this statutory obligation for any HAP just because it believes the measurement of emissions of another HAP is not practicable.

In addition, § 112(f)(2) requires EPA to assure an "ample margin of safety to protect public health" and "prevent . . . an adverse environmental effect." Because it is possible for EPA to provide more of a margin of safety now exists for public health by setting numeric emission limits for organic HAPs, EPA must do so.

EPA must thoroughly evaluate the emissions data for all organic HAPs and determine which of these pollutants are practicable to measure. For each such HAP, EPA must set numeric emission limits.

B. EPA Must Eliminate The Extended Startup Period During Which Numeric Emission Limits Do Not Apply.

In the RTR, EPA unlawfully and arbitrarily failed to amend the MATS rule to remove the option for owners and operators of EGUs to choose an extended period of startup during which numeric emission limits do not apply.

In late 2014, EPA revised the MATS rule's provisions to increase the length of time that EGUs are subject to work practice standards when they start up—giving EGUs the option of complying with a second, more expansive definition of "startup" that ends four hours after EGUs generate electricity. At the same time, EPA retained the first definition of startup, under which startup ends at generation of electricity. EPA based its revisions on its assertion that EGUs cannot measure their emissions during the first four hours they generate electricity, claiming that Clean Air Act § 112(h) allows EPA to promulgate work practice requirements in lieu of numeric limits standards under these circumstances.

Yet the notifications and reports that coal-fired EGUs have since filed with EPA show that at least 90 percent of these units—at least 370 of the 407 coal-fired units subject to MATS—have elected the definition of startup that requires complying with numeric standards beginning with electricity generation. In fact, of the coal-fired EGUs that we could discern choices for, 96 percent of them had chosen the shorter startup definition.[175] As discussed below in more detail, this is a development in practices and/or processes that, under Clean Air Act § 112(d)(6), EPA must take into account as part of the RTR—one that requires EPA to revise the MATS rule to remove the second, more expansive definition of startup because it shows that emissions can be measured during the four-hour extended startup period. Removal of the second definition is especially necessary because, in the 2014 final MATS startup rule, EPA based the length of the startup period on when the best-performing EGUs can purportedly begin to measure emissions. That the overwhelming majority of EGUs have chosen the first definition shows that the best performers can measure their emissions in the four hours after they first generate electricity. Indeed, because the data reveals that only a very limited number of coal-fired units (possibly as low as 3 percent of them but, at most, 9 percent) have chosen the second definition, there is no reason why this small fraction of units cannot measure their emissions during the four-hour extended startup period when at least 90 percent of other coal-fired units can do so.

Removing the extended period is also necessary because EPA asserted in the MATS startup rule that it would, during the RTR, assess whether retaining the period is appropriate, and the U.S. Court of Appeals for the D.C. Circuit relied on similar representation by EPA in rejecting a challenge to the startup provisions that EPA promulgated as part of the MACT standards for industrial boilers. The industrial boilers startup provisions are almost identical to those in MATS, and, in the boilers rule, EPA primarily relied on EGU data in determining that industrial boilers cannot measure emissions during the four-hour extended startup period.

Revising MATS to remove the extended startup period is also necessary because it would achieve emissions reductions. During startup, emissions can be elevated because EGUs may be burning their primary, dirty fuel but not operating controls.

1. BACKGROUND

a. Elevated EGU Emissions During Startup

Air pollution from EGUs can be particularly problematic during periods when these facilities are starting up and shutting down, which can occur many times in the course of a year. EPA found that the "average EGU had between 9 and 10 startup events per year during 2011-2012, but data from a small number of EGUs indicated significantly more startup events (e.g., the EGUs with the most startup events had <u>over 100 startup events</u> in 2011 and <u>over 80</u> in 2012)." Assessment of startup period at coal-fired electric generating units - Revised, EPA-HQ-OAR-2009-0234-20451 at 4 (Nov. 2014) ("Measurability Analysis").[176] As environmental groups have previously pointed out in comments, as coal-fired EGUs are forced into more and

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[175] Our review of the data revealed that 14 coal-fired EGUs had chosen the second definition. We were unable to determine the startup choice of 23 coal-fired EGUs.

[176] EPA noted that it may have double-counted some startup events. *Id.* at n.10.

more intermittent use by less expensive gas-fired units and renewable energy, the number of startups will likely increase. *See* EPA-HQ-OAR-2009-0234-20427 at 3, Ex. C.

EPA has recognized that EGUs' pollution can be significant during periods of startup and shutdown. In EPA's "SSM SIP call," EPA stated that startup and shutdown emissions have "real-world consequences that adversely affect public health." 80 Fed. Reg. 33,840, 33,850 (June 12, 2015). In a memo that EPA cited in the preamble to that rule, EPA stated that it is "concerned about the amounts of excess emissions that occur during" periods of startup, shutdown, and malfunction. *Id.* at 33,850 n.22; Memorandum: Statutory, Regulatory, and Policy Context for this Rulemaking, EPA-HQ-OAR-2012-0322-0029 at 22 ("Rulemaking Context Memo"). "Available evidence suggests that the amount of extra emissions that occurs during these … periods is potentially large." Rulemaking Context Memo at 23.

Regarding the level of emissions that can occur during startup when EGUs are not running pollution controls, EPA found that, across the 24 hours after EGUs first generate electricity, the average sulfur dioxide emissions at those units equipped with controls for this pollutant were approximately 40 to 90 percent lower than the emission rates for units without the controls, depending on the boiler and control type. Measurability Analysis at 9-10, 14-15. *See also id.* at 10 n.14 ("Several startup events … had high [sulfur dioxide] emissions for more than 24 hours after the start of generation indicating the [control] equipment was likely not in use").

Presumably in large part because of the elevated pollution that can occur during startup, at least ten power plants in Texas obtained permits with extremely high limits for particulate matter during planned startup, shutdown, and maintenance. *See* Petition for Reconsideration of MATS Startup Provisions, EPA-HQ-OAR-2009-0234-20461 ("Recon. Pet.") at 6, Ex. 1. These special limits far exceed the limits that apply during "normal" operations. *Id.* For example, the two units at the Limestone Electric Generating Station are each allowed to emit 7,616 pounds of particulate matter per hour during planned startup, shutdown, and maintenance—<u>over 30 times higher</u> than the 236 pounds per hour that these units are normally allowed to emit. *Id.* at Ex. 5, pdf pp. 2, 14-16.

b. The Clean Air Act Only Allows EPA to Establish Work Practices in Lieu of Numeric Emission Standards in Limited Circumstances.

The Clean Air Act requires most standards for hazardous air pollutants to be in the form of a numeric limit on emissions. 42 U.S.C. § 7412(h)(4). Non-numeric standards are authorized only "if it is not feasible in the judgment of the Administrator to prescribe or enforce an emission standard for control of a hazardous air pollutant or pollutants." *Id.* § 7412(h)(1). Section 7412(h)(2) then defines the phrase "not feasible to prescribe or enforce an emission standard" as a "situation in which the Administrator determines that … a hazardous air pollutant or pollutants cannot be emitted through a conveyance designed and constructed to emit or capture such pollutant, or … <u>the application of measurement methodology to a particular class of sources is not practicable due to technological and economic limitations</u>." *Id.* § 7412(h)(2) (emphasis added). As relevant here for the MATS extended startup period, EPA has relied only on the second part of this definition.

Section 7412(h) further provides that work practice standards must be "consistent with the provisions of subsection (d) or (f) [of § 7412]." *Id.* § 7412(h)(1). *See also id.* § 7412(d)(2)(D) (listing work practices among the measures EPA may employ in pursuit of the "maximum" reduction "achievable"). Under § 7412(d), each standard EPA promulgates must require the "maximum" degree of reduction in emissions that is "achievable," considering cost and other factors, "for new or existing sources in the category or subcategory to which such emission standard applies." *Id.* § 7412(d)(2). Regardless of cost, standards for existing sources in categories or subcategories with 30 or more sources must be no less stringent than the "average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has emissions information) … in the category or subcategory." *Id.* § 7412(d)(3)(A), (B).

c. The 2014 Rule's Four-Hour Extended Startup Period and Ineffective Work Practices

In its final 2014 startup rule, EPA adopted two alternative definitions of startup—retaining the definition from the 2012 MATS rule, but also giving EGUs the option of complying with a more expansive definition of startup. 79 Fed. Reg. 68,777, 68,792 (Nov. 19, 2014) (40 C.F.R. § 63.10042). Under the first definition of startup from § 63.10042, startup "ends when any of the steam from the boiler is used to generate electricity for sale over the grid or for any other purpose (including on-site use)." Under the second, more expansive definition added in 2014, startup "ends 4 hours after the EGU generates electricity that is sold or used for any other purpose (including on site use), or 4 hours after the EGU makes useful thermal energy (such as heat or steam) for industrial, commercial, heating, or cooling purposes …, whichever is earlier." In lieu of numeric limits, those EGUs that choose the second definition of startup must comply with certain work practice standards during the extended startup period. 40 C.F.R. pt. 63, subpart UUUUU, tbl. 3. In its 2014 final startup rule, EPA asserted that work practice standards were proper during this period under 42 U.S.C. § 7412(h)(2)(B), which (as noted above) allows EPA to establish work practice standards when the "application of measurement methodology … is not practicable due to technological and economic limitations." *See* 79 Fed. Reg. at 68,782.

EPA arrived at the four-hour extended startup period by identifying when the "best performing 12 percent" of 414 coal-fired EGUs could purportedly begin to measure their emissions—which EPA equated with when units initiated operation of certain pollution controls for reducing sulfur dioxide and nitrogen oxides. Measurability Analysis at 2-3. Citing to 42 U.S.C. § 7412(h)(1)'s requirement that work practice standards be "consistent with" the stringency requirements from § 7412(d)(3), EPA said that its 2014 final-rule technical analysis had changed from the proposed-rule technical analysis to "more appropriately track this statutory directive." 79 Fed. Reg. at 68,782.

Of the work practice standards that apply for those EGUs that choose the extended startup period, only three of them could even possibly reduce emissions during this period:

- A requirement that plants use clean fuels to the "maximum extent possible, taking into account considerations such as boiler or control device integrity, throughout the startup period."
- A requirement to "engage and operate" particulate matter controls within one hour of first firing a plant's primary fuel (*e.g.*, coal).

- A requirement to start all other control devices "as expeditiously as possible, considering safety and manufacturer/supplier recommendations, but, in any case, when necessary to comply with other standards made applicable to the EGU by a permit limit or a rule other than this Subpart that require operation of the control devices."

40 C.F.R. pt. 63, subpart UUUUU, tbl. 3.

Although the first of these requirements mentions using clean fuels throughout the first four hours of electricity generation, many industry commenters said that they begin generating electricity "after adding the primary fuel"—*i.e.*, coal or oil—or that they add coal or oil simultaneously with commencing generation. Response to Comments, EPA-HQ-OAR-2009-0234-20447 at 113 (Nov. 2014). *See also* 79 Fed. Reg. at 68,779 ("introduction of coal to the boiler is … always associated with generation of electricity"). In addition, as they are producing electricity at the levels EPA recognizes are achieved during the first four hours of generation,[177] most coal-fired EGUs are not designed to burn clean fuels at the same time as their primary fuel. Recon. Pet. at Ex. 14, ¶¶ 8-10, 13-19.[178] In other words, many EGUs are burning only dirty fuels during the four hours after they first generate electricity.

Thus, EGUs that select the extended startup definition may be excused from compliance with both the numeric emission standards and the clean fuels requirement each time they start up, beginning around the point of generation of electricity and ending four hours later. During that time, except for a requirement to start particulate matter control devices within one hour, they are only subject to a requirement to start control devices "as expeditiously as possible, considering safety and manufacturer/supplier recommendations"—*i.e.*, on each EGU's own schedule as determined by that EGU, meaning that some EGUs could not engage their controls at all during the extended startup period. And even the requirement to "engage and operate" particulate controls may be ineffectual: many EGUs have electrostatic precipitators with multiple fields that all need to be operative to fully reduce emissions, but these units could satisfy this requirement by operating only a limited number of these fields. Recon. Pet. at Ex. 14, ¶ 11.

d. EPA Previously Committed to Assessing Whether to Retain the Extended Startup Period in the RTR.

In the 2014 MATS startup rule, EPA committed to reviewing, in the RTR for the 2012 MATS rule, the appropriateness of the extended startup period: "As explained in the final [2012] rule preamble, collection of startup and shutdown information will provide the EPA with information to more fully analyze the ability and appropriateness of establishing numeric emissions and operating limits during startup periods or shutdown periods so the issue can be addressed as part of the ongoing 8-year review of this rule." 79 Fed. Reg. at 68,786 (citing 77 Fed. Reg. 9382 (Feb. 18, 2012)) (emphasis added). EPA elaborated:

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[177] EPA found that, once they begin generating electricity, EGUs increase generation "rapidly." Measurability Analysis at 7. EPA determined that, depending on their design, EGUs on average generate between 30 and 42 percent of their maximum output of electricity three hours after they first generate electricity—and between 38 percent and 49 percent by the fourth hour. *Id.*

[178] For ease of reference, commenters are reattaching this declaration from Dr. Ranajit Sahu as Attachment 4 to these comments.

> We are maintaining the final [2012] rule approach and will evaluate the continued need for the alternative definition during our ongoing 8-year reviews. We intend to use HAP and HAP surrogate data collected during periods of startup and periods of shutdown to evaluate the accuracy of CEMS from the start of electricity generation to the end of startup as defined under the alternative included in this final rule (i.e., 4 hours after electricity generation). We will use these data to help determine whether it is appropriate to make changes to the rule in the future.

Id. at 68,779 n.3. *See also id.* at 68,780 ("During the 8- year review required under CAA section 112(d)(6), the agency intends to further assess HAP emissions during startup and shutdown based on data collected from sources complying with the final rule …."). Likewise, in denying these commenters' petition for reconsideration of the 2014 startup rule, EPA reiterated: "[T]he EPA believes the information that will be collected for the alternative option in the final [2014] rule will be useful in further refining the work practice and potentially moving to a numeric standard in lieu of a work practice during subsequent reviews pursuant to section 112(d)(6)." Denial of Petitions for Reconsideration of Certain Startup/Shutdown Issues: MATS, EPA-HQ-OAR-2009-0234-20581 at 26 (July 2016) (emphasis added).

e. The D.C. Circuit Relied on EPA's Assurances that It Would Perform a RTR Review of the Startup Provisions from the Industrial Boilers Rule.

In the NESHAP for industrial boilers, EPA promulgated startup work-practice provisions that are almost identical to those in MATS. *See* 40 C.F.R. § 63.7575 at definition (2) of "startup" (providing that startup "ends four hours after when the boiler or process heater supplies useful thermal energy (such as heat or steam) for heating, cooling, or process purposes, or generates electricity, whichever is earlier"); 40 C.F.R. pt. 63, subpart DDDDD, tbl. 3 (listing startup work practice standards). In determining the length of the four-hour extended startup period for boilers, EPA relied primarily upon the technical analysis that the agency performed to determine that the best-performing EGUs can begin to measure emissions four hours after they generate electricity. 80 Fed. Reg. 72,790, 72,795 (Nov. 20, 2015).

EGUs and boilers are very similar equipment, with the distinction that EGUs sell their electricity and boilers produce power for on-site use. *See* 40 C.F.R. §§ 63.10042 (defining EGU as "a fossil fuel-fired combustion unit of more than 25 megawatts electric (MWe) that serves a generator that produces electricity for sale"); 63.7575 (defining industrial boiler as a "boiler used in manufacturing, processing, mining, and refining or any other industry to provide steam, hot water, and/or electricity"—and commercial/institutional boiler as a "boiler used in commercial establishments or institutional establishments … to provide electricity, steam, and/or hot water"). EPA recognized the similarities between EGUs and boilers in establishing the startup period for boilers. *See* 80 Fed. Reg. 3,090 (Jan. 21, 2015) ("Since the types of controls used on EGUs are similar to those used on industrial boilers and the start of electricity generation is similar to the start of supplying useful thermal energy, we believe that the controls on the best performing industrial boilers would also reach stable operation within 4 hours after the start of supplying useful thermal energy …."). *See also Sierra Club v. EPA*, 884 F.3d 1185, 1200 (D.C. Cir. 2018)

("Although EPA had scant data about the boilers to be regulated, it had a better dataset on technologically similar boilers whose primary function is electricity generation").

In establishing work practice standards for boilers for the extended startup period, EPA—like in MATS—represented that it would revisit those startup provisions through a RTR. *See* Boilers Response to Comments, EPA-HQ-OAR-2002-0058-3937 at II-4 (Oct. 2015) ("We are maintaining the January 2013 final rule approach and will evaluate the continued need for the alternative [startup] definition during our ongoing 8-year reviews"). In a case brought by environmental groups challenging the startup provisions for boilers, the D.C. Circuit summarized EPA's representations regarding RTR review as follows:

> EPA's approach was crafted with one eye to the future periodic reviews the Act requires. *See* 42 U.S.C. § 7412(d)(6). Once boiler operators either provide improved data to EPA or <u>opt for the shorter startup period and succeed in complying with it, EPA assures us that it will consider further refining and tightening these standards</u>. Resp't's Br. 40.

Sierra Club, 884 F.3d at 1200 (emphasis added). In rejecting the challenge to the boiler startup provisions, the court specifically relied on EPA's representations:

> EPA's data, though admittedly scant, pass muster in part because <u>EPA's reliance thereon is only a stopgap</u>; as noted, the data collection and recordkeeping requirements in EPA's work practices standard are designed to generate more directly relevant data that <u>promise to provide grounds to further revise the rule (or to confirm its appropriateness)</u>.

Id. at 1201 (emphasis added). *See also id.* at 1202 ("[EPA's] approach reasonably offered eased recordkeeping and reporting as an incentive for a subset of industrial boilers to reduce emissions …, even as EPA recognized the need to collect additional data from the rest of the field").

Now, in an ongoing case in the D.C. Circuit challenging EPA's denial of environmental groups' petition for reconsideration of the MATS startup provisions, EPA has also relied upon its commitment to assess the MATS startup provisions through the RTR: "As it did with the industrial boiler rule, EPA committed to assessing the new data on utility boilers to evaluate whether changes to the rule are appropriate in the future." Proof Brief of Respondent at 41, *Chesapeake Climate Action Network v. EPA*, No. 15-1015 (D.C. Cir. March 27, 2019), ECF No. 1779907.

2. The Proposed RTR Unlawfully And Arbitrarily Fails To Remove The MATs Rule's Second Definition Of Startup.

Under Clean Air Act § 112(d)(6), EPA "shall review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards promulgated under this section no less often than every 8 years." 42 U.S.C. § 7412(d)(6). As part of the RTR proposal here, EPA proposed no revisions to the MATS startup provisions (or any other of the rule's provisions)—and apparently has not even considered whether to revise the startup provisions. *See* 84 Fed. Reg. at 2,680-2,700.

Such review and revision of the startup provisions, however, is required under § 112(d)(6), and EPA's failure to so review and revise the provisions to remove the extended startup period is arbitrary and unlawful. Since EPA promulgated the MATS rule in 2012 (and the startup rule in 2014), owners and operators of EGUs have filed notifications and reports indicating their choice between 40 C.F.R. § 63.10042's two definitions of startup. We believe that we have reviewed (from EPA's WebFIRE website) these filings for all of the coal-fired EGUs subject to MATS, and our review shows that nearly all of these EGUs (96 percent of the EGUs that we could discern choices for and, at the least, 90 percent overall) have chosen the first definition, under which startup ends at generation of electricity:

Startup Definition	**Number of Units**
1 (startup ends at generation)	370
2 (startup ends four hours after generation)	14
Unable to determine	23

For more details, see the accompanying Attachment 3, which details these choices by EGUs. At least some of the units noted above as having chosen the second startup definition have since ceased operation.[179]

That the overwhelming majority of EGUs have chosen—and filed reports and notifications detailing the choice of—the first, more narrow definition of startup is a development in practices and processes that makes it necessary to revise the MATS rule to remove the second, more expansive startup definition. As discussed above, the Clean Air Act only allows work practice standards in certain specific, very limited situations, only one of which EPA has relied upon for the MATS startup provisions—when "the application of measurement methodology to a particular class of sources is not practicable due to technological and economic limitations." 42 U.S.C. § 7412(h)(2)(B). Because the development in EGUs' choice of startup definition shows that emissions can be measured during the four-hour extended startup period, EPA has no statutory basis for retaining work practice standards in lieu of numeric emission standards for this period. The statute is clear that EPA "shall … revise" previously-promulgated standards when "necessary." In these circumstances, when information shows that EPA no longer has a statutory basis for retaining work practice standards, it is "necessary" to revise the rule and impose numeric standards.

It is especially necessary to revise the rule because EPA's position—as evidenced by the 2014 final MATS startup rule—is that the length of the startup period should be based on when the best-performing 12 percent of EGUs can begin to measure emissions. That the overwhelming

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[179] For example, the two units at the St. John's River power plant closed in January 2018. *See* https://www.jea.com/about/electric_systems/electric_facilities/st__johns_river_power_park/
And the units at Henderson Municipal Power and Light Station 2 ceased operation in early 2019. *See* http://www.14news.com/2019/03/02/hmpl-signs-new-contracts-provide-power-next-years/

majority of EGUs (far more than 12 percent) have chosen the first definition shows that the best performers can measure their emissions in the four hours in question. EPA cannot retain the extended startup period (and it is necessary to remove it) when these reports and notifications—submitted since the 2012 MATS rule and 2014 startup rule were promulgated—so clearly shows that EPA's determination that served as the basis for the extended work practice period (that the best performers cannot measure emissions until four hours after electricity generation) was flatly wrong. And even if EPA were to now assert that the length of startup should not be based on what the best performers achieve, the choice of the overwhelming majority of EGUs shows that all EGUs can measure emissions from generation of electricity forward. There is no reason to suspect that the small remainder of EGUs that have chosen the second definition cannot measure emissions beginning at generation. And there is nothing distinctive about the EGUs that have chosen the second definition that could possibly render them any less capable of measuring emissions during the extended startup period than those units that have chosen the first definition.[180]

Revising MATS to remove the extended startup period is especially necessary because EPA has characterized the 2014 startup rule as a stopgap and asserted (both in the administrative record and in briefing in the D.C. Circuit) that it would assess the appropriateness of maintaining the extended work practice period during the RTR.[181] Further, the D.C. Circuit relied on similar representation by EPA in rejecting the environmental groups' challenge to the extended startup period for industrial boilers—a period that was based primarily on when EGUs can purportedly begin to measure emissions. In fact, for boilers, which are very technologically similar to EGUs, EPA specifically "assure[d]" the D.C. Circuit that it would consider tightening the startup standards when operators "opt for the shorter startup period and succeed in complying with it" (884 F.3d at 1200)—which is exactly what EGU operators have done in choosing (and complying with) the shorter startup period in MATS.[182]

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[180] Our review of the characteristics of the EGUs that have chosen the second definition shows that they burn a range of different types of coals and use a range of different pollution controls.

[181] Here, Clean Air Act § 112(d)(6)'s 8-year deadline for reviewing and revising all aspects of the MATS standards (including the startup provisions) runs from the 2012 promulgation of the original MATS rule—not the 2014 promulgation of the startup revisions to the MATS rule. Any position to the contrary by EPA would be inconsistent with the plain language of § 112(d)(6) and otherwise unreasonable and arbitrary. Even if the 8-year period did run from the date of the 2014 startup rule, removal of the second startup definition is necessary now because the data so clearly shows that EGUs can measure their emissions during the four-hour extended startup period—and that EPA has no statutory basis for that extended work practice period.

[182] There is no question that all EGUs (even those that have chosen the second startup definition) can comply with the MATS rule's numeric standards if emissions from the first four hours of electricity generation are included in determining compliance. In the 2014 startup rule, EPA found that, even without the extended startup period, the MATS rule's numeric limits "contain sufficient variability to include [emissions from] startup periods …." 79 Fed. Reg. at 68,778 n.1. *See also* 77 Fed. Reg. 9304, 9381 (Feb. 16, 2012) (stating the same). This is especially so because of the MATS rule's 30-day averaging period and because, in establishing the rule's numeric standards, EPA used the "upper prediction limit" to account for variability. *See* 76 Fed. Reg. 24,976, 25,041 (May 3, 2011) ("… if we were to randomly select a future test … from any of these sources … we can be 99 percent confident that the reported level will fall at or below the [upper prediction limit] value.").

Revising MATS to remove the extended startup period is also necessary because it would achieve emissions reductions. As discussed above, startups can take place many times every year, and startup emissions from those EGUs that choose the second startup definition can be elevated during the extended startup period because the work practice standards for that period allow EGUs to burn dirty fuels such as coal and not operate their pollution controls at all (for non-particulate controls) or not operate them at levels that would fully reduce emissions (for electrostatic precipitators for particulate control). Requiring all EGUs to comply with numeric standards during the four hours after they first generate electricity would better ensure reductions of hazardous air pollutants during this period to the levels required by Clean Air Act § 112(d).

Because removing the extended startup period is "necessary," that is the end of the matter. EPA must "revise" the emission standards "as necessary." 42 U.S.C. § 7412(d)(6). The factors that EPA sometimes considers in determining whether and how much to strengthen numeric emission limits are irrelevant here.[183] *See* 84 Fed. Reg. at 2,687 (listing factors EPA considers in reviews under § 112(d)(6)). Regardless, those factors do not counsel in favor of retaining the extended startup period. For example, requiring measurement and compliance at electricity generation involves little to no extra costs for EGUs—especially given that at least 90% of EGUs are already complying with numeric standards at that point and given that EGUs that choose the second startup definition presumably incur more costs because they are required to monitor and report additional data that those units that comply with the first definition do not. *See* 40 C.F.R. §§ 63.10020(e), 63.10031(c)(5), 63.10030(e)(8). Further, there are no negative energy implications or non-air environmental impacts associated with removing the extended startup period. And measuring emissions beginning at electricity generation and complying with numeric standards at that point is not technically infeasible, as discussed above.

To the extent that EPA asserts that it has statutory discretion regarding whether to remove the extended startup period (or whether to consider the fact that the majority of EGUs have chosen the first startup definition a "development" in "practices" or "processes") (EPA has neither sort of discretion in at least the circumstances presented here), EPA must exercise any such discretion to remove the second startup definition for all the reasons discussed above. This is especially so given EPA's prior representations that it would, through the RTR, assess the data and revise the MATS rule's startup provisions as needed—and given the D.C. Circuit's reliance on such representations in upholding the industrial boilers rule against environmental groups' challenge.

Further, apart from EPA's failure to revise the MATS rule to remove the second startup definition, EPA's failure to even <u>review</u> the extended startup period and associated work practice standards in the RTR is a separate and distinct violation of Clean Air Act § 112(d)(6). At the very least, § 112(d)(6) required EPA to review—and consider revisions to—those provisions, which EPA did not do. The statute is clear that EPA "shall review" the previously-promulgated standards, including the startup work practice standards. This is especially so when EPA previously committed to such review of the startup provisions.

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[183] For this reason, the holding in *Association of Battery Recyclers, Inc. v. EPA*, 716, F.3d 667, 673-74 (D.C. Cir. 2013) regarding EPA's consideration of cost and other factors in the RTR for secondary lead smelting facilities is inapposite.

In addition, Clean Air Act § 112(f)(2) requires EPA to assure an "ample margin of safety to protect public health" and "prevent . . . an adverse environmental effect." Because of the risk EPA has found, the elevated emissions that can occur during startup, and the MATS startup work practice standards' ineffectiveness at reducing emissions, EPA should find is unacceptable to allow EGUs to choose the second startup definition. And because it is possible for EPA to provide more of a margin of safety for public health and to prevent adverse environmental effects by requiring all EGUs to comply with numeric emission limits beginning at electricity generation, EPA must do so.

If EPA, in its final action on the open proposal and in response to the above comments, intends to revise the MATS rule's startup provisions in any way other than removing the extended startup period, the agency must provide a new round of comment on those proposed revisions. Failure to do so would violate the notice and comment requirements from Clean Air Act § 307(d).

C. EPA Must Require The Use Of All Available Continuous Emissions Monitoring Systems For Continuous Compliance Monitoring.

EPA's existing standards give EGUs the option of demonstrating compliance with certain standards through the use of continuous emissions monitoring systems (CEMs). 77 Fed. Reg. at 9370-73. Now that the standards have been implemented and EGUs are in compliance with them, it is plain that these CEMs can be used for compliance purposes – i.e., to demonstrate compliance on a continuous basis as required by the Clean Air Act and to identify any violations of emission standards. The widespread demonstration that CEMs can be used for these purposes is a "development" under § 112(d)(6). Accordingly, EPA must revise its emission standards for EGUs by requiring the use of CEMs for compliance purposes for all the emission limits in the MATs rule, rather than simply making CEMs use an option.

D. EPA Must Set Strong Fence-Line Monitoring Requirements Because Fenceline Monitoring Is A "Development" Within The Meaning Of §7412(D)(6).

Fence-line monitoring is an important tool to identify sources of fugitive emissions and other undercounted sources of toxic pollution. EPA must require fence-line monitoring for four reasons.

First, the Clean Air Act requires EPA to set monitoring provisions to assure continuous compliance with emission standards. For example, 42 U.S.C. § 7414(a)(3) mandates that EPA "shall in the case of . . . a major stationary source . . . require enhanced monitoring and submission of compliance certifications." The Clean Air Act also requires permits to contain "conditions as are necessary to assure compliance with applicable requirements of [the Act]."[184] 40 C.F.R. Part 70 adds detail to this requirement. 40 C.F.R. § 70.6(a)(3) requires "monitoring sufficient to yield reliable data from the relevant time period that are representative of the source's compliance." Section 70.6(c)(1) requires all Part 70 permits to contain "testing,

[184] 42 U.S.C. § 7661c(a).

monitoring, reporting, and recordkeeping requirements sufficient to assure compliance with the terms and conditions of the permit."[185]

Second, EPA has acknowledged that its policy is to implement the Act's enhanced monitoring requirements by setting such requirements in air toxics standards. EPA previously stated that it recognized the need to implement this requirement in connection with specific air toxics rulemakings, and that it intended to do so. EPA's own Enforcement Division is also implementing enhanced monitoring requirements to assure compliance, and EPA must require, at least, what its division is requiring as part of its "next generation compliance" policy. EPA therefore must follow this policy and implement the Act's enhanced monitoring requirements in this rulemaking.

Third, significant "developments" in monitoring have occurred in recent years and 42 U.S.C. § 7412(d)(6) requires EPA to "take account of" such developments by revising the standards. As EPA acknowledges, there are newly available technologies and monitoring techniques available now to assure compliance with the standards.

Fourth, 42 U.S.C. § 7412(f)(2) requires EPA to assure an "ample margin of safety to protect public health" and "prevent . . . an adverse environmental effect." Because of the risk EPA has found, which as discussed above, in Part 0, *supra*, EPA should find is currently unacceptable, and because it is possible for EPA to provide more of a margin of safety now exists for public health using fence-line monitoring, EPA should do so. Strong fence-line monitoring provisions would assure not only that the standards are met, but that, due to the increased public information available to assure compliance, there is indeed a "margin of safety" such that no community faces greater health risks than EPA has found to exist, because of fugitive and other emissions it acknowledges that it has not accounted for.

As explained below, to meet each of these legal responsibilities, EPA must adopt a rule that requires open-path monitoring because that is the type of monitoring system that can achieve EPA's intended and required objective of reducing fugitive emissions and it is also a feasible technology. Open-path monitoring is technologically feasible, cost-effective, and will resolve EPA's and the industry's longstanding problem with excess fugitive emissions and malfunctions. Commenters thus urge EPA to strengthen the proposed fence-line monitoring provisions by requiring open-path monitoring. Passive sampling alone, with the protocol EPA has proposed, is insufficient to assure compliance or satisfy each of EPA's legal duties, outlined above, and as further explained below.

1. Developments in Fence-line Monitoring

EPA found significant developments in fence-line monitoring technology. EPA's stated goal for the fence-line monitoring program is to reduce fugitive emissions. To achieve that goal and satisfy the Act's requirements as described above, to account for developments and assure compliance, and follow own EPA policies, EPA must finalize a fence-line monitoring protocol that satisfies each of the following criteria, which developments in fence-line monitoring make possible.

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[185] 40 C.F.R. § 70.6(a)(3).

- **Time Resolution** – Ability to measure multiple pollutants and report data to the public in real-time or near real-time, at least every 5 minutes to 1 hour.

- **Multi-Pollutant Monitoring** – Measure multiple hazardous air pollutants accurately at low concentrations.

- **Geographic Coverage** – Cover a significant portion of the fence-line to assure measurement of pollution regardless of wind direction.

- **Assure Compliance and Incentivize Emission Reductions** – Establish enforceable corrective action levels that create an incentive to identify fugitive and undercounted sources of toxic pollution.

On each of these criteria, open-path monitoring is the method EPA should require. EPA has recognized open-path monitoring is a "development" in fence-line monitoring technology. Moreover, open-path monitoring technology satisfies the needs of a fence-line monitoring system because it: (1) provides real-time analysis and data on air pollution; (2) can analyze multiple pollutants simultaneously and at low, near-ambient concentrations; (3) has complete geographic coverage; and (4) the above qualities of open-path monitoring make it possible for EPA to assure emissions reductions through mandating enforceable corrective actions. For all of these reasons, the Bay Area Air Quality Management District is now working to finalize open-path fence-line monitoring requirements, and EPA should ensure that its final rule assures the same protection.

EPA's current standards do not include any fenceline monitoring requirements. There can be no question that such requirements would benefit people who live near EGUs and are impacted by their emissions. EPA itself states that "[u]nderstanding what is in the air near sources of pollution such as industrial applications, oil and gas production facilities, coal-fired power plants and highways is critical to safeguard public health and the environment from six common air pollutants and other hazardous air pollutants regulated by EPA."[186]

When EPA promulgates fenceline monitoring requirements for EGUs, they should include the specifications:

- **Time Resolution**

Open-path monitoring is capable of measuring the ambient concentration of multiple pollutants in as low as five minute increments.[187] High time resolution is an important characteristic for fence-line monitoring because it enables facilities and regulators to identify the source of fugitive emissions. The underlying principle is that an individual can trace a particular measurement back to its source by analyzing the wind during the period of the measurement.

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[186] https://www.epa.gov/air-research/air-monitoring-measuring-and-emissions-research.

[187] *Id*; Shell Deer Park Consent Decree; *see also* BP Whiting Monitoring Site Data, *available at* http://raqis.radian.com/pls/raqis/bpw.whiting.

Data that is collected every five minutes makes this possible because specific wind direction and speed can be matched to a specific pollutant reading.

Highly time resolved data also provides the benefit of enabling plant operators and regulators to trace pollutants to specific process operations so the operator takes the right kind of corrective action. Also, real-time monitoring significantly alleviates the problem identifying background concentrations. This is a direct result of the fact that it is easier to triangulate the source of the pollution.

- **Multiple Pollutants**

Just as the Act requires EPA to set limits on all hazardous air pollutants[188], EPA needs to assure compliance with all of the limits. Open-path monitoring is capable of measuring multiple pollutants simultaneously.

- **Fence-line Coverage**

Maximum fence-line coverage is important to assure that all hazardous emissions into neighboring homes and communities are detected. Fence-line monitoring can only measure and identify the pollutants that are encountered by the sampler. An open-path system addresses this concern by monitoring all of the air between two points, an energy source that emits an electromagnetic beam and a detector that can translate disturbances in the beam into pollutant concentrations for various pollutants.[189] Each energy source and detector pair can be placed between 100-500 meters apart,[190] ensuring complete coverage within that span.

2. Corrective Action Requirements Must Assure Compliance And Incentivize Emissions Reductions

A meaningful fence-line monitoring program requires strict implementation provisions and adequate reporting and corrective action requirements. Proper implementation of the fence-line monitoring program is essential for ensuring that facilities place monitors properly. Real-time reporting is necessary to provide operators, regulators, and citizens with prompt data about pollution concentrations and potential problems. And, the corrective action requirements must set a level that is low enough to protect public health and include mandatory requirements to fix the source of the elevated HAP readings as expeditiously as practicable.

a. Public Review and Comment.

Regardless of the technology that EPA chooses, EPA must require all facilities to submit monitoring plans, data, and corrective action plans for agency review and public comment. Under the current requirement EPA only proposes this for a plan that aims to account for offsite upwind sources or onsite excluded sources.[191] When EPA has acknowledged that the monitoring requirements are needed to assure compliance, it cannot rationally allow sources to

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[188] *Nat'l Lime Ass'n v. EPA*, 233 F.3d 625, 634 (D.C. Cir. 2000).
[189] 79 Fed. Reg. at 36,921.
[190] *Id*.
[191] 79 Fed. Reg. at 36,978-79 (§ 63.658(i)).

set up their monitoring plans with no oversight whatsoever. Public notice and comment would be consistent with EPA's commitment to environmental justice and ensure that concerned community members have the ability to review and offer concerns or ways to strengthen monitoring plans before they are implemented. This also would make sure EPA has the ability to consider community concerns in deciding whether to approve a plan.

EPA also must require corrective action plans to be submitted for notice and comment. That can occur at the same time as EPA is reviewing the plans, without causing delay. Sources should be required to begin implementing corrective action while receiving input from the public and EPA, and EPA must then decide whether to add or modify corrective action requirements after considering public comment. If community members have no opportunity to review or provide comment on corrective action plans, they will be cut out of the most important part of the fence-line monitoring plan: the part that is supposed to reduce harmful fugitive emissions.

b. Real-Time Public Reporting

Open-path monitoring allows facilities to provide real-time public reporting of emissions. Making pollution data public is a low-cost, efficient manner to drive pollution reduction. It is widely recognized that this is a key benefit of the Toxic Release Inventory program.[192] Further, contemporaneous data enables all stake holders to respond to problem in real-time before the damage of excess exposure has already occurred. The data become less and less valuable to the community the longer facilities wait to report them.

EPA should require:

- **Root Cause Analysis and Corrective Action Analysis** – EPA must require facilities to complete these actions within 5 days of initiating the root cause analysis.
- **Initial Corrective Action** – EPA must require facilities to complete the corrective action within 5 days. Without a concrete deadline, a problem could linger indefinitely and become catastrophic. Furthermore, facilities could delay completing the initial corrective action and might never trigger the second corrective action requirement of submitting a plan to EPA.
- **Further Corrective Action –** A facility should have no longer than 14 days to develop a new corrective action plan and begin to implement it. A facility also should not wait to implement that plan until receiving EPA approval. EPA should review promptly, but if it does not, the facility should be required immediately to start implementing the plan to reduce fugitive emissions. EPA should set a shorter deadline, such as 14 days, for the agency to review and decide whether to approve a plan, or if changes are needed. Otherwise, leaking air toxics can go on for <u>5 months</u> after repeated exceedances, before a facility takes any corrective action.

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[192] Archon Fung, Reinventing Environmental Regulation From the Grassroots Up: Explaining and Expanding the Success of the Toxics Release Inventory, 25 Env. Mgmt. 2, 115-127 (Feb. 2000) *available at* http://www.ncbi.nlm.nih.gov/pubmed/10594186.

- **Specific Reporting and Action –** The rules should require immediate reporting and specific corrective action, such as automatic shutdown and additional higher-quality monitoring (such as UV-DOAS), with oversight such as an inspection and audit by EPA expert staff or an independent expert, until the problem has been fully resolved to prevent its repetition.

c. Open-path Monitoring is Required to Comply With EPA's Stated Policy to Mandate Enhanced Monitoring.

Also, open-path monitoring will enable EPA to comply with the Act's requirement to assure enhanced monitoring and its own policy to implement the Act's enhanced monitoring requirements by setting such requirements in air toxics standards.[193] EPA previously stated that it recognized the need to implement this requirement in connection with specific air toxics rulemakings, and that it intended to do so.[194]

- **EPA should require the use of continuous emission monitoring.**

EPA must require continuous monitoring of emissions from EGUs. As EPA is aware, there is technology available to perform CEMS for Hg, HCl, HF, PM, and opacity.[195] EPA should require the use of all developments in continuous emission monitoring under § 7412(d) and § 7412(f), for the same reasons described above regarding fence-line monitoring. Stronger emission monitoring is particularly needed due to the problematic compliance and exceedance history. EPA should require immediate reporting on the Internet of all monitoring reports.

VIII. CONCLUSION

For the reasons explained above, Commenters urge EPA to fully satisfy all legal requirements and protect public health in this important rulemaking for EGUs. EPA must address and incorporate each issue discussed in these comments, including by considering new science and taking a health-protective approach where there is uncertainty, in order to fulfill the important regulatory duties of CAA §§ 7412(f)(2) and 7412(d)(2)-(3) and 7412(d)(6).

Thank you for your time and consideration of these comments. For additional information, please contact James Pew, Earthjustice (jpew@earthjustice.org, (202) 745-5214) and Patton Dycus, Environmental Integrity Project (pdycus@environmentalintegrity.org, (404) 446-6661).

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[193] *See, e.g.*, 42 U.S.C. § 7414; Notice, 78 Fed. Reg. 69,082.

[194] Proposed Compliance Assurance Monitoring Rule, 58 Fed. Reg. 54,648, 54,661 (Oct. 22, 1993) ("EPA intends to address the enhanced monitoring requirements pursuant to section 114(a)(3) in the requirements developed for such pollutants"; "EPA intends that the general provisions of part 63, MACT standards promulgated by rulemaking in individual subparts of part 63 . . . will include, pursuant to the authority in section 114(a)(3) of the Act, appropriate enhanced monitoring provisions."); see also Final Compliance Assurance Monitoring Rule, 62 Fed. Reg. 54,900 (Oct. 22, 1997) ("One method is to establish monitoring as a method for directly determining continuous compliance with applicable requirements. The Agency has adopted this approach in some rulemakings and, as discussed below, is committed to following this approach whenever appropriate in future rulemakings.").

[195] Inst. of Clean Air Companies (ICAC), Continuous Emissions Monitoring Systems (CEMS), http://www.icac.com/?page=Emissions_Monitoring.

LIST OF APPENDIX DOCUMENTS

EPA Documents

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3. EPA, *Report of the Task Group of the Children's Health Protection Advisory Comm. on America's Children & the Env't*, 3d Ed. (2010), *available at* http://yosemite.epa.gov/ochp/ochpweb.nsf/content/ACETask.htm/$file/ACE%20Task%20Group%20Report.pdf.
4. Letter from Pamela Shubat, Chair, Children's Health Protection Advocacy Council,CHPAC to Lisa Jackson, Administrator, EPA, (Oct. 21, 2010), http://yosemite.epa.gov/ochp/ochpweb.nsf/content/CHPAC_NRC_Report.htm.

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5. Thoma et al., *Facility Fence Line Monitoring using Passive Samplers*, EPA, *available at* http://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=501667.
6. FluxSense, *Pilot Study to Quantify Industrial Emissions of VOCs, NO2, and SO2 by SOF and Mobile DOAS in the Carson Area* (Mar. 27, 2014).
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8. Envtl. Integrity Project, *Gaming the System: How Off-the-Books Industrial Upset Emissions Cheat the Public Out of Clean Air* (Aug. 2004).

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12. Rachel Morello-Frosch, Zuk, Jerrett, Shamasunder & Kyle, *Understanding The Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, 30(5) Health Affairs 879, (2011).
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Attachment 12

Comments on EPA's Proposed Reversal of the MATS Appropriate and Necessary Finding and Residual Risk and Technology Review.
Docket ID: EPA-HQ-OAR-2018-0794

As scientists, health professionals and children's health advocates with expertise in toxic chemicals and children's brain development, we are writing to express our concern with the U.S. EPA's Proposed Reversal of the MATS Appropriate and Necessary Finding and Residual Risk and Technology Review. We take exception to the EPA proposal that it is no longer "appropriate and necessary" to regulate mercury and hazardous air pollution emitted from power plants under the Clean Air Act.

Coal-fired power plants emit many toxic chemicals, including lead, mercury, and polycyclic aromatic hydrocarbons (PAH) that harm children's brain development even before birth and result in long-lasting impairments in learning abilities and behavioral problems.[1] For many chemicals, including lead, methyl mercury, and PAH, we know that the developing brain is an especially sensitive target organ and that neurodevelopmental effects can occur at extremely low levels of exposure.[2]

The developing fetus and young child are particularly vulnerable to toxic chemicals. Among the toxic chemicals found in the vast majority of pregnant women are lead and mercury, and PAH,[3] all of which are emitted by coal-fired power plants.

In EPA's Proposed Reversal of the MATS Appropriate and Necessary Finding and Residual Risk and Technology Review, EPA fails to account for the unique exposures to children and the developing fetus, and their unique vulnerability. Yet EPA has the best available scientific methods at its disposal – for example, the Exposure Factors handbook provides values to account for exposures such as placental transfer, breast milk and object to mouth ingestion. How much longer will EPA ignore scientific guidance while leaving the nation's children in harm's way from toxic chemicals and pollutants?

We call on EPA to follow scientific guidance to assess how mercury, lead and PAH emissions from coal- and oil- fired power plants affect brain development, such as taking into account the special vulnerabilities of the developing fetus and children, cumulative effects resulting from combined exposures to multiple toxic chemicals and stressors, and the lack of a safety threshold for many of these chemicals.

Lead:
No level of lead exposure is safe for a fetus or young child.[4] Nevertheless, lead exposure remains a major preventable cause of neurodevelopmental impairments in US children. The key to preventing lead toxicity in children is to reduce or eliminate sources of lead exposure in their environments.

More than one-half million children 1 to 5 years of age have a blood lead concentration

greater than 5 µg/dL, and approximately 50% have a concentration greater than 1 µg/dL.[5] Children with a blood lead concentration of 5 µg/dL or greater will experience an average IQ score deficit of approximately 6 points.[6] In 2012, the US National Toxicology Program reported that the evidence was sufficient to conclude that intellectual deficits, diminished academic abilities, attention deficits, and problem behaviors, including impulsivity, aggression, and hyperactivity, occur in children who have blood lead concentrations less than 5 µg/dL.[7]

The economic costs of childhood lead toxicity are substantial. Despite the recent reduction in population blood lead concentrations, the estimated annual cost of childhood lead exposure in the United States is $50 billon.[8]

The EPA's Proposed Reversal of the MATS Appropriate and Necessary Finding and Residual Risk and Technology Review wrongly assumes the risk from lead exposures from coal-fired power plants is zero.This is because EPA uses only the 2008 National Ambient Air Quality Standards (NAAQS) for lead to assess health risks, and finds that the maximum annual lead concentrations resulting from power plant emissions would not exceed the Lead NAAQS. Based on this determination, EPA assumes there is no additional health risk, including for children, from the additional lead emissions from power plants. Yet this lead goes into the air and falls onto playgrounds, schoolyards and backyards in communities near power plants, where it remains and accumulates over time. As a result, children in these communities are disproportionately exposed to lead in air pollution. The nation's science and medical experts, including the EPA's own Children's Health Protection Advisory Committee, have repeatedly recognized that the lead NAAQS fails to protect pregnant women and children[9].

We firmly believe:

- EPA should not rely solely on the Lead NAAQS, but should do a cumulative risk assessment for all major industrial sources of lead, including coal-fired power plants, as required under section 112 of the Clean Air Act.
- In its cumulative risk assessment for lead and other air toxics, EPA should determine a standard that provides an ample margin of safety for fetal and children's health.

Mercury

More than 600,000 babies are born every year with sufficient mercury in their bodies to lower their IQ.[10] These babies are likely to have reduced potential for productivity, achievement and wellbeing for their entire lives. According to EPA's own analysis, coal plants caused over 40 percent of mercury pollution in the United States in 2016.[11] The EPA's Proposed Reversal of the MATS Appropriate and Necessary Finding and Residual Risk and Technology Review reverses course on the progress this country has been making for over a decade to protect children from life-altering exposures to mercury.

PAH:
PAH, a component of $PM_{2.5}$, have been associated with developmental delay; reduced IQ; symptoms of anxiety, depression, and inattention[12]; ADHD; and reduced size of brain regions important for processing information and impulse control.[13] The effect of PAH exposures during fetal development on cognitive and behavioral outcomes is magnified by material hardship or maternal demoralization.[14] Low-income communities are thus both disproportionately exposed and uniquely vulnerable because of family and community economic hardship.
As health professionals, health scientists and health-focused organizations, we call on President Trump and the EPA to maintain the critical health-protective Mercury and Air Toxics Standards (MATS) safeguards for power plants. We also call on President Trump and the EPA to strengthen those standards to protect vulnerable populations, including pregnant women and children. In setting MATS we call on EPA to follow scientific guidance, taking into account cumulative effects, aggregate sources of exposure and the unique vulnerability of children's developing brains.

Thank you.

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Attachment 13

April 17, 2019

Administrator Andrew Wheeler
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Docket No. EPA-HQ-OAR-2018-0794

Subject: Comments on "National Emission Standard for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units—Reconsideration of Supplemental Finding and Residual Risk and Technology Review"

As academic researchers studying mercury fate, transport, and impacts, we appreciate the opportunity to comment on the Reconsideration of Supplemental Finding and Residual Risk Technology Review. We write to encourage the Environmental Protection Agency to withdraw its Proposed Finding and Residual Risk Review, given limitations in its assessment methodologies and developments in scientific research on mercury processes and impacts since 2011. This assessment is based on our own research (Giang and Selin 2016; Perlinger et al. 2018; attached; Angot et al. 2018), as well as our review of relevant scientific literature. In the below, we focus on mercury as one important component of Hazardous Air Pollutants (HAPs). Our comments are in response to solicitations for comments C-2 and C-24.

(C-2) The Regulatory Impact Analysis (RIA) from 2011 quantifies a very limited range of mercury-related benefits of regulation. Recent evidence indicates that benefits that were unquantified in the RIA may be substantial, and larger than the subset that were monetized.

In Giang and Selin (2016), we estimated the benefits of the Mercury and Air Toxics Standards (MATS) policy for US populations. Annualized, our estimates out to 2050 are $3.7 billion/year, using a similar methodology to the RIA. Although methodological differences between our analysis and the RIA prevent direct comparison of numerical results, our research suggests that including a larger subset of health endpoints (IQ and heart attacks) and affected populations (consumers of self-caught freshwater fish and consumers of commercial marine and estuarine fish in the US market) may lead to mercury-related benefits estimates that are orders of magnitude larger than those reported in the RIA. Considering these additional mercury-related benefits could result in benefits that are of comparable magnitude to estimated costs (Rice et al. 2010; Grandjean and Bellanger 2017).

Other recent research supports the conclusion that the subset of mercury-related benefits monetized in the RIA represent an incomplete picture of mercury impacts—both in terms of health and wellness impacts considered, and in the populations considered. There are several health benefits from reducing mercury emissions that could not be quantified in the RIA: cardiovascular effects, neurobehavioral effects aside from IQ loss, and immune endpoints (Karagas et al. 2012; Roman et al. 2011; Genchi et al. 2017). While efforts to develop dose-response relationships for use in regulatory benefit-cost analysis are underway, these potentially large health benefits should be taken into account in a holistic assessment of benefits and costs. Other benefits to individual and community health and well-being that are not easily quantifiable should also be included in a holistic assessment of benefits and costs, such as socio-cultural integrity (Ranco et al. 2011; O'Neill 2004). New evidence has also affirmed the importance of considering additional exposure pathways to self-caught freshwater fish: US Electricity Generating Units (EGU) also contribute to mercury pollution in coastal fisheries, and marine fish make up the vast majority of seafood diet for the US population as a whole (Sunderland et al. 2018, 2016).

In the Proposed Finding, the EPA affirms that benefits described above that were not quantified in the RIA "are relevant to any comparison of the benefits and costs of a regulation" (p. 2678). If the EPA chooses to focus only on benefits associated with HAPs in its "appropriate and necessary"

determination—an approach that does not consider the full public health benefits of MATS—it should take into account recent research on the full scope and potential magnitude of mercury-related impacts.

(C-24) The residual risk analysis methodology underestimates non-cancer risks associated with dietary exposure to mercury through fish for most-exposed populations. Recent research using state-of-the-science atmospheric and aquatic modelling suggests that fish-dependent communities may be exposed to levels exceeding EPA's reference dose—even with policies like MATS in place.

The multi-pathway exposure and risk screening assessment described in the Proposed Finding, and based on the National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants (Benzene NESHAP), may not be appropriate for methylmercury risk assessment. The assessment focuses on local (<50 km) impacts of single-facilities, rather than aggregate and cumulative effects of multiple facilities over regional scales. Mercury is indeed a local pollutant—the importance of US EGUs as a source of domestic deposition may in fact be underestimated in the RIA (Zhou et al. 2017; Sunderland et al. 2016). However, due to its different chemical forms, mercury also has regional impacts. As a result, regions with a high density of facilities that may be below the Tier 1 screening threshold emission rate, may still experience substantial mercury inputs. Further, the complex dynamics of mercury in aquatic and terrestrial ecosystems mean that some landscapes are more sensitive to mercury inputs than others (Perlinger et al. 2018). These dynamics are not captured in the exposure and risk screening assessment used by the EPA.

Assessment methods that better capture the complex biogeochemistry of mercury indicate that highly-exposed populations (such as subsistence fishers and Tribal Nations where harvesting fish is an important dietary, socio-cultural, and rights-based practice) may be exposed to methylmercury at levels exceeding EPA's reference dose, even with policies like MATS in place. In Perlinger et al. (2018), with colleagues, we model changes in atmospheric deposition and fish mercury concentrations in the Great Lakes resulting from policies at multiple jurisdictional scales (including MATS). We explore the environmental justice implications of these policy changes for a tribe in Michigan's Upper Peninsula (UP) with a high fish consumption rate, the Keweenaw Bay Indian Community (KBIC). We find that even with regional, domestic, and global policy, KBIC members may be exposed to levels above the EPA reference dose at their desired level of fish consumption (454 g/day).[1] The UP landscape is highly sensitive to Hg deposition, with nearly 80% of lakes estimated to be impaired. Sensitivity to mercury is caused primarily by the region's abundant wetlands. This finding suggests that landscape factors should be considered in the risk assessment process.

Assessment methodologies such as the one described in the Proposed Finding also do not take into account legacy emissions (i.e., recycling of previously deposited mercury), and therefore underestimate health risks (Angot et al. 2018). Because it is persistent in the environment, mercury once emitted can circulate for decades to centuries. In Angot et al. (2018), with colleagues, using an integrated modelling approach, we quantify the impact of growing legacy reservoirs of mercury and find that due to this legacy penalty, aggressive maximum feasible reductions in emissions are needed for fish mercury concentrations to approach target levels by 2050 for high fish-consuming communities such as the Aroostook Band of Micmacs.

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[1] Research suggests that there is no threshold level of methylmercury exposure below which neurodevelopmental effects do not occur—consequently, the EPA reference dose is a non-conservative benchmark for health risk.

In closing, we urge that the EPA consider up-to-date information in both its appropriate and necessary finding, and its assessment of residual risk.

Respectfully,

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[Attachments: Giang & Selin 2016; Perlinger et al. 2018; Angot et al. 2018]

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Attachment 14

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By Electronic Submission to www.regulations.gov

Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Docket ID No. EPA-HQ-OAR-2018-0794

Re: COMMENTS ON NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS: COAL-OIL-FIRED ELECTRIC UTILITY STEAM GENERATING UNITS—RECONSIDERATION OF SUPPLEMENTAL FINDING AND RESIDUAL RISK AND TECHNOLOGY REVIEW, 84 FED. REG. 2670 (FEB. 07, 2019)

On behalf Elsie M. Sunderland, Charles T. Driscoll, Jr., Kathy Fallon Lambert, Joel Blum, Celia Y. Chen, David C. Evers, Philippe Grandjean, Robert P. Mason, and Noelle Eckley Selin, as well as itself, the Emmett Environmental Law & Policy Clinic at Harvard Law School respectfully submits these comments on the National Emission Standards for Hazardous Air Pollutants: Coal- and Oil- Fired Electric Utility Steam Generating Units—Reconsideration of Supplemental Finding and Residual Risk and Technology Review, 84 Fed. Reg. 2670 (Feb. 7, 2019) ("Proposed Finding"). The Emmett Environmental Law and Policy Clinic works on a variety of local, national, and international projects covering the spectrum of environmental law and policy issues under the direction of Professor Wendy B. Jacobs. The other signatories are scientists with considerable expertise in the fields of atmospheric transport, ecosystem fate and effects, bioaccumulation, human exposures, and health outcomes associated with environmental mercury contamination.

The signatories urge the Environmental Protection Agency ("EPA") to withdraw the Proposed Finding, which is based on outdated and inaccurate estimates of both the public health benefits achievable through the Mercury and Air Toxics Standards ("MATS") and the compliance costs. Regardless of the methodology of cost analysis that EPA chooses to adopt, scientific research on the public health consequences of mercury emissions and data on actual compliance costs compel the conclusion that it is appropriate and necessary to regulate hazardous air pollutant ("HAP") emissions from coal-fired electric utility steam generating units ("EGUs" or "coal-fired power plants") under section 112 of the Clean Air Act ("CAA"). To fulfill its duty of reasoned decision-making, EPA must account for up-to-date information when reconsidering the appropriate and necessary finding.

Our comments focus on the following issues:

- Since EPA completed the MATS Regulatory Impact Analysis ("RIA") in 2011, the scientific literature has developed significant new evidence demonstrating the benefits of regulating power plant mercury emissions. This literature includes attempts to quantify the benefits that are orders of magnitude greater than the calculation of monetized mercury-related benefits in the RIA.

- In addition, it is now clear that reductions in mercury emissions from power plants result in localized and regional reductions in atmospheric mercury deposition, which amplifies the benefits of decreasing domestic emissions.

- The entire industry has by now come into compliance with the MATS rule. It is therefore no longer necessary to rely on *ex ante* predictions of the compliance costs. Multiple analyses have estimated that the actual costs of compliance are less than a billion dollars per year compared to the $9.6 billion per year EPA predicted in 2011.

- The 2011 RIA contains flawed analysis and has been made obsolete. In making the Proposed Finding, EPA should not rely solely on the RIA but must consider the updated information on the benefits of regulation and the compliance costs. Without considering this updated information, it is arbitrary and capricious for the Proposed Finding to conclude that the costs of MATS grossly outweigh the HAP benefits.

- The Proposed Finding misinterprets *Michigan v. EPA* to elevate cost above other considerations.

- In light of the regulatory focus of section 112(n)(1) on public health harm, the Proposed Finding's heavy reliance on cost-effectiveness is irrational.

- Even if EPA were to base its Finding on a cost-benefit analysis using the 2011 RIA, the agency should assign more weight to the unquantified, HAP-related benefits and to the co-benefits.

- Regardless of whether EPA could reverse its appropriate and necessary finding, the plain text of section 112 and the D.C. Circuit's binding decision in *New Jersey v. EPA* prohibit EPA from either delisting EGUs or repealing the emissions standards without going through the section 112(c)(9) delisting process.

I. THE PROPOSED FINDING IGNORES SIGNIFICANT NEW INFORMATION REGARDING BOTH THE BENEFITS AND COSTS OF REGULATING POWER PLANT MERCURY EMISSIONS

Although coal-fired power plants release a variety of HAPs, our comments focus specifically on the benefits associated with reducing emissions of mercury and exposures to its organic form, methylmercury, which is formed in aquatic and terrestrial ecosystems and bioaccumulates in food webs. The peer-reviewed scientific literature demonstrates that the monetized benefits for EGU mercury emissions reductions identified by EPA in the 2011 RIA vastly understate the

benefits associated with reductions of those emissions. In addition, the actual costs of compliance have proven to be much lower than EPA predicted. It is unreasonable for EPA to claim that MATS is not appropriate in the face of this updated evidence that strongly points to the contrary conclusion.

A. Coal-fired Power Plants are the Largest Domestic Source of Mercury, a Potent Neurotoxicant

Methylmercury is a highly toxic, bioaccumulative, and persistent pollutant. Over the last century and a half, anthropogenic mercury emissions have dramatically increased mercury levels in the environment. Cumulatively, anthropogenic inputs of mercury since 1850 have been 78 times as large as natural inputs.[1] Coal-fired power plants are the largest source of mercury emissions in the United States, accounting for 42% of emissions in 2014.[2]

Once mercury is deposited in the environment, it can be transformed by microbial processes into methylmercury and in this form is taken up by organisms at the base of the food chain. These organisms are subsequently consumed by other organisms—and then passed to predators such as piscivorous fish, brook trout, bald eagle, mink, river otter, insectivorous songbirds, and other mammals and birds.[3] Methylmercury biomagnifies, that is, increases with each level of the food chain, and attains its highest concentrations in predatory species at the top of the food chain.[4] This process of biomagnification occurs in both freshwater and marine ecosystems and extends to terrestrial food-webs that are linked to an aquatic ecosystem. Species with a longer life span are at a greater risk of having elevated methylmercury concentrations due to accumulation of this toxicant as they age; human exposure to methylmercury occurs primarily through consuming fish in which methylmercury has bioaccumulated.[5]

B. Mercury Harms Human Health and the Environment in a Variety of Ways

1. Methylmercury is a Neurotoxicant

Methylmercury is a highly toxic substance that targets the nervous system. Infants and fetuses are at the highest risk, both because the developing central nervous system is particularly sensitive to methylmercury and because methylmercury can cross the placental and blood-brain barriers. At the highest levels of exposure, the result might be indistinguishable from cerebral

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[1] David G. Streets, et al., *Total Mercury Released to the Environment by Human Activities*, 51 Envtl. Sci. & Tech. 5969, 5973 (2017).

[2] Emissions Inventory and Analysis Group, Air Quality Assessment Div., Office of Air Quality Planning and Standard, EPA, *2014 National Emissions Inventory, Version 1: Technical Support Document*, 2-25 (2016).

[3] James G. Wiener et al., *Toxicological Significance of Mercury in Yellow Perch in the Laurentian Great Lakes Region*, 161 Envtl. Pollution 350 (2012); Reed C. Harris et al., *Whole-Ecosystem Study Shows Rapid Fish-Mercury Response to Changes in Mercury Deposition*, 104 Proc. Nat'l Acad. of Sci. 16,586 (2007); David C. Evers et al., *Biological Mercury Hotspots in the Northeastern United States and Southeastern Canada*, 57 BioScience 29 (2007).

[4] Wiener et al., *supra* note 3, at 354-55.

[5] *Mercury and Health: Key Facts*, World Health Org., https://www.who.int/news-room/fact-sheets/detail/mercury-and-health (last visited Apr. 15, 2019).

palsy and may lead to "microcephaly, hyperreflexia, and gross motor and mental impairment, sometimes associated with blindness or deafness."[6]

Even at lower levels, prenatal exposure to methylmercury can cause neurological harm. One traditional, well-attested measure is reductions in cognitive test performance,[7] including reductions in IQ.[8] Studies also show a connection to changes in brainstem response to auditory signals,[9] decreased performance on motor speed, attention, and language tests,[10] impeded memory functions,[11] and the likelihood of developing Attention Deficit Hyperactivity Disorder ("ADHD").[12] A series of studies of children in the Faroe Islands, where inhabitants were exposed to methylmercury from the meat of pilot whales, showed that children exposed *in utero* exhibited adverse neurological effects at ages 7, 14, and 22.[13] Cumulatively, these studies demonstrate that the effects of prenatal methylmercury exposure results in life-long neurocognitive deficits.

Methylmercury also causes neurological harm to older children and adults. The effects include symptoms such as "paresthesia, malaise, and blurred vision," and at higher levels can lead to "concentric constriction of the visual field, deafness, dysarthria, ataxia, and ultimately coma and death."[14] The negative effects of methylmercury on adult cognitive functions are so large that they can outweigh the benefits of omega-3 fatty acid intake from fish consumption among individuals who consume large amounts of some species of fish.[15] Methylmercury can also

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[6] United Nations Env't Programme, *Global Mercury Assessment* 38 (2002), *available at* http://www.unep.org/gc/gc22/Document/UNEP-GC22-INF3.pdf.

[7] Emily Oken et al., *Maternal Fish Intake during Pregnancy, Blood Mercury Levels, and Child Cognition at Age 3 Years in a US Cohort*, 167 Am. J. Epidemiology 1171, 1177–79 (2008).

[8] Margaret R. Karagas et al., *Evidence on the Human Health Effects of Low-Level Methylmercury Exposure*, 120 Envtl. Health Persp., 799 (2012); Philippe Grandjean et al., *Calculation of Mercury's Effects on Neurodevelopment*, 120 Envtl. Health Persp., a452, a452 (2012).

[9] Katsuyuki Murata, et al., *Delayed Brainstem Auditory Evoked Potential Latencies in 14-year-old Children Exposed to Methylmercury*, 144 J. Pediatrics 177 (2004).

[10] Frodi Debes et al., *Impact of Prenatal Methylmercury Exposure on Neurobehavioral Function at Age 14 Years*, 28 Neurotoxicology & Teratology 536, 544–46 (2006).

[11] Nat'l Research Council, *Toxicological Effects of Methylmercury* 4 (2000), *available at* https://www.nap.edu/read/9899/chapter/1.

[12] D. K. L. Cheuk & Virginia Wong, *Attention-Deficit Hyperactivity Disorder and Blood Mercury Level: A Case-Control Study in Chinese Children*, 37 Neuropediatrics 234, 236–39 (2006); Olivier Boucher et al., *Prenatal Methylmercury, Postnatal Lead Exposure, and Evidence of Attention Deficit/Hyperactivity Disorder among Inuit Children in Arctic Québec*, 120 Envtl. Health Persp. 1456, 1459–60 (2012).

[13] Philippe Grandjean et al., *Cognitive Deficit in 7-Year-Old Children with Prenatal Exposure to Methylmercury*, 19 Neurotoxicology & Teratology 417, 417 (1997); Debes et al., *supra* note 10, at 536; Youssef Oulhote et al., *Aerobic Fitness and Neurocognitive Function Scores in Young Faroese Adults and Potential Modification by Prenatal Methylmercury Exposure*, 125 Envtl. Health Persp. 677, 680 (2017).

[14] United Nations Env't Programme, *supra* note 6, at 38.

[15] Steven C. Masley, et al., *Effect of Mercury Levels and Seafood Intake on Cognitive Function in Middle-aged Adults*, 11 Integrative Med. 32, 32 (2012).

decrease several visual and motor functions, such as visual contrast sensitivity, restricted visual fields, hand-eye coordination, manual dexterity, and muscular fatigue.[16]

Methylmercury's neurological impacts might be even greater than revealed by these studies. New research demonstrates that some people are more genetically predisposed to the neurotoxic effects of methylmercury,[17] which means that studies with null findings might mask significant impacts among genetically susceptible subpopulations of the study group.[18]

2. Methylmercury Compromises Cardiovascular Health

High concentrations of methylmercury in blood and tissue samples have been strongly associated with acute coronary events, coronary heart disease, and cardiovascular disease.[19] A 2000 National Research Council report stated that it was reasonable to conclude that methylmercury accumulates in the heart and leads to blood pressure alterations and abnormal cardiac functions.[20] Subsequent research has strengthened these findings. An expert panel convened in 2011 to study the health effects of methylmercury concluded that there was sufficient scientific evidence to incorporate cardiovascular health benefits in EPA's regulatory assessments.[21] According to the panel, methylmercury is both directly linked to acute myocardial infarction and intermediary impacts that contribute to myocardial infarction risk.[22] These intermediary impacts include oxidative stress, atherosclerosis, heart rate variability, and to a certain degree, blood pressure and hypertension. A 2017 systematic review of the association between methylmercury exposure and heart diseases shows that it enhances production of free radicals resulting in a long-lasting range of effects on cardiac parasympathetic activity, such as myocardial infarction, hypertension, blood pressure, and death.[23]

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[16] Jean Lebel et al., *Neurotoxic Effects of Low-Level Methylmercury Contamination in the Amazonian Basin*, 79 Envtl. Res. 20, 28 (1998).

[17] Jordi Julvez et al., *Prenatal Methylmercury Exposure and Genetic Predisposition to Cognitive Deficit at Age 8 Years*, 24 Epidemiology 643, 643 (2013).

[18] Jordi Julvez & Philippe Grandjean, *Genetic Susceptibility to Methylmercury Developmental Neurotoxicity Matters*, 4 Frontiers Genetics 1, 2 (2013).

[19] *See* Jyrki K. Virtanen et al., *Mercury, Fish Oils, and Risk of Acute Coronary Events and Cardiovascular Disease, Coronary Heart Disease, and All-Cause Mortality in Men in Eastern Finland*, 25 Arteriosclerosis, Thrombosis, & Vascular Biology 228, 232 (2004).

[20] Nat'l Research Council, *supra* note 11, at 168–69.

[21] Henry A. Roman et al., *Evaluation of the Cardiovascular Effects of Methylmercury Exposures: Current Evidence Supports Development of a Dose–Response Function for Regulatory Benefits Analysis*, 119 Envtl. Health Persp. 607, 607 (2011).

[22] *Id.*

[23] Giuseppe Genchi et al., *Mercury Exposure and Heart Diseases*, 14 Int'l J. Envtl. Res. & Pub. Health 74 (2017).

3. Methylmercury has Additional Impacts on Human Health

Methylmercury also causes a variety of other adverse health impacts. Both animal studies and human epidemiological observations establish methylmercury as a possible carcinogen,[24] especially with regard to leukemia and liver cancer.[25] Methylmercury can have toxic effects on the renal, reproductive, and hematological systems.[26] There are also potential risks of chromosomal damage[27] and weakening of the immune system.[28] Finally, some studies indicate that methylmercury is associated with endocrine disruption[29] and diabetes.[30]

The consumption of methylmercury in fish also counteracts the health benefits associated with consumption of seafood.[31] While fatty acids in seafood are recommended for cardiovascular health and neurocognitive development,[32] the mercury accumulated in the fish can offset the health benefits,[33] a finding confirmed by studies conducted in Boston[34] and New York City.[35] In fact, it is difficult to consume the amount of fish recommended by the American Heart Association while simultaneously remaining below EPA's mercury reference dose because of the high levels of mercury present in most fish.[36]

The inverse is also true: past studies analyzing the effects of methylmercury in the human body have underestimated the dangers because nutrients in fish mask the true adverse effects of

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[24] Int'l Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 58 Beryllium, Cadmium, Mercury, and Exposures in the Glass Manufacturing Industry* 277–83 (1993), *available at* https://monographs.iarc.fr/wp-content/uploads/2018/06/mono58.pdf.

[25] Nat'l Research Council, *supra* note 11, at 150–51.

[26] *Id.* at 153–54, 161–63, 173–74.

[27] Marúcia I. M. Amorim et al., *Cytogenetic Damage Related to Low Levels of Methyl Mercury Contamination in the Brazilian Amazon*, 72 Anais da Academia Brasileira de Ciências 497, 497 (2000), *available at* http://www.scielo.br/pdf/aabc/v72n4/0048.pdf.

[28] Nat'l Research Council, *supra* note 11, at 156–61; Jennifer F. Nyland et al., *Biomarkers of Methylmercury Exposure Immunotoxicity among Fish Consumers in Amazonian Brazil*, 119 Envtl. Health Persp. 1733, 1736–38 (2011).

[29] Shirlee W. Tan et al., *The Endocrine Effects of Mercury in Humans and Wildlife*, 39 Critical Rev. Toxicology 228, 228 (2009).

[30] Ka He et al., *Mercury Exposure in Young Adulthood and Incidence of Diabetes Later in Life: The CARDIA Trace Element Study*, 36 Diabetes Care 1584, 1587–89 (2013).

[31] Eliseo Guallar et al., *Mercury, Fish Oils, and the Risk of Myocardial Infarction*, 347 New England J. Med. 1747, 1753 (2002).

[32] Emily Oken et al., *Maternal Fish Intake during Pregnancy, Blood Mercury Levels, and Child Cognition at Age 3 Years in a US Cohort*, 167 Am. J. Epidemiology 1171–81 (2008).

[33] Anna L. Choi et al., *Negative Confounding in the Evaluation of Toxicity: The Case of Methylmercury in Fish and Seafood*, 38 Critical Reviews in Toxicology, 877, 877 (2008).

[34] Oken et al., *supra* note 7, at 1177–79.

[35] Sally Ann Lederman et al., *Relation between Cord Blood Mercury Levels and Early Child Development in a World Trade Center Cohort*, 116 Envtl. Health Persp. 1085, 1090 (2008).

[36] *See* Rune Dietz et al., *Anthropogenic Contributions to Mercury Levels in Present-Day Arctic Animals—A Review*, 407 Sci. Total Env't 6120, 6125–26 (2009).

methylmercury.[37] Although the mercury-related damage may be masked, the result is that the benefits that consumers would otherwise obtain from a healthy diet are diminished, thus counteracting the purpose of including fish in the diet.

4. Methylmercury Causes Multiple Environmental Harms

Even at low levels, methylmercury threatens numerous aquatic and terrestrial species of birds and mammals.[38] For example, studies report that mercury has severe reproductive effects on fish such as trout, bass, and salmon.[39] Predatory species that consume fish, such as birds and freshwater and marine mammals, suffer more severe impacts. For example, there are well-documented effects of mercury on loons, including behavioral, physiological, and reproductive impairments.[40] Other piscivorous birds have exhibited decreased foraging efficiency,[41] decreased reproductive success,[42] and liver and kidney damage.[43] Insectivorous birds have likewise shown reduced reproductive capacity,[44] survival rate,[45] immune function,[46] and singing

[37] Esben Budtz-Jorgensen et al., *Separation of Risks and Benefits of Seafood Intake*, 115 Envtl. Health Persp. 323, 325–26 (2007); Anna L. Choi et al., *Selenium as a Potential Protective Factor Against Mercury Developmental Neurotoxicity*, 107 Envtl. Res. 45, 51 (2008).

[38] David C. Depew et al., *Toxicity of Dietary Methylmercury to Fish: Derivation of Ecologically Meaningful Threshold Concentrations*, 31 Envtl. Toxicology & Chemistry 1536, 1538–45 (2012).

[39] Kate L. Crump et al., *Mercury-Induced Reproductive Impairment in Fish*, 28 Envtl. Toxicology & Chemistry 895, 902–04 (2009).

[40] David C. Evers et al., *Adverse Effects from Environmental Mercury Loads on Breeding Common Loons*, 17 Ecotoxicology 69, 69 (2008); Matthew G. Mitro et al., *Common Loon Survival Rates and Mercury in New England and Wisconsin*, 72 J. Wildlife Mgmt. 665, 665–66 (2008).

[41] Evan M. Adams & Peter C. Frederick, *Effects of Methylmercury and Spatial Complexity on Foraging Behavior and Foraging Efficiency in Juvenile White Ibises (Eudocimus Albus)*, 27 Envtl. Toxicology & Chemistry 1708, 1708 (2008).

[42] Peter Frederick & Nilmini Jayasena, *Altered Pairing Behaviour and Reproductive Success in White Ibises Exposed to Environmentally Relevant Concentrations of Methylmercury*, 278 Proc. Royal Soc'y B: Biological Sci. 1851 (2010).

[43] David J. Hoffman et al., *Mercury and Drought Along the Lower Carson River, Nevada: III. Effects on Blood and Organ Biochemistry and Histopathology of Snowy Egrets and Black-Crowned Night-Herons on Lahontan Reservoir, 2002-2006*, 72 J. Toxicology & Envtl. Health, Part A 1223, 1223 (2009).

[44] Rebecka L. Brasso & Daniel A. Cristol, *Effects of Mercury Exposure on the Reproductive Success of Tree Swallows (Tachycineta Bicolor)*, 17 Ecotoxicology 133, 133 (2008).

[45] Kelly K. Hallinger et al., *Mercury Exposure and Survival in Free-Living Tree Swallows (Tachycineta Bicolor)*, 20 Ecotoxicology 39, 39 (2011).

[46] Dana M. Hawley et al., *Compromised Immune Competence in Free-Living Tree Swallows Exposed to Mercury*, 18 Ecotoxicology 499, 499 (2009).

behavior.[47] Mammals that also heavily depend on fish as a food source, such as river otters, suffer from reduced mobility, abnormal reflexes, and impaired escape behavior.[48]

C. The 2011 RIA Monetized Only a Small Subset of the Benefits of Regulating Power Plant Mercury Emissions

In the Proposed Finding, EPA concludes that it is not "appropriate and necessary" to regulate power plant mercury emissions under section 112 "because the costs of such regulation grossly outweigh the HAP benefits." 84 Fed. Reg. at 2676. In reaching this conclusion, the Proposed Finding relies on the analysis in the RIA that the agency completed in 2011. As we will discuss below, this analysis is outdated and EPA must consider more current information on both the costs and benefits. However, even on its own terms the analysis of quantified HAP-related benefits in the 2011 RIA was incomplete and incorporated multiple conservative assumptions and methods that resulted in an underestimation of the benefits. EPA cannot reasonably rely on the RIA to reverse the appropriate-and-necessary finding.

First, the RIA only quantified the impacts to a tiny fraction of the U.S. population. Specifically, it only accounted for children born to a limited population of recreational fishers who consume freshwater fish during pregnancy from watersheds where EPA had fish tissue data.[49]

Second, even among this small population, the RIA did not consider all pathways of exposure. Instead it considered only exposure from non-commercially-caught freshwater fish, even though marine fish account for more than 80% of methylmercury intake in the United States.[50] Recent research suggests the regulation of domestic U.S. mercury emissions will have a substantial effect on mercury inputs to coastal waters. For example, recent studies reported marked decreases in mercury concentrations in Atlantic bluefin tuna and bluefish attributed to decreases in U.S. mercury emissions.[51]

Third, even for this limited population and limited set of exposure pathways, the RIA did not quantify all of the health benefits described above. It monetized only neurological benefits and even within these considered only impacts on IQ. 77 Fed. Reg. 9304, 9428 (Feb.16, 2012). Therefore, even at the time it was completed, it failed to consider other neurological impacts such as ADHD and non-neurological impacts such as cardiovascular harms. In addition, when translating IQ's benefits to society, the RIA only examined the relationship between lost IQ and

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[47] Leen Gorissen et al., *Heavy Metal Pollution Affects Dawn Singing Behaviour in a Small Passerine Bird*, 145 Oecologia 504, 504 (2005).

[48] Anton M. Scheuhammer et al., *Effects of Environmental Methylmercury on the Health of Wild Birds, Mammals, and Fish*, 36 Ambio 12, 12 (2007).

[49] Health & Envtl. Impacts Div., Office of Air Quality Planning & Standards, EPA, *EPA-452/R-11-011*, *Regulatory Impact Analysis for Final Mercury and Air Toxics Standards* at 4-49 [hereinafter "*Regulatory Impact Analysis*"].

[50] Elsie M. Sunderland et al., *Decadal Changes in the Edible Supply of Seafood and Methylmercury Exposure in the United States*, 126 Envtl. Health Persp. 017006 (2018).

[51] Ford A Cross et al., *Decadal Declines of Mercury in Adult Bluefish (1972–2011) from the Mid-Atlantic Coast of the U.S.A.*, 49 Envtl. Sci. & Tech. 9064 (2015); Cheng-Shiuan Lee et al., *Declining Mercury Concentrations in Bluefin Tuna Reflect Reduced Emissions to the North Atlantic Ocean*, 50 Envtl. Sci. & Tech. 12825 (2016).

an individual's earning potential. *Id.* This approach omitted lost IQ's other societal impacts, such as costs of requiring medical care or additional special education programs.

Furthermore, recent epidemiological data have revealed a suite of more sensitive neurodevelopmental effects than full-IQ, the impact valued in the EPA's 2011 RIA. Even in 2000, the National Research Council panel on the *Toxicological Effects of Methylmercury* had conceded that full-IQ was not the most sensitive indicator of neurodevelopment.[52] In addition, neurodevelopmental impacts of methylmercury have more recently been documented at exposure levels below the reference dose established by the panel in 2000.[53] As a result, a full quantification of the neurodevelopmental impacts of EGU mercury emissions would take into account both other kinds of fish consumption and effects other than reductions in IQ.

Even within its analysis of this subset of impacts to this one small group, the RIA adopted several assumptions that erred on the side of underestimating the benefits. For example, in deciding which watersheds to include in the analysis, EPA included only those in which either (1) the total potential exposures exceeded the reference dose, *and* in which power plants contributed more than 5% of the mercury deposition, or (2) the power plant emissions alone would result in an exposure in excess of the reference dose. 77 Fed. Reg. at 7311. As EPA explained, "[r]equiring at least a 5 percent EGU contribution is a conservative approach given the increasing risks associated with incremental exposures above the" reference dose. *Id.* at 9311 n.15. EPA also excluded watersheds near coastal areas and the Great Lakes due to modeling uncertainty.[54] EPA omitted these areas even though they "may have elevated U.S. [power plant] deposition relative to the average levels in the continental U.S."[55] Both of these assumptions mean that the RIA underestimated the benefits, even on its own terms.

In addition, when assessing the public health risk of exposure to methylmercury, EPA assumed the existence of a reference dose, which is "a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime."[56] As a result, only watersheds with female subsistence fish consumer exposures above the reference dose were "considered to have the potential for consumers of self-caught fish from that watershed to experience a public health hazard due to [methylmercury] exposure."[57] In other words, exposures below the reference dose were not included as part of the risk assessment. However, there is no evidence from epidemiological studies for a health effects

[52] Nat'l Research Council, *supra* note 11.

[53] Martine Bellanger et al., *Economic Benefits of Methylmercury Exposure Control in Europe: Monetary Value of Neurotoxicity Prevention*, 12 Envtl. Health 3 (2013).

[54] EPA, *EPA-452/R-11-009, Revised Technical Support Document: National-Scale Assessment of Mercury Risk to Populations with High Consumption of Self-caught Freshwater Fish* 7 n.10, (2011) [hereinafter "*Revised Technical Support Document*"].

[55] *Id.*

[56] *Regulatory Impact Analysis*, *supra* note 49, at 4-31.

[57] *Revised Technical Support Document*, *supra* note 54, at 43.

threshold below which neurodevelopmental effects from methylmercury exposure do not occur.[58]

Furthermore, the reference dose that EPA relied on in conducting its risk assessment is outdated: The calculation was published by EPA in the Integrated Risk Information System in 2001, based on a study conducted by the National Research Council in 2000.[59] EPA itself recognizes the need to update the reference dose: the agency recently published a document calling for a reassessment "in light of recent epidemiological studies that analyzed effects at lower methylmercury exposure levels than those in studies used to derive the existing [reference dose]."[60] For example, one recent study suggests an association between methylmercury exposure and anxiety even at very low levels of prenatal exposure where the mean blood mercury concentration was 0.67 μg/L,[61] which is below the geometric mean for women in every year of National Health and Nutrition Examination Survey data.[62]

The final quantification of the benefits was also undervalued for another two reasons. First, when EPA estimated the sensitivity of IQ to cord blood methylmercury, it relied on dose-response information from a 2007 study by Axelrad et al.[63] This study is outdated and results in a severe underestimation of the actual harms. Estimates that rely on more recent information present a much greater magnitude of harm.[64]

Second, when translating the relationship between mercury and IQ, EPA applied a linear model that underestimated the true effect of the exposure.[65] In reality, the relationship between daily intake and brain mercury is a power function with a coefficient greater than 1.0. Therefore, "a decrease in [mercury] intake will produce a greater-than-linear decrease in brain concentration."[66] However, EPA decided on a linear model because the calculation would be much simpler. As the Science Advisory Board explained, this approach would underestimate the benefits of mercury reduction not only because of the modeling procedure but also its inputs.[67]

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[58] Karagas et al., *supra* note 8.

[59] *Id.*

[60] EPA, *Integrated Risk Information System (IRIS) Assessment Plan for Methylmercury (Scoping and Problem Formulation Materials)* at 6:16 (2019).

[61] Nimesh B. Patel et al., *Very Low-Level Prenatal Mercury Exposure and Behaviors in Children: The HOME Study*, 18 Envtl. Health 4 (2019).

[62] Ctrs. Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, January 2019, Volume One*, at 321-22 (2019), *available at* https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume1_Jan2019-508.pdf.

[63] *Regulatory Impact Analysis*, *supra* note 49, at 4-31.

[64] Grandjean et al., *supra* note 8.

[65] Science Advisory Board Mercury Panel, *EPA-SAB-11-017, Review of EPA's Draft National-Scale Mercury Risk Assessment* 20 (2011).

[66] *Id.*

[67] *Id.*

Although EPA may have appropriately adopted assumptions that minimized the benefits of regulating EGU mercury emissions in 2012, now that the agency is proposing to reverse course, it is no longer logically supportable to retain them. The effect of the assumptions in the 2012 rulemaking was to discount information that would have only strengthened the agency's conclusion, whereas the effect now is to ignore information that undermines it. As the Supreme Court has stated, "[s]o long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions . . . *risking error on the side of overprotection rather than underprotection*."[68] The Proposed Finding would do the reverse.

D. The RIA Substantially Underestimated the Contribution of Coal-fired Power Plants to Local Mercury Deposition

The RIA also underestimated the significance of U.S. power plant mercury emissions to atmospheric mercury deposition to land and waters in the United States. It calculated the benefits of MATS based on atmospheric modeling that suggested that only approximately 2% of total mercury deposition in the United States is derived from U.S. power plant emissions.[69] However, more recent scientific studies demonstrate that the contribution of U.S. coal-fired power plants to local deposition is much higher than previously understood. Accordingly, the RIA underestimated the domestic benefits of reducing those emissions.

Mercury emissions from power plants occur in three forms: (1) gaseous elemental mercury, (2) gaseous oxidized mercury (also called "reactive gaseous mercury"), and (3) mercury bound to particles. In general, oxidized mercury and particle-bound mercury travel shorter distances than elemental mercury before falling to the Earth because they are more water-soluble and chemically reactive. A substantial portion of the mercury emitted by coal-fired power plants is in the oxidized and particle-bound forms.

A substantial fraction of mercury from power plant emissions has been demonstrated to be deposited locally. For example, one study of mercury deposition in Ohio concluded that forty-two percent of the average atmospheric mercury wet deposition was traceable to a nearby coal-fired power plant.[70] Another study identified biological mercury hotspots in the northeastern United States driven mainly by domestic emissions.[71]

For the past two decades, mercury researchers have noted slow and steady declines in atmospheric mercury concentrations in the Northern Hemisphere. Initial attempts to rationalize these observations from a scientific perspective were confounded by a commonly held (but incorrect) assumption among researchers that global mercury emission trends from anthropogenic sources were steady or increasing over this same time period. Zhang et al. recently corrected an error in previous emissions inventories on the form of mercury released by power plants over time. In particular, they demonstrated that as utilities implemented selective

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[68] *Indus. Union Dep't AFL-CIO v. API*, 448 U.S. 607, 656 (1980) (emphasis added).

[69] *Revised Technical Support Document*, *supra* note 54, at 65.

[70] Emily M. White et al., *Spatial Variability of Mercury Wet Deposition in Eastern Ohio: Summertime Meteorological Case Study Analysis of Local Source Influences*, 43 Envtl. Sci. & Tech. 4946, 4952 (2009).

[71] Evers et al., *supra* note 3, at 41.

catalytic reduction, the fraction of mercury emissions released as oxidized or particle-bound mercury decreased—reducing local impacts by more than the reduction in overall emissions. This correction helps enable global models to reproduce the observed declining atmospheric mercury trends.[72] This analysis shows spatial patterns and temporal trends in atmospheric mercury concentrations and deposition are much more influenced by local and regional actions than previously assumed. The Proposed Finding is arbitrary for not taking this updated information on mercury emissions, atmospheric transformations, and deposition into account.

E. The Quantifiable Benefits of Reducing Mercury Emissions are Much Larger than Estimated in the RIA

It is not surprising—given the significant gaps in the 2011 RIA's analysis of the monetized benefits of regulating mercury emissions from coal-fired power plants described above—that recent studies suggest that the mercury-related benefits of the MATS Rule are actually orders of magnitude larger than those monetized in the RIA. For example, a 2016 study indicated that when policymakers account for lost wages, medical costs from IQ deficits and nonfatal heart attacks, and premature fatalities quantified into a value of statistical life (VSL) model, the benefits of the Rule exceed $43 billion.[73] Another study estimated an annual benefit of $860 million associated with a 10% reduction in methylmercury exposure in the U.S. population.[74] A 2017 study estimated that the total economic costs from methylmercury exposure in the United States are $4.8 billion per year.[75] Even an earlier study had concluded that, factoring in the impact of lower IQ on schooling, probability of workforce participation, and lifetime earnings, U.S. power plant mercury emissions cost the economy about $1.3 billion every year.[76]

F. As U.S. Power Plant Mercury Emissions Have Declined, Health Has Improved

Given that the MATS Rule has been in effect since 2012, the benefits of the rule are no longer hypothetical. Domestic mercury emissions have declined dramatically: according to Toxics Release Inventory ("TRI") data, mercury emissions from U.S. coal-fired power plants decreased

[72] Yanxu Zhang et al., *Observed Decrease in Atmospheric Mercury Explained by Global Decline in Anthropogenic Emissions*, 113 Proc. Nat'l Acad. of Sci. 526 (2016).

[73] Amanda Giang & Noelle E. Selin, *Benefits of Mercury Controls for the United States*, 113 Proc. Nat'l Acad. of Sci. 286 (2016).

[74] Glenn E. Rice et al., *A Probabilistic Characterization of the Health Benefits of Reducing Methyl Mercury Intake in the United States*, 44 Envtl. Sci. & Tech. 5216 (2010).

[75] Philippe Grandjean & Martine Bellanger, *Calculation of the Disease Burden Associated with Environmental Chemical Exposures: Application of Toxicological Information in Health Economic Estimation*, 16 Envtl. Health 123 (2017).

[76] Leonardo Trasande et al., *Public Health and Economic Consequences of Methyl Mercury Toxicity to the Developing Brain*, 113 Envtl. Health Persp. 590 (2005).

by 86% (79,000 pounds) between 2006 and 2016,[77] and by 89% (83,000 pounds) between 2007 and 2017.[78]

These declines have been correlated with reductions in environmental mercury levels, fish advisories, adult blood mercury levels, and prenatal methylmercury exposures. For example, several U.S. studies have measured substantial declines in domestic atmospheric and ecologic mercury concentrations attributable to reductions in mercury emissions from power plants. Castro and Sherwell observed declines in atmospheric mercury concentrations at a pristine site in Maryland downwind of power plants in Ohio, Pennsylvania, and West Virginia.[79] Drevnick et al. observed a mean ~20% decline in mercury accumulation in 104 sediment cores from the Great Lakes regions attributable to domestic emissions reductions.[80] Similarly, Hutcheson et al. noted declines in methylmercury concentrations in freshwater fish in the United States concurrent with domestic mercury emissions reduction.[81] It is important to note that even though bioaccumulated methylmercury levels in fish is a good indicator of mercury emission changes, it is estimated that not all of the mercury emitted into the air will be reflected in fish until 10 years later due to the persistent nature of mercury in water.[82] Accordingly, the health benefits from MATS will continue to manifest themselves in the years to decades to come.

G. Actual MATS Compliance Costs Have Been Much Lower than Predicted in 2011

In the 2011 RIA, EPA estimated that the utility industry's annual compliance costs for the MATS Rule would be approximately $9.6 billion per year. Multiple sources of information have now made it clear that this number dramatically overestimated the actual costs.[83]

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[77] EPA, *TRI National Analysis 2016: Comparing Industry Sectors* 31 (2018), *available at* https://www.epa.gov/sites/production/files/2018-01/documents/comparing_industry_sectors.pdf.

[78] *Mercury Air Releases Trend*, EPA, https://www.epa.gov/trinationalanalysis/mercury-air-releases-trend (last visited Apr. 15, 2019).

[79] Mark S. Castro & John Sherwell, *Effectiveness of Emission Controls to Reduce the Atmospheric Concentrations of Mercury*, 49 Envtl. Sci. & Tech. 14000 (2015).

[80] Paul E. Drevnick et al., *Spatial and Temporal Patterns of Mercury Accumulation in Lacustrine Sediments across the Laurentian Great Lakes Region*, 161 Envtl. Pollution 252 (2012).

[81] Michael S. Hutcheson et al., *Temporal and Spatial Trends in Freshwater Fish Tissue Mercury Concentrations Associated with Mercury Emissions Reductions*, 48 Envtl. Sci. & Tech. 2193 (2014).

[82] Giang & Selin, *supra* note 73.

[83] This scenario—in which the predicted compliance costs turn out to be much higher than the actual costs—is common with environmental regulations. When a new or more stringent emissions limit is introduced, demand for control technology increases and companies are incentivized to innovate. These changes, combined with more widespread use of and experience with the technology and with the regulatory process results in technological advancements and cost reductions. *See generally* Brief of *Amici Curiae* Technological Innovation Experts Nicholas Ashford, M. Granger Morgan, Edward Rubin, and Margaret Taylor in Support of Respondents, *North Dakota v. EPA*, No. 15-1381 (D.C. Cir. Dec. 21, 2016), *available at* https://www.edf.org/sites/default/files/content/2017.02.06_tech_experts_final_brief.pdf.

A 2015 analysis by Andover Technology Partners showed that the actual cost of compliance in the initial years of implementation was approximately $2 billion per year—more than $7 billion lower than EPA estimated.[84] The analysis attributed the lower costs:

> to the facts that: (1) improvements in dry sorbent injection ("DSI") and activated carbon injection ("ACI") technologies have significantly lowered the costs of those pollution control systems; (2) natural gas prices have been significantly lower than those upon which EPA's estimates were premised; and (3) EPA overestimated the generation capacity that would require installation of fabric filters (also known as baghouses), dry flue gas desulfurization ("FGD") systems and wet FGD upgrades.[85]

This analysis also estimated that the annual costs after 2015 would be less than $1 billion.[86] To complement this "top-down" analysis, a subsequent report by James Staudt of Andover Technology Partners estimated ongoing operating costs using a "bottom-up" methodology; this report concluded that the annual operating costs were roughly $620 million.[87]

Even representatives of the utility industry, in a letter sent to EPA in the summer of 2018, estimated that the total cost to the industry over the six years that MATS had been in effect was approximately $18 billion—also much lower than EPA had predicted.[88]

These estimates are bolstered by reviews of utility company securities filings, which demonstrate a pattern of decreasing cost estimates over time.[89] For example, FirstEnergy initially projected that it would cost the company $2 billion to $3 billion to comply with MATS. By the time of its 2011 Fourth Quarter Earnings Call, this estimate had declined to $1.3 billion to $1.7 billion. By 2014, the company was reporting that its "total capital cost for compliance (over the 2012 to 2018 time period) is currently expected to be approximately $370 million."[90]

Similar declines can be seen at the level of a single plant. In 2014, the Southwestern Electric Power Company (SWEPCo), a subsidiary of American Electric Power predicted that the cost of installing mercury controls for units 1 and 3 of its J. Robert Welsh Power Plant in Texas was

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[84] Declaration of James E. Staudt, Ph.D., CFA, at 3, *White Stallion Energy Center v. EPA*, No. 12-1100 (D.C. Cir. Dec. 24, 2015).

[85] *Id.*

[86] *Id.* at 7.

[87] James E. Staudt, Ph.D., Update of the Cost of Compliance with MATS—Ongoing Costs of Control (May 25, 2017) (Exhibit 1 to Letter from Brian Leen, President and Chief Executive Officer, ADA Carbon Solutions, LLC, to Peter Tsirigotis, Director, Office of Air Quality Planning and Standards, EPA (June 29, 2018) [hereinafter "Staudt Update"], *available at* https://www.sierraclub.org/sites/www.sierraclub.org/files/blog/ADA%20Carbon%20Solutions%20Letter.pdf.

[88] Letter from Edison Electric Institute, et al., to William L. Wehrum, Assistant Administrator, Office of Air and Radiation, EPA (July 10, 2018) [hereinafter "EEI Letter"].

[89] Staudt Update, *supra* note 87, at 6 & Ex. 3; Envtl. Defense Fund, *Power Companies' Declining Estimates of the Compliance Costs of the Mercury & Air Toxics Standards (MATS)* (2014), *available at* http://blogs.edf.org/climate411/files/2014/05/Declining-costs-of-MATS-compliance.pdf.

[90] Staudt Update, *supra* note 87, Ex. 3 at 1.

approximately $410 million.[91] By 2015, the cost estimated had declined to approximately $400 million.[92] After completing the control projects for MATS compliance in 2016, SWEPCo reported that the actual cost was approximately $370 million.[93]

All of these sources of information demonstrate that the actual MATS compliance costs for the utility industry were much lower than EPA predicted in 2011. It is irrational for the Proposed Funding to conclude that the benefits of regulating power plant HAP emissions are not "moderately commensurate" with the costs when the cost number used for that comparison is inflated by many billions of dollars per year.

II. EPA HAS THE AUTHORITY AND THE OBLIGATION TO RE-EVALUATE ITS COST-BENEFIT ANALYSIS IN LIGHT OF THE NEW INFORMATION

Instead of conducting an original analysis of the impacts of regulating power plant HAP emissions, the Proposing Finding uses data from the 2011 RIA. Continuing to rely on eight-year-old data when significant new information regarding both benefits and the costs is available is arbitrary and capricious. Moreover, the Proposed Finding does not provide a reasoned explanation for its failure to update the analysis, which is also a violation of the rulemaking procedures mandated by the CAA.

A. As a Matter of Rational Decision-making, EPA Should Rely on Up-to-Date Information

"Federal administrative agencies are required to engage in reasoned decision-making. Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational." *Michigan v. EPA*, 135 S. Ct. 2699, 2706 (2015). An agency violates this duty when, for example, it "entirely fail[s] to consider an important aspect of [a] problem" or "offer[s] an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 44 (1983). In addition, "when an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012).

If EPA finalizes the Proposed Finding without considering new evidence regarding the costs and benefits of regulating power plant HAP emissions, it will be committing both of these errors.

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[91] Am. Elec. Power, *American Electric Power 2014 Annual Report: Audited Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations* at 91 (2014), *available at* https://aep.com/assets/docs/investors/AnnualReportsProxies/docs/14annrep/2015_Official_Appendix_A.pdf.

[92] Am. Elec. Power, *American Electric Power 2015 Annual Report: Audited Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations* at 107 (2015), *available at* https://aep.com/assets/docs/investors/AnnualReportsProxies/docs/15annrep/2015AnnualReportAppendixAtoProxy.pdf.

[93] Am. Elec. Power, *American Electric Power 2016 Annual Report: Audited Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations* at 107 (2016), *available at* https://aep.com/assets/docs/investors/AnnualReportsProxies/docs/16annrep/2016AnnualReportAppendixAtoProxy.pdf.

Updated evidence regarding the health impacts and the fate and transport of those emissions, as well as information on the actual costs of compliance for the electric utility industry, are all central aspects of the "problem" before the agency when it decides whether regulating power plant HAP emissions is "appropriate and necessary." Moreover, such a finding would run counter to the evidence before EPA. Unless EPA can explain why the 2011 data reflects reality more accurately than the new evidence or offer other sufficient justifications, its choice to rely on the 2011 RIA "bears no rational relationship to the reality it purports to represent." *Sierra Club v. United States EPA*, 167 F.3d 658, 662 (D.C. Cir. 1999) (quoting *Columbia Falls Aluminum Co. v. EPA*, 139 F.3d 914, 923 (D.C. Cir. 1998)).

Courts have frequently held that an agency action is arbitrary and capricious if it is based on outdated information, particularly when it is clear that more recent data are available. For instance, the Eighth Circuit once held that EPA's consideration of costs when promulgating a new source performance standard under the Clean Water Act was inadequate because the agency "based its cost figures on 1971 prices, even though the Development Document and the regulations were published in March of 1974." The Court further opined that "[m]ore current figures than this are available, and should be used by the EPA in setting forth projected capital and operating costs for new plants." *CPC Int'l, Inc. v. Train*, 515 F.2d 1032, 1051 (8th Cir. 1975). Similarly, in a case involving the Department of Energy's setting of appliance efficiency standards, the D.C. Circuit held that "it would be patently unreasonable for DOE to begin further proceedings in the last half of 1985 based on data half a decade old." *Natural Resources Defense Council, Inc. v. Herrington*, 768 F.2d 1355, 1408 (D.C. Cir. 1985). As the Ninth Circuit recently summed up the principle:

> [W]e should not silently rubber stamp agency action that is arbitrary and capricious in its reliance on old data without meaningful comment on the significance of more current compiled data. We hold that EPA's failure to even consider the new data and to provide an explanation for its choice rooted in the data presented was arbitrary and capricious.

Sierra Club v. U.S. E.P.A., 671 F.3d 955, 968 (9th Cir. 2012); *see also Alvarado Cmty. Hosp. v. Shalala*, 155 F.3d 1115, 1122 (9th Cir. 1998), *amended*, 166 F.3d 950 (9th Cir. 1999) (finding that Medicare reimbursement decision was arbitrary and capricious because it was based on 1981 data when 1984 data were available).

The failure to consider these new data is also inconsistent with EPA's internal policies regarding the role of science in its regulatory decision-making. EPA has long taken the position that all of its decisions must be based on the "best available science." For instance, the agency's 1997 strategic plan provided that one of EPA's overall purposes was to ensure that "efforts to reduce environmental risk are based on the best available scientific information."[94] In 2002, the agency issued Information Quality Guidelines in which it took the position that this standard should apply to all of its risk assessments.[95] As recently as April of last year, EPA reiterated in a notice of proposed rulemaking that "*[t]he best available science must serve as the foundation of EPA's*

[94] EPA, *EPA/190-R-97-002, EPA Strategic Plan* 16 (1997).

[95] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* 22 (2005).

regulatory actions."[96] Taking action based on an eight-year-old assessment in the face of significant new scientific information plainly does not constitute using "the best available science."

In fact, EPA previously recognized the importance of using up-to-date science in making the section 112(n) appropriate-and-necessary determination. When promulgating the MATS Rule in 2012 EPA conducted "additional technical analyses" to build on its original finding from 2000. 77 Fed. Reg. at 9301. According to EPA, although the agency was "not required to reevaluate the 2000 finding," it updated the risk assessments "[b]ecause over 10 years had passed since the 2000 finding, and EPA wanted to evaluate HAP emissions from U.S. EGUs based on the most accurate information available." *Id.* at 9337.

Cases decided under the National Environmental Policy Act ("NEPA") also demonstrate this principle, even though the standard of review for NEPA ("hard look") is not precisely the same as the reasoned decision-making requirement that applies to the Proposed Finding. These cases show that, when an agency is developing an Environmental Impact Statement ("EIS"), "reliance on out-of-date or incomplete information may render the analysis of effects speculative and uncertain." *City of Dallas, Tex. v. Hall*, 562 F.3d 712, 720 (5th Cir. 2009). For example, a recent D.C. Circuit decision involved the Federal Energy Regulatory Commission's NEPA review during the licensing of a hydroelectric project. *Am. Rivers & Ala. Rivers Alliance v. FERC*, 895 F.3d 32 (D.C. Cir. 2018). When analyzing the fish mortality that would be caused by the project, "the Commission's only cited evidence for the amount of fish deaths was a more-than-decade-old-survey of fish entrainment studies and estimates provided by the license applicant itself, Alabama Power." *Id.* at 50. The court held that "[t]he Commission's acceptance, hook, line, and sinker, of Alabama Power's outdated estimates, without any interrogation or verification of those numbers is, in a word, fishy. *And it is certainly unreasoned*." *Id.* (emphasis added). Other cases are to the same effect. *See, e.g.*, *Custer Cty. Action Ass'n v. Garvey*, 256 F.3d 1024, 1034 (10th Cir. 2001) (holding that "agencies must take a hard look at the environmental consequence of proposed actions utilizing public comment and the best available scientific information"); *San Juan Citizens Alliance v. United States BLM*, 326 F. Supp. 3d 1227, 1249 (D.N.M. 2018) (rejecting the Bureau of Land Management's "rel[iance] on outdated scientific tools and analyses").

The Proposed Finding's failure to take into account updated information regarding costs is particularly troubling because the distinction is not between relatively older and new predictions, but rather between a prediction and reality. Now that EPA is equipped with knowledge about the actual compliance costs, the outdated prediction from the 2011 RIA has very limited, if any, value. Therefore, EPA is obligated to confront the fact that $9.6 billion per year is a highly

[96] EPA, Strengthening Transparency in Regulatory Science (Proposed Rule), 83 Fed. Reg. 18,768, 18,769 (Apr. 30, 2018) (emphasis added).

inflated cost figure. In fact, the power industry has already absorbed the costs relatively smoothly and would not be better off if the regulations are repealed.[97]

B. The Proposed Finding Provides no Meaningful Explanation for its Failure to Consider New Information

The Proposed Finding cites no legal authority for the appropriateness of continuing to rely on data from 2011. In fact, it provides no meaningful justification for this decision at all. That failure alone is sufficient reason for EPA to withdraw the Proposed Finding.

The Proposed Finding refers to a memorandum entitled "Compliance Cost, HAP Benefits, and Ancillary Co-Pollutant Benefits for 'National Emission Standards for Hazardous Air Pollutants: Coal-and Oil-Fired Electric Utility Steam Generating Units -- Reconsideration of Supplemental Finding and Residual Risk and Technology Review.'" 84 Fed. Reg. at 2678 & n.16. According to the Proposed Finding,

> *as explained in the memorandum*, given that the CAA section 112(n)(1)(A) finding is a threshold analysis that Congress intended the Agency would complete prior to regulation, the EPA believes it is reasonable for purposes of this reconsideration to rely on the estimates projected prior to the rule's taking effect, *i.e.*, the estimates of costs and benefits calculated in the 2011 RIA.

84 Fed. Reg. at 2678 (emphasis added).

The memorandum,[98] however, contains no such explanation. In fact, the sentence quoted above *is the entire explanation* that the Proposed Finding provides for ignoring eight years of scientific research on the benefits of regulating HAP emissions from power plants, as well as data indicating the actual costs of compliance.

Accordingly, the Proposed Finding violates EPA's duty to set forth "the major legal interpretations . . . underlying the proposed rule." 42 U.S.C. § 7607(d)(3)(C).

> It is not the role of the courts to speculate on reasons that might have supported an agency's decision. We may not supply a reasoned basis for the agency's action that the agency itself has not given. Whatever potential reasons the Department might have given, the agency in fact gave almost no reasons at all. In light of the serious reliance interests at stake, the Department's conclusory statements do not suffice to explain its decision.

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[97] *See* EEI Letter, *supra* note 88 ("It is important to note that all covered plants have implemented the regulation and that pollution controls—where needed—are installed and operating . . . . Therefore, we urge EPA . . . to leave the underlying MATS rule in place and effective."). Similarly, it has now been demonstrated that reducing power plant mercury emissions actually results in lower levels of methylmercury exposure in the United States. *See Mercury Air Releases Trend*, *supra* note 78.

[98] The Memorandum was made available to the public in the docket folder for the Proposal at: https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0794-0007.

Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2127 (2016) (citations and internal quotation marks omitted). EPA should therefore withdraw the Proposed Finding and conduct further analysis in light of the new evidence. If EPA were to provide the missing legal interpretation in a final Finding without first issuing a new proposal, that course of action would be impermissible because it would deprive the public of any opportunity to comment on the legal interpretation.

III. EVEN IF THE PROPOSED FINDING COULD RELY SOLELY ON DATA FROM THE 2011 RIA, ITS ANALYSIS OF THE DATA IS IRRATIONAL

A. The Proposed Finding Assigns a Determinative Role to Cost, which is Inconsistent with *Michigan* and the Statutory Text

In the Proposed Finding, EPA rejects its previous "cost-reasonableness" approach, and instead focuses its analysis on the comparison between monetized costs and monetized HAP-specific benefits. Although the agency does not specify exactly what standard it uses to measure costs against benefits, the Proposed Finding concludes that it is not appropriate and necessary to regulate power plants primarily based on the "gross disparity between monetized costs and [quantified] HAP benefit." 84 Fed. Reg. at 2677. In reaching the conclusion, however, EPA is ambiguous regarding the magnitude of benefits relative to costs necessary to make regulation of power plants under section 112 "appropriate," the precise way in which unquantified HAP benefits are accounted for, and the weight, if any, assigned to quantified co-benefits. Because the determinative role the Proposed Finding assigns to costs is inconsistent with the statutory text of section 112(n) as interpreted by the *Michigan* decision, the Proposed Finding is arbitrary and capricious.

To begin with, "appropriate and necessary" is a capacious phrase under which EPA must consider multiple factors—not only costs. In *Michigan*, Justice Scalia explicitly recognized that section 112(n)(1)'s "broad reference to appropriateness encompasses *multiple* relevant factors (which include but are not limited to cost)," and *Michigan* in no way suggested that cost should be the central factor in the Finding. 135 S. Ct. at 2709. Understood properly, the *Michigan* decision, by pointing out that "agencies have long treated cost as a centrally relevant factor when deciding whether to regulate," simply reiterates that cost should be *one* of the factors that EPA considers when making the finding. *Id.* at 2707 (emphasis added). In other words, what *Michigan* requires is that cost play *some* role in the finding, not that cost considerations should dominate the finding. The Proposed Finding, by focusing exclusively on the balance between the compliance costs and the quantified HAP benefits, is inconsistent with this direction from the Court.

Next, the text of section 112(n)(1) more generally makes it clear that Congress intended that public health, not cost, play the main role in the "appropriate and necessary" finding. Congress put health at the forefront of 112(n)(1) by requiring the Administrator to perform "a study of the hazards to public health reasonably anticipated to occur as a result of" power plant HAP emissions. 42 U.S.C. § 7412(n)(1)(A). This study is the only one that Congress explicitly instructed EPA to consider when making the appropriate and necessary finding. *Id.* ("The Administrator shall regulate electric utility steam generating units under this section, if the Administrator finds such regulation is appropriate and necessary *after considering the results of*

the study required by this subparagraph.") (emphasis added). Moreover, Congress mandated three studies in section 112(n)(1) and while health impacts are part of all three studies, cost factors into only one of them. *Id.* § 7412(n)(1)(A)-(C). It is telling that while public health was clearly Congress's primary focus in section 112(n)(1)(A), cost comes into consideration only indirectly through "the classic broad and all-encompassing term" "appropriate." *Michigan*, 135 S. Ct. at 2707. Although *Michigan* rejected the argument that this language foreclosed EPA from ignoring costs in the finding, Congress did not intend to make cost the central consideration.

The Proposed Finding's narrow focus on cost-effectiveness also thwarts the purpose of section 112 as a whole. Section 112 addresses HAPs that Congress determined to be "inherently harmful," and—as EPA previously recognized—Congress expressly instructed the agency to "protect the most sensitive populations from those harms."[99] 81 Fed. Reg. at 24,424. The emphasis on public health is also evident in section 112(c)(9), which conditions delisting of any sources upon a finding that emissions from the source category do not "exceed a level which is adequate to protect public health with an ample margin of safety and [pose] no adverse environmental effect." 42 U.S.C. § 7412(c)(9). Similarly, section 112(e)(2) specifically instructs the agency, when setting its priorities to promulgate emission standards for different source categories, to consider "the known or anticipated adverse effects of [pollutants] on public health and the environment" in tandem with "the quantity and location of emissions or reasonably anticipated emissions of [HAPs] that each category . . . will emit." 42 U.S.C. § 7412(e)(2). As explained below, section 112(n)(1) is an integral part of section 112, which Congress enacted explicitly in response to EPA's lack of action in addressing the harmful effects of HAPs, and therefore shares the section's overall focus on harm prevention. In this context, it is impermissible for the agency to allow a cost-benefit analysis that overstates costs and understates benefits to dictate the appropriate-and-necessary finding.

B. The Proposed Finding's Consideration of Unquantified Benefits is Incoherent and Incomplete

It is a long-standing principle that agencies should carefully consider non-monetized benefits in decision making that requires cost-benefit analysis. Office of Management and Budget ("OMB") Circular A-4 specifically instructs agencies to identify important non-monetary values in any analysis, warns that "the most efficient alternative will not necessarily be the one with the largest quantified and monetized cost-benefit estimate," and instructs agencies to "exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis." OMB, *Circular A-4: Regulatory Analysis* 26 (2003).

The Proposed Finding "acknowledges the importance of [the non-monetized] benefits and the limitations on the [a]gency's ability to monetize HAP-specific benefits," 84 Fed. Reg. at 2677, and further mentions that "such benefits are relevant to any comparison of the benefits and costs

[99] In the Proposed Finding, EPA contends that to accommodate statutory objectives when interpreting section 112(n)(1)(A) would be to "harmonize" the provision with the rest of the section and the CAA as a whole, 85 Fed. Reg. at 2675, which is it asserts is impermissible under *Michigan*. *See* 135 S. Ct. at 2710. However, nothing in *Michigan* suggests that the differences in treatment automatically make cost the determinative factor in regulatory decisions regarding EGUs; *Michigan* never affirmatively explains the different treatments in terms of the kind of role that cost should play.

of a regulation," *id.* at 2678. Its consideration of these unquantified benefits, however, suffers from two fatal flaws.

First, the Proposed Finding's discussion of non-monetized, HAP-specific benefits does not go further than a mere acknowledgement of their existence. Without providing any further discussion of the nature, seriousness, and magnitude of the unquantified benefits, EPA nevertheless concludes that "the gross disparity between monetized costs and HAP benefits, which [the agency] believe to be the primary focus of the . . . determination in CAA section 112(n)(1)(A), is too large to support an affirmative appropriate and necessary finding." 84 Fed. Reg. at 2678. In fact, EPA asserts that "even assuming that actual costs and benefits differed from projections made in 2011, given the large difference between target HAP benefits and estimated costs, the outcome of the Agency's proposed finding here would likely stay the same." *Id.* But EPA cannot rationally make such a statement before it demonstrates at least a rough sense of the magnitude of the non-monetized benefits, especially when it ignores published scientific developments since 2011 that have allowed some previously unquantifiable benefits to be quantified. Without a reasonable attempt to articulate a general grasp of the non-monetized benefits, it is arbitrary and capricious for EPA to reach this conclusion. After all, section 112(n)(1) imposes on EPA the statutory duty to understand the public health consequences of EGU emissions, a responsibility EPA "cannot shirk . . . simply because it may be difficult." *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010). Considering the critical role that EPA assigns to cost-benefit analysis, the Proposed Finding's cursory treatment of unquantified benefits constitutes a failure "to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Second, the Proposed Finding reverses EPA's previous approach to non-monetized benefits without explanation. Such an "'unexplained inconsistency' in agency policy" is arbitrary and capricious. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2119, 2125 (2016) (quoting *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)). In evaluating the unquantified benefits, the Proposed Finding relies on the same 2011 RIA as did the 2016 Supplemental Finding, yet reaches the opposite conclusion. This reversal signals a changed evaluation of the magnitude of HAP-specific benefits relative to compliance costs: in the 2016 Supplemental Finding, EPA stated that "the final RIA demonstrates that the benefits (monetized *and non-monetized*) of MATS are substantial and far outweigh the costs." 81 Fed. Reg. 24,420, 24,425 (April 25, 2016) (emphasis added). In the Proposed Finding, however, EPA reverses this position by concluding that even taking into account non-monetized HAP benefits and co-benefits, "the gross disparity between monetized costs and HAP benefits . . . is too large to support an affirmative . . . finding." 84 Fed. Reg. at 2677.

A policy change is not arbitrary and capricious if:

> the agency (1) displays awareness that it is changing position, (2) shows that the new policy is permissible under the statute, (3) believes the new policy is better and (4) provides good reasons for the new policy, including 'a reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy.

Organized Vill. of Kake v. U.S. Dep't of Agric., 795 F.3d 956, 966 (9th Cir. 2015) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009) (internal quotation marks omitted)). EPA's treatment of non-monetized HAP-related benefits violates the first and the fourth requirements of this test. As discussed above, the Proposed Finding summarily reaches the conclusion that costs grossly outweigh HAP-related benefits without analyzing the relevant factors in the comparison. In this process, EPA fails to address the fact that the non-monetized benefits were treated differently or were given different weights in the 2016 finding. The lack of analysis demonstrates that EPA does not display awareness that "it is changing position" regarding unquantified HAP benefits. Further, because the Proposed Finding turns on the magnitude of the unquantified HAP benefits, to adequately explain the reversal, EPA is obligated to provide a "reasoned explanation" for rejecting the conclusion it reached in 2016. The agency acts arbitrarily and capriciously when it fails to either confront the significance of the non-monetized benefits "or explain why [they have been] rendered . . . irrelevant." *Nat'l Parks Conservation Ass'n v. Semonite*, 916 F.3d 1075, 1085 (D.C. Cir. 2019).

C. EPA Should Consider All Benefits, Including Those Related to PM Emission Reductions, under a Cost-Benefit Approach

The Proposed Finding is also irrational because it ignores entirely the significant benefits the 2011 RIA identified from reductions in particulate matter ("PM") emissions. Although PM is not the direct target of section 112, the quantifiable public health benefits of PM reductions are undeniable, and they do not become less real merely because PM is not the regulatory focus. Rather, consideration of co-benefits is consistent with the public health focus of section 112.

Agencies and courts have increasingly recognized that agencies should take into account both indirect costs and co-benefits to provide a more accurate and complete understanding of the net impact of a regulation. OMB Circular A-4 codifies these developments, explicitly requiring agencies to "look beyond direct benefits and direct costs" and to "consider any important ancillary benefits countervailing risks," and stating that "the same standards of information and analysis quality that apply to direct benefits and costs should be applied to ancillary benefits and countervailing risks."[100] EPA itself acknowledges the relevance of co-benefits in its current guidelines for cost-benefit analyses, which require an economic analysis of regulations to include both "directly intended effects . . . as well as ancillary benefits and costs." EPA, *Guidelines for Preparing Economic Analyses* 11-2 (2010).

EPA has recognized that section 112's overarching emphasis on public health makes co-benefits particularly relevant to regulatory decisions under that section. In *Sugar Corp v. EPA*, 830 F.3d 579 (D.C. Cir. 2016), the agency had declined to set a less stringent, health-based standard for hydrogen chloride emissions from industrial boilers, finding that such a standard was not appropriate because—among other things—the more stringent Maximum Achievable Control Technology ("MACT") standard resulted in "potential co-benefits . . . in lowering emissions of other HAP and non-HAP pollutants," *id.* at 625. EPA argued that "its consideration of these co-benefits was not a regulation of other pollutants; rather, it was simply choosing not to ignore the purpose of the CAA—to reduce the negative health and environmental effects of HAP emissions." *Id.* The D.C. Circuit agreed with EPA, holding that the statutory "text does not

[100] OMB, *Circular A-4: Regulatory Analysis* 26 (2003).

foreclose the Agency from considering co-benefits and doing so is consistent with the CAA's purpose—to reduce the health and environmental impacts of hazardous air pollutants." *Id.*

It is clear from *Sugar Corp.* that EPA can consider co-benefits when making regulatory decisions under section 112. Importantly, the D.C. Circuit has also held that agencies are *required* to account for some secondary risks created by their regulations. For example, in *Competitive Enterprise Int. v. Nat'l Highway Traffic Safety Admin.*, 956 F.2d 321, 323-35 (D.C. Cir. 1992), the D.C. Circuit struck down a regulation promulgated by the National Highway Traffic Safety Administration because the agency failed to consider the indirect costs of its fuel efficiency standards, specifically the potential increased safety risks associated with smaller, more fuel efficient cars. In the context of National Ambient Air Quality Standards ("NAAQS"), the same court once deemed an EPA regulation unreasonable because the agency failed to consider the potential health detriments from lowering the ozone and PM NAAQS (which arise because ground-level ozone has an ultraviolet radiation screening function). *See Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1036-37 (D.C. Cir. 1999) (reversed on other grounds); *see also U.S. Telecom Ass'n v. FCC*, 290 F.3d 415, 424-25 (D.C. Cir. 2002) (overturning two Federal Communications Commission rules because of the agency's failure to consider the rules' indirect cost differentials in different competitive markets, and "the relevance of competition in broadband services coming from cable" and satellite companies, another indirect cost).

If agencies cannot ignore major countervailing risks, then logically a balanced cost-benefit analysis calls for inclusion of co-benefits. To account for one while leaving out the other is incoherent and unreasonable. In the Proposed Finding, EPA explains its exclusion of co-benefits by stating that the reduction of HAP emissions is the "explicit focus of regulations to reduce emissions under CAA section 112," while the ancillary co-benefits only occur when the technologies to control for HAPs are deployed "outside the direct regulatory focus of CAA section 112."[101] But this line of reasoning is flawed, as it is clear that agencies are required to take into account "indirect costs" that, by virtue of being "indirect," are never the "direct regulatory focus."

Additionally, the 2011 RIA for the MATS breaks down the estimated compliance costs into three components: capital and operating costs, fuel costs, and value of electricity generated.[102] Among the three, only the costs to implement and operate pollution control technologies *result directly* from the regulation, in the sense that only these technologies are specifically required by the regulations, while changes in both fuel cost and electricity cost are derivative products of the regulations. If EPA advocates a cost-benefit analysis that factors in only the benefits derived from the direct regulatory target, then the agency should analyze costs in a similarly narrow approach and thus could consider only the capital investment and operating costs.

[101] EPA, *Memorandum: Compliance Cost, HAP Benefits, and Ancillary Co-Pollutant Benefits for "National Emission Standards for Hazardous Air Pollutants: Coal-and Oil-Fired Electric Utility Steam Generating Units -- Reconsideration of Supplemental Finding and Residual Risk and Technology Review*" at 3 (2018).

[102] *Regulatory Impact Analysis*, supra note 49, at 7-14.

IV. EVEN IF EPA CONCLUDES THAT IT IS NOT APPROPRIATE AND NECESSARY TO REGULATE EGU HAP EMISSIONS, IT DOES NOT HAVE THE AUTHORITY TO DELIST POWER PLANTS OR TO RESCIND THE EMISSION STANDARDS (*COMMENTS C-4 – C-10)*

In the 2012 MATS Rule, EPA—after making the finding that it was appropriate and necessary to regulate HAP emissions from power plants—added coal- and oil-fired power plants to the source category list under section 112(c)(1) and established emission standards under section 112(d). In the Proposed Finding, EPA states that it does not intend to rescind the section 112(c)(1) listing or remove the section 112(d) emission standards. 84 Fed. Reg. at 2678-79. The Proposed Finding, however, seeks comment on "two alternative interpretations of the impact of reversing the 2016 Supplemental Finding." *Id.* at 2679. As described below, neither of these alternative interpretations is legally supportable and EPA must therefore keep both the listing and the standards in place even if it rescinds the "appropriate and necessary" finding.

A. EPA Cannot Delist EGUs Without Satisfying the Section 112(c)(9) Criteria Because *New Jersey* is not Distinguishable (*Comment C-7*)

In 2008, the D.C. Circuit held that EPA could not remove the EGU source category from the section 112(c) list unless the agency made the findings required under section 112(c)(9). *New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008). Under the first proposed alternative interpretation, EPA would conclude that *New Jersey* decision is distinguishable because at the time of the *New Jersey* decision, EPA had not yet finalized section 112(d) standards for power plants and the "appropriate and necessary" was therefore not "final agency action" subject to judicial review. 84 Fed. Reg. at 2679. However, because the *New Jersey* decision did not depend upon the result of the appropriate and necessary finding, it cannot be distinguished from the situation here. EPA is therefore bound by *New Jersey* and cannot remove EGUs from the 112(c) list without satisfying the delisting criteria in section 112(c)(9).

New Jersey concerned EPA's authority to remove power plants from the source category list after a previous reversal of an appropriate and necessary finding. EPA had originally issued an appropriate and necessary finding in 2000.[103] In 2005, EPA reversed course; instead of issuing MACT standards under section 112, EPA decided to regulate power plants under section 111, and concurrently removed power plants from the section 112(c)(1) list without going through section 112(c)(9). EPA justified its decision by explaining that section 112(n)(1)(A) provided the agency the authority to remove power plants from section 112(c) list "at any time that it makes a negative appropriate and necessary finding under the section." 70 Fed. Reg. at 16,032.

New Jersey struck down EPA's delisting decision on the ground that the delisting requirements in section 112(c)(9) applied to all listed sources, regardless of whether EPA can or did revise its appropriate and necessary finding. Section 112(c)(9) provides that:

> The Administrator may delete any source category from the [section 112(c)(1) list] . . . whenever the Administrator . . . [determines] that emissions from no

[103] EPA, Regulatory Finding on the Emissions of Hazardous Air Pollutants from Electric Utility Steam Generating Units, 65 Fed. Reg. 79,830 (Dec. 20, 2000).

> source in the category or subcategory concerned . . . exceed a level which is adequate to protect public health with an ample margin of safety and no adverse environmental effect will result from emissions from any source.

42 U.S.C. § 7412 (c)(9).

The D.C. Circuit read the plain language of this provision to mean that section 112(c)(9) was the exclusive avenue for delisting. The Court reasoned that:

> [B]ecause section 112(c)(9) governs the removal of 'any source category' (emphasis added) from the section 112(c)(1) list, and nothing in the CAA exempts EGUs from 112(c)(9), the *only* way EPA could remove EGUs from the section 112(c)(1) list was by satisfying section 112(c)(9)'s requirements.

517 F.3d at 582 (emphasis added).

In reaching the conclusion that EPA failed to follow its statutory mandate when making the delisting decision, however, the court did not opine on the reasonableness of the negative finding. Nor did the court analyze the reviewability of the finding. In fact, the court acknowledged EPA's authority to change its determination, stating that "nothing in the CAA would have prevented [EPA] from revising its determination about whether it was 'appropriate and necessary' to [regulate]." *Id.* at 583. However, neither EPA's authority to reverse its finding, nor the reasonableness of such reversal, was factored by the Court into its analysis of the plain meaning of section 112(c)(9). According to the court, EPA's authority to reverse the preliminary finding was irrelevant because when it comes to delisting, Congress "unambiguously limit[ed] EPA's discretion to remove sources, including EGUs, from the section 112(c)(1) list once they have been added to it," which "precludes EPA's inherent authority claim." *Id.* *New Jersey* therefore explicitly rejected the relevance of the appropriate and necessary finding to the mandatory delisting procedure in section 112(c)(9), and as a result, the reviewability of the finding cannot be used to distinguish *New Jersey* from the action at hand.

Therefore, although the initial decision whether to list EGUs is governed by a separate program under section 112(n)(1), the delisting of EGUs is subject to the section 112(c)(9) scheme. The finding became legally irrelevant to EPA's delisting authority once EGUs were listed.

B. Section 112(d) Requires that EPA Regulate EGUs under Section 112(d) as Long as the Sources are Listed under Section 112(c) (*Comment C-8*)

EPA further suggests under its second alternative interpretation that it could rescind emission standards for power plants without delisting them. According to EPA, even if *New Jersey* is applicable, the decision does not prevent EPA from rescinding emission standards promulgated under section 112(d) since *New Jersey* addressed only delisting but not standard rescission. Furthermore, EPA reasons that 112(n)(1) grants the agency the authority to rescind emission standards for sources listed under this provision even if those sources would remain listed, because "CAA 112(n)(1)(A) plainly establishes that the Administrator must find regulation under CAA section 112 is appropriate and necessary as a prerequisite to undertaking such regulation." 84 Fed. Reg. 2679. The agency's reasoning is mistaken in its reading of the statutory text and understanding of *New Jersey*.

First, as a matter of statutory language, section 112(d) is as clear as 112(c). Section 112(d) states that EPA "*shall* promulgate regulations establishing emission standards for *each* category or subcategory of major sources and area sources of hazardous air pollutants listed for regulation pursuant to subsection (c) of this section." 42 U.S.C. § 7412(d)(1) (emphasis added). The word "shall" establishes a mandatory duty, leaving EPA no discretion to exempt any source categories. *See United States v. Monsanto*, 491 U.S. 600, 607 (1989) (in using the word "shall," "Congress could not have chosen stronger words" to express its intent that [a statutory duty] be mandatory."). The non-discretionary nature of EPA's duty is further supported by the word "each," which unambiguously indicates that this mandatory duty applies to *every* source category listed under section 112(c).[104] The language of 112(d) is unambiguous and mandatory; EPA must establish emission standards for "each" source category listed under 112(c), which means EPA is obligated to regulate EGUs as long as they are listed under 112(c). Because, as explained above, EPA does not have the discretion to delist without going through the section 112(c)(9) process, a reversal of the "appropriate and necessary" finding would have no effect on the existing emission standards for EGUs.

Second, in the context of the clear text of 112(d) and 112(c), *New Jersey* implicitly rejects EPA's assertion that the agency could derive the authority to rescind emission standards from its authority to reverse the appropriate and necessary finding. *New Jersey* stands for the proposition that the separate regime of section 112(n) does not take EGUs out of the general structure of section 112. If section 112(n) does not exempt EGUs from the section 112(c)(9) delisting procedures, then logically this provision does not create an exemption for EGUs under section 112(d) either, given that section 112(d) is automatically triggered upon listing. Because listing is the necessary and sufficient trigger for standard-setting, to rescind any emission standard, EPA must go through the delisting process; section 112(c)(9) is the required mechanism for EPA to retract any standards that are already in place.

In its effort to render *New Jersey* inapplicable to emission standards, EPA effectively asserts its inherent authority to rescind the standards. However, EPA's attempt to revoke emission standards under section 112(n) falls squarely within the ambit of principle that "when Congress has provided a mechanism capable of rectifying mistaken actions . . . it is not reasonable to infer authority to reconsider agency action." *Am. Methyl Corp. v. EPA*, 749 F.2d 826, 835 (D.C. Cir. 1984); *see also Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81 (D.C. Cir. 2014) (ruling that because FDA concededly could have used a statutory provision to reclassify a device, it could not rely on "inherent reconsideration authority" to short-circuit that statutory process and revoke its prior substantial equivalence determination to achieve that same result). To emphasize, once

[104] Courts have consistently interpreted "each" according to its ordinary meaning and equated "each" with "every." For example, in a case involving permits issued under Title V of the CAA, the D.C. Circuit interpreted a provision requiring that "[e]ach permit . . . shall set forth . . . monitoring . . . requirements to assure compliance with the permit terms and conditions." 42 U.S.C. § 7661c(c)) (emphasis added). The court held that: "There can be no doubt about the plain meaning of this phrase. 'Each' means '[e]very one of a group considered individually." AMERICAN HERITAGE DICTIONARY 269 (4th ed. 2001). Title V requires that '[e]very one' of the permits issued by permitting authorities include adequate monitoring requirements." *Sierra Club v. E.P.A.*, 536 F.3d 673, 678 (D.C. Cir. 2008); *see also, e.g., Exelon Wind 1, L.L.C. v. Nelson*, 766 F.3d 380, 403 (5th Cir. 2014) ("The option belongs to each qualifying facility, which means that it belongs to 'every' qualifying facility."); *Dickenson-Russell Coal Co., LLC v. Sec'y of Labor*, 747 F.3d 251, 258 (4th Cir. 2014) (giving "each" its dictionary meaning, which is "every one of two or more people or things considered separately").

a source is triggered into the regulatory program under section 112, the agency's "inherent authority" to reconsider its preliminary appropriate and necessary finding cannot trump the statutory text that establishes the exclusive mechanism to rescind standards.

***

For all these reasons, the Proposed Finding is arbitrary and capricious, as it is inconsistent with scientific knowledge and EPA's statutory mandate. It is appropriate and necessary to regulate HAP emissions from power plants; MATS has been proven effective in addressing the public health and environmental threats of power plant mercury emissions. The Proposed Finding should therefore be withdrawn.

Thank you for your attention to these comments.

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Attachment 15

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments on PFAS National Leadership Summit
and Engagement, Docket ID No. EPA-HQ-OW-2018-0270

Submitted via Regulations.gov

September 28, 2018

Alabama Rivers Alliance * Alaska Community Action on Toxics * Alliance for the Great Lakes * Buxmont Coalition for Safer Water * Center For A Sustainable Coast * Center for Environmental Health * Childhood Lead Action Project * Citizens Coal Council * Clean and Healthy New York * Clean Water Action * Colorado Interfaith Power and Light * Comite Civico Del Valle * Conservation Law Foundation * Ecology Center * Environmental Clinic, University of Texas School of Law * Environmental Health Strategy Center * Environmental Working Group * Freshwater for Life Action Coalition * GreenLatinos * Gulf Restoration Network * Headwater LLC * Illinois Council of Trout Unlimited * League of Conservation Voters * National Resources Defense Council * Natural Heritage Institute * Newburgh Clean Water Project * Noorzad, Seth – Law Student * Ohio Environmental Council * OVEC-Ohio Valley Environmental Coalition * PolicyLink * Rumult, Kenneth - Professor, Vermont Law School * Riverkeeper, Inc. * Safer States * Sierra Club * Toxic-Free Future * Union of Concerned Scientists * Waterkeeper Alliance * WE ACT for Environmental Justice * Women's Voices for the Earth * Zero Waste Washington

Earthjustice submits these comments on behalf of the undersigned organizations and individuals in response to EPA's request for information from the public for the purpose of "informing specific near-term actions, beyond those already underway, that are needed to address challenges caused by per- and polyfluoroalkyl substances (PFAS) currently facing states and local communities."[1] EPA has stated its commitment "to supporting states, tribes and local communities in addressing challenges with PFAS."[2] We urge EPA to demonstrate its commitment through prompt, comprehensive measures such as those outlined below.

PFAS are a family of approximately 5,000 manmade fluorinated organic chemicals characterized by the strong bond between fluorine and carbon. According to a senior CDC official, the presence and concentrations of PFAS chemicals in U.S. drinking water is "one of the most seminal public health challenges for the next decades."[3]

EPA itself has, since at least 2010, publicly recognized the dangers PFAS pose, stating that once released, PFAS "are expected to persist in the environment, may bioaccumulate, and may be highly toxic."[4] Specific medical harms associated with PFAS include: kidney cancer, testicular cancer, bladder cancer, liver function impairment, impaired fetal development, chronic

intestinal inflammation, disruption of critical thyroid hormones, weakened immune system, and high cholesterol.[5]

As EPA officials have recognized, because of the sheer number of PFAS, their makeup, and the dangers scientific studies show they pose, EPA should not regulate PFAS on an individual basis.[6] Instead, EPA should regulate PFAS as a class. That PFAS pose dangers to human health has largely been based on studies of perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonate ("PFOS"), two "long-chain" PFAS that have been the most extensively produced and studied PFAS.[7] While domestic PFAS manufacturers are replacing production and use of PFOA and PFOS with shorter-chain PFAS, those replacements are structurally similar to their long-chain predecessors,[8], and no studies demonstrate that they are safe. Indeed, shorter-chain PFAS may be similarly persistent as long-chain PFAS and more mobile in the environment, thus posing a greater potential for long-range contamination.[9] Thus, it would be illogical to keep states and communities informed of the manufacture, use and release of only some PFAS and not others, especially when new PFAS continue to be developed.

Before states, tribes and local communities can meaningfully *prevent* and *address* PFAS contamination, they must first know whether and where *all* known PFAS are manufactured, used, or released in their vicinity. Unfortunately, EPA has failed to meaningfully and comprehensively require disclosure of PFAS. EPA should correct that immediately, and, at a minimum, implement the following:

- **Test Drinking Water Systems for the Presence of PFAS**. The best, most immediate near-term actions EPA can take to assist states, tribes and communities with this challenge is to require comprehensive testing for PFAS in all public water systems, and public disclosure of all results, so that states and municipalities can begin to design and implement measures to ensure safe drinking water is available. Testing should be required for all PFAS for which analytic methods for testing have been developed.

- **Develop Analytical Methods.** Analytical methods for testing for PFAS have been developed for only approximately 30 of the 3000 known PFAS. EPA should invest resources to develop analytical test methods for widely-used PFAS, using the lowest available detection limits. It should then add those PFAS to its Priority Pollutant List ("PPL"), a set of chemical pollutants for which EPA has published analytical test methods.[10] States and tribes consult the PPL when developing ambient water quality criteria.[11]

- **Facilitate Testing for the Presence of PFAS:** EPA should also add all PFAS for which analytical testing methods exist to the next round of testing pursuant to the Unregulated Contaminant Monitoring Rule (UCMR) under the Safe Drinking Water Act (SDWA), so that data on the presence of PFAS in drinking water is collected. In addition, the thresholds at which the presence of six PFAS currently on the UCMR should be detected and reported should be significantly lowered in accordance with the latest science. As you are aware, a recent draft toxicological profile of PFAS issued by ATSDR indicated that the safe levels of PFAS in drinking water are much lower than reflected in EPA's 2016 Health Advisory Levels.

- **<u>Add PFAS to the Toxics Release Inventory:</u>** As you are aware, the Emergency Planning and Community Right to Know Act (EPCRA), 42 U.S.C. §§ 11001, *et seq.*, is the primary federal law designed to alert communities to toxic contamination. The Toxics Release Inventory (TRI) program serves several purposes, including "to inform persons about releases of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; [and,] to aid in the development of appropriate regulations, guidelines, and standards."[12] EPA is authorized to use its rulemaking authority to "add or delete a chemical from the [TRI list] at any time."[13]

EPA has failed to add *any* PFAS to the TRI despite indicating over a decade ago that it would take steps to do so. EPA should promptly initiate a rulemaking to require PFAS as a class to be listed on the TRI, as it has done for several other classes of chemicals like PCBs. In 2005, EPA settled an administrative complaint it had filed against E.I. DuPont de Nemours (now Chemours), accusing it of concealing information for more than 20 years regarding the harms of PFOA, for the largest civil administrative penalty it had ever obtained.[14] Alarmed by the risks posed by PFOA and PFOS, EPA then convinced domestic manufacturers to cease manufacturing those PFAS. At that time, EPA also announced that it would "initiate efforts to add PFOA and related chemicals to the Toxics Release Inventory (TRI) to help monitor the results" of the agreement."[15] Twelve years later, EPA has not even initiated a rulemaking to add PFOA or PFOS—or any PFAS—to the TRI list. EPA should act immediately on this front for all PFAS. When it does so, it should establish a reporting threshold of 1,000 pounds, consistent with other chemicals, or classes of chemicals such as PCBs, of special concern.[16] It should also ensure that the requirement to report releases apply to facilities that are in Standard Industrial Classification Codes 45 (airports) and 97 (military), as it is imperative that the public know when these types of facilities in particular, which are known responsible parties for significant PFAS pollution, release these toxic substances into the environment.

- **<u>Designate PFAS as Toxic Pollutants under the Clean Water Act:</u>** As it has done for other groups of contaminants, EPA can and should add PFAS as a group to its Toxic Pollutant List pursuant to section 307(a)(1) of the Clean Water Act (CWA).[17] This addition will cause PFAS to be added to the CERCLA hazardous substance list, which will in turn require federal, state and local government to be notified when PFAS over a certain amount are released into the environment. States and tribes would then use this list to establish ambient water quality criteria for PFAS.

- **<u>Close Loopholes That Allow New PFAS on Market Without Safety Review:</u>** EPA should also take steps to ensure that no new PFAS are manufactured without going through the approval process set forth in section 5 of the Toxic Substances Control Act (TSCA). TSCA requires manufacturers to seek approval of new chemicals by submitting a premanufacture notice (PMN) to EPA.[18] This pre-market review and approval process is often avoided due to regulatory loopholes. For example, EPA allows companies to evade pre-market safety review requirements for PFAS if they are produced in low volume, as byproducts, or if they are used for

research and development or test marketing.[19] . Given the persistent, bioaccumulative, and toxic qualities associated with PFAS, no exemption from premanufacture notice and safety review should be available for PFAS.

- **Inform the Public of Active PFAS:** The public does not know how many PFAS chemicals are on the TSCA "inventory" of active chemicals in commerce. At EPA's May 2018 PFAS Summit, Jeff Morris, Director of the Office of Pollution Prevention and Toxics, stated that nearly 900 PFAS chemicals have come through EPA's TSCA program since 2006.[20] EPA's website indicates that almost 500 PFAS, including 330 non-confidential PFAS, have been reported to EPA. [21] Yet, government officials, tribes, and communities cannot readily determine which substances on the Toxics Substances Control Act Inventory are PFAS, and which PFAS are manufactured or used for industrial purposes in their area. EPA should develop, publish on EPA.gov, and regularly update a database of known and active PFAS. For each PFAS, the database should identify: where it is manufactured, processed, or otherwise used for industrial purposes; an estimated amount of the maximum amount of total PFAS present at the facility; and the general category or categories of use. A PFAS database would keep officials and communities apprised about PFAS near them, and help them prepare for possible contamination.

* * *

States, tribes, and local communities will be able to address the ubiquitous existence of PFAS and the dangers they pose only if EPA and the public are made aware of: 1) the manufacture, use, and release of PFAS; and, 2) PFAS contamination of drinking water. EPA should act immediately to implement the actions outlined above. Only a comprehensive approach to disclosure of PFAS will provide the needed information, and there is no scientific, legal, or public health basis for failing to implement all of the suggestions outlined above.

Submitted by:

Earthjustice on *behalf of*

Alabama Rivers Alliance
Alaska Community Action on Toxics
Alliance for the Great Lakes
Buxmont Coalition for Safer Water
Center For A Sustainable Coast
Center for Environmental Health
Childhood Lead Action Project
Citizens Coal Council
Clean and Healthy New York
Clean Water Action
Colorado Interfaith Power and Light
Comite Civico Del Valle
Conservation Law Foundation
Ecology Center
Environmental Clinic, University of Texas School of Law

Environmental Health Strategy Center
Environmental Working Group
Freshwater for Life Action Coalition
GreenLatinos
Gulf Restoration Network
Headwater LLC
Illinois Council of Trout Unlimited
League of Conservation Voters
National Resources Defense Council
Natural Heritage Institute
Newburgh Clean Water Project
Noorzad, Seth – Law Student
Ohio Environmental Council
OVEC-Ohio Valley Environmental Coalition
PolicyLink
Rumult, Kenneth - Professor, Vermont Law School
Riverkeeper, Inc.
Safer States
Sierra Club
Toxic-Free Future
Union of Concerned Scientists
Waterkeeper Alliance
WE ACT for Environmental Justice
Women's Voices for the Earth
Zero Waste Washington

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[1] U.S. Envtl. Prot. Agency, *PFAS National Leadership Summit and Engagement*, https://www.epa.gov/pfas/pfas-national-leadership-summit-and-engagement (last updated Aug. 21, 2018).
[2] U.S. Envtl. Prot. Agency, *EPA Actions to Address PFAS*, https://www.epa.gov/pfas/epa-actions-address-pfas (last updated May 14, 2018).
[3] Pat Rizzuto et al., *CDC Sounds Alarm on Chemical Contamination in Drinking Water*, Bloomberg Env't. (Oct. 17, 2017, 4:23 PM), https://news.bloomberglaw.com/environment-and-energy/cdc-sounds-alarm-on-chemical-contamination-in-drinking-water.
[4] Premanufacture Notification Exemption for Polymers; Amendment of Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers, 75 Fed. Reg. 4295, 4296 (Jan. 27, 2010) (to be codified at 40 C.F.R. pt. 723).
[5] *See, e.g.*, C8 Science Panel, *C8 Probable Link Reports*, http://www.c8sciencepanel.org/prob_link.html (last updated Oct. 29, 2012).
[6] *See* Jeff McMenemy, *EPA Region 1 Leader: PFAS Treatment Could Change*, Fosters.com (Jun. 25, 2018, 7:51 PM), http://www.fosters.com/news/20180625/epa-region-1-leader-pfas-treatment-could-change; Suzanne Yohannan, *EPA Eyes Individual PFAS But Sees Limits in Chemical-Specific Approach*, InsideEPA.com (Jun. 14, 2018), https://insideepa.com/weekly-focus/epa-eyes-individual-pfas-sees-limits-chemical-specific-approach.
[7] U.S. Envtl. Prot. Agency, *Fact Sheet: PFOA & PFOS Drinking Water Health Advisories* (2007), https://www.epa.gov/sites/production/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf

[8] *See* Jesper Kjølholt et al., *Short-Chain Polyfluoroalkyl Substances (PFAS)* (Danish Ministry on Env't, Envtl. Project No. 1707, 2015), https://www2.mst.dk/Udgiv/publications/2015/05/978-87-93352-15-5.pdf
[9] *See* Stephan Brendel et al., *Short-Chain Perfluoroalkyl Acids: Environmental Concerns and a Regulatory Strategy under REACH* 1, 3-4 (30:9 Envtl. Sci. Eur., 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5834591/pdf/12302_2018_Article_134.pdf.
[10] *See* 40 C.F.R. § pt. 423, App'x A; U.S. Envtl. Prot. Agency, *Toxic and Priority Pollutants under the Clean Water Act*, https://www.epa.gov/eg/toxic-and-priority-pollutants-under-clean-water-act (last updated Mar. 15, 2018).
[11] *See id.*
[12] 42 U.S.C. § 11023(h); *See, e.g.*, *Dayton Power & Light Co. v. Browner*, 44 F. Supp. 2d 356, 358 (D.D.C. 1999).
[13] 42 U.S.C. §11023(d)(1).
[14] *See* U.S. Envtl. Prot. Agency, *E.I. DuPont de Nemours and Company PFOA Settlements*, https://www.epa.gov/enforcement/ei-dupont-de-nemours-and-company-pfoa-settlements (last updated Aug. 24, 2017).
[15] *See* Press Release, EPA,100 Percent Participation and Commitment in EPA's PFOA Stewardship Program, (Mar. 2, 2006), https://archive.epa.gov/epapages/newsroom_archive/newsreleases/95de36c6115a523a8525712500693772.html [https://perma.cc/2NZ3-27DD].
[16] *See* 40 C.F.R. § 372.28.
[17] *See* 33 U.S.C.A. § 1317(a)(1); 40 C.F.R. § 401.15 (2015).
[18] *See* 15 U.S.C.A. § 2604(a)(1); *id.* § 2604(i)(1); 40 C.F.R. § 720.22 (1986).
[19] *See* 40 C.F.R. § 720.30.
[20] Jeff Morrison, *Per- and Polyfluoroalkyl Substances under the Toxic Substances Control Act, (TSCA)*, [PowerPoint slides] EPA (2018), https://www.epa.gov/sites/production/files/2018-05/documents/pfas_summit_jeff_morris_22_may_2018.pdf, at slide 2.
[21] *See PFAS Laws and Regulations*, EPA (2018), https://www.epa.gov/pfas/pfas-laws-and-regulations (last updated July 30, 2018).

Attachment 16

EARTHJUSTICE

April 15, 2019

via Regulations.gov federal rulemaking portal

U.S. Environmental Protection Agency
EPA Docket Center
Office of Water Docket
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

Re: Revised Definition of "Waters of the United States;" Docket ID No. EPA-HQ-OW-2018-0149; Comments of Sierra Club, Puget Soundkeeper Alliance, Idaho Conservation League, Pacific Coast Federation of Fishermen's Associations, Institute for Fisheries Resources, Tucson Audubon Society, National Association for the Advancement of Colored People ("NAACP"), and Southeast Alaska Conservation Council

To U.S. Environmental Protection Agency and U.S. Dep't of the Army, Corps of Engineers:

These comments in opposition to the Revised Definition of Waters of the United States, 84 Fed. Reg. 4154 (Feb. 14, 2019) ("Dirty Water Rule" or "proposed rule"), are submitted by Earthjustice on behalf of the Sierra Club, Puget Soundkeeper Alliance, the Idaho Conservation League, Pacific Coast Federation of Fishermen's Associations, Institute for Fisheries Resources, Tucson Audubon Society, the National Association for the Advancement of Colored People ("NAACP"), and Southeast Alaska Conservation Council (collectively "Clean Water Groups").[1] We rely on clean water for drinking, to irrigate crops, for swimming and fishing, and as habitat for wildlife. Wetlands and other waters also reduce flooding and filter pollution. Since 1972, the Clean Water Act, one of our earliest and most important environmental laws, has helped restore and protect our Nation's waters. The Clean Water Groups are opposed to the Dirty Water Rule as contrary to law, contrary to science, and contrary to the overwhelming evidence in the record that this rule will leave America's waters unprotected from pollution, and subject to destruction and degradation. This Dirty Water Rule is contrary to the intent and purpose of the Clean Water Act and will reverse decades of progress on protecting and cleaning up one of our most precious natural resources: clean and healthy water for all. Further, this Dirty Water Rule will increase degradation of the Nation's waters by incrementally allowing human alterations to waters of the U.S. to remove or cut off otherwise protected waters from the reach of the Clean Water Act.

[1] These comments are also submitted with, and fully incorporate, the separately submitted exhibits A through K-20, submitted to the federal rulemaking portal for EPA-HQ-OW-2018-0149 by Earthjustice on behalf of Sierra Club, et al. on April 12, 2019.

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I. THE AGENCIES OFFER NO RATIONAL JUSTIFICATION FOR THEIR POLICY REVERSAL AND THEIR PROVIDED EXPLANATIONS ARE IRRATIONAL, ARBITRARY, AND CAPRICIOUS UNDER THE ADMINISTRATIVE PROCUEDURE ACT.

The Agencies have pointed to no need or reasoned bases for their proposed rule to replace the 2015 Clean Water Rule with an entirely different rule that substantially narrows the scope of the Clean Water Act. The Agencies' few provided rationales contradict the Clean Water Act and its legislative history, and are arbitrary and capricious under the Administrative Procedure Act ("APA"). Specifically, the Agencies' claims that the Dirty Water Rule is intended to better align the definitions of "waters of the United States" with the text and legislative history of the Clean Water Act, to increase certainty, and reduce confusion with the 2015 Clean Water Rule, are all belied by the record. *See* 84 Fed. Reg. at 4156, 4196-97.

A. <u>The Dirty Water Rule Contradicts the History, Intent, and Purpose of the Clean Water Act.</u>

The Agencies' proposed severe narrowing of the term "navigable waters" and accompanying purported reliance on states to absorb losses in Clean Water Act coverage is not supported by the text and legislative history of the Clean Water Act, and also ignores important limitations in states' abilities to successfully regulate water pollution.

1. Congress Passed The Clean Water Act Because States Had Failed To Adequately Protect Waters.

The Federal Water Pollution Control Act of 1972 (the "Clean Water Act" or "CWA") was the culmination of years of failed efforts by states to protect and clean up the Nation's waters through the implementation of state-based water quality standards. S. Rep. No. 92-414 at 7 (1971), *reprinted in* 1972 U.S.C.C.A.N. 3668, 3672; James Salzman & Barton H. Thompson, Jr., Envtl. L. and Pl'y 141 (2d ed. 2007); *see also* Glicksman, Robert L. and Matthew R. Batzel, *Science, Politics, Law, and the Arc of the Clean Water Act*, 32 Wash. U. J. L. & Pol'y 099, 102-03 (2010). At the time of the passage of the Clean Water Act, half of the states had not adopted standards and there was little to no implementation of limits or enforcement against polluters, despite significant funding for the states' water quality standards programs. *See* Glicksman, *supra*, at 102*; see also EPA v. California*, 426 U.S. 200, 202-09 (1976); *American Paper Inst., Inc. v. EPA*, 890 F.2d 869, 870-71 (7th Cir. 1989). Because the situation had reached a critical stage, and because waters are national resources, Congress realized that a national strategy and system of requirements—a federal "floor" —would be necessary to ensure that waters would be cleaned up and protected into the future. *See* Glicksman, *supra*, at 102. Against this backdrop, Congress passed the Clean Water Act, wherein Congress' stated purpose and intent was to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a).

2. Congress Intended The Broadest Possible Interpretation Of Navigable Waters.

The Clean Water Act's legislative history does not support the narrow reading of "navigable waters" that the Environmental Protection Agency ("EPA") and the Army Corps of Engineers ("Corps") (collectively, "the Agencies") propose in the Dirty Water Rule. To the contrary, the legislative history repeatedly points to the breadth of both the term "navigable waters" and the overall statutory scheme to protect all waters. In a Senate floor debate in 1971, Senator Randolph called the bill "perhaps the most comprehensive legislation ever developed in its field." A Legislative History of the Water Pollution Control Amendments of 1972 (Cong. Res. Serv. 1973) ("CWA Legislative History"), Sen. Debate on S.2270 at 1269 (Nov. 2, 1971). In Senate debate on overriding President Nixon's veto of the bill the next year, Senator Cooper described the Clean Water Act as "one of the most significant, most comprehensive, most thoroughly debated pieces of environmental legislation ever to be considered by the Congress," and Senator Eagleton remarked: "If one word best describes the [CWA], it is the word 'comprehensive.'" CWA Legislative History, Senate Debate on Overriding the President's Veto of S. 2770 at 189, 218 (Oct. 17, 1972). As Justice Rehnquist later observed, "[t]he most casual perusal of the legislative history demonstrates that these views on the comprehensive nature of the legislation were practically universal." *City of Milwaukee v. Illinois & Michigan*, 451 U.S. 304, 319, n.12 (1981).

In developing a law that would provide more consistent and comprehensive protections to waters across the Nation, Congress directed the "broadest possible" definition of "navigable waters" of the United States, unencumbered by earlier narrower interpretations made for administrative purposes. H.R. Rep. No. 92-911 at 76-77 (1972); *see also EPA v. California*, 426 U.S. at 202-09; *American Paper Inst., Inc.*, 890 F.2d at 870-71; *Montgomery Envtl. Coal.*, 646 F.2d at 574; and H.R. 11,896, 92nd Cong. (1971) and S. 2770, 92nd Cong. (1971) (the Clean Water Act bills were written to expand federal authority and control over waters in order to control and eliminate pollution across the country). In so doing, Congress spoke to the science of waters being interconnected and the need to ensure that aquatic ecosystems—waters upstream of and within connections with "traditionally navigable" waters—be protected if the Clean Water Act's purpose is to be fulfilled. Congress recognized that "[w]ater moves in hydrologic cycles and it is essential that discharge of pollutants be controlled at the source." S. Rep. No. 92-414 at 77. Members noted that the intent was to move away from the constrained notions of jurisdiction and in particular notions regarding navigation, in order to ensure that waters are

protected in a full and comprehensive way. *See* CWA Legislative History at 178-79, 250-51, 327, 818, 1495. [2]

With respect to the term "navigable waters" specifically, the Conference Report states: "the conferees fully intend that the term 'navigable waters' be given *the broadest possible constitutional interpretation unencumbered by agency determinations which have been made or may be made for administrative purposes*." CWA Legislative History, Senate Consideration of the Rpt. Of the Conference Committee, Oct. 4, 1972, at 178 (emphasis added). Congress originally defined navigable waters to mean "the navigable waters of the United States," but the word "navigable" was later deleted from this definition in an amendment intended to broaden the term. CWA Legislative History, Joint Explanatory Statement of the Committee of Conference at 327; *see also* H.R. Rep. No. 92-911; S. Rep. No. 92-1236 (Sept. 28, 1972). During the course of the Clean Water Act's passage, discussion centered on ensuring that the term navigable waters would not be defined or construed narrowly, as to do so would defeat the intent of the Act. H.R. Rep. No. 92-911 at 76–77 and S. Rep. No. 92-414 at 77; *see also* 118 Cong. Rec. 33,756–57 (Oct. 4, 1972). Congress recognized that to achieve its ambitious goal of restoring and protecting our Nation's waters, it would be necessary to "control pollution at the source," and not just rely on inadequately enforceable state by state standards. S. Rep. No. 92-414 at 77. Indeed, the Senate Committee on Public Works, in considering the bill, "was reluctant to define" the term navigable waters "based on the fear that any interpretation would be read narrowly." CWA Legislative History at 818. After expressing this concern, the Committee then again reiterated that it "fully intends that the term 'navigable waters' be given the broadest possible constitutional interpretation." *Id*.

During debate on the bill, Representative Dingell expounded further on Congress' intended definition of the term "navigable waters," stating it "means all 'the waters of the United States' in a geographical sense. It does not mean 'navigable waters of the United States' in the technical sense as we sometimes see in some laws." CWA Legislative History, House Consideration of the Rpt. Of the Conference Committee, Oct. 4, 1972, at 250 (remarks of Rep. Dingell). He explained that the new, broad definition of the term was explicitly intended to go beyond the scope of the definition of "navigable waters" in the *Daniel Ball* case, *id*., which was very similar to the definition that was (and still is) used in the Rivers and Harbors Act. 33 C.F.R. § 329.4. The definition of "navigable waters" used in the Rivers and Harbors Act and outlined in the 1871 *Daniel Ball* case only covers waters that have been used or are susceptible to being used to transport commerce. *Id*.; *The Daniel Ball*, 77 U.S. 557 (1870) (superseded by statute as stated in *Rapanos v. U.S*., 547 U.S. 715 (2006)). The explicit rejection of the existing definitions

[2] A pointed reminder that Congress intended the definition of "navigable waters of the United States" to mean waters beyond those considered traditionally navigable can be found in the provisions directing states to adopt and implement water quality standards that are protective of water uses "taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial and other purposes, and also taking into consideration their use and value for navigation." 33 U.S.C. § 1313(c). Plainly, navigation was only one consideration in the direction to protect water quality.

of navigability found in other statutes and case law bars any interpretation of navigability that harkens back to a commerce-based navigability test. Therefore, the Agencies' repeated citations to the old superseded definition of navigability in *The Daniel Ball* in this proposed rule—including their statement that in that case the Supreme Court "long ago recognized the distinction between federal waters traditionally understood as navigable and waters 'subject to the control of the States,'" 84 Fed. Reg. at 4168—are simply wrong and contrary to law and Congress' plain intent.[3] Congress made clear that in contrast to the old, pre-Clean Water Act legal definition of the term "navigable waters," "this new definition clearly encompasses all water bodies, including main streams and their tributaries, for water quality purposes." CWA Legislative History, House Consideration of the Rpt. Of the Conference Committee, Oct. 4, 1972, at 250 (remarks of Rep. Dingell). Therefore, the Act applies not just to navigable-in-fact waters and waters susceptible to being navigable-in-fact, but to the "waters of the United States," with Congress recognizing that waters are hydrologically-connected, necessitating broad application in order to ensure the Nation's waters are clean and safe. S. Rep. No. 92-414 at 77 and H.R. Rep. No. 92-911 at 76-77.

Finally, when Congress enacted the major 1977 amendments to the Clean Water Act, it specifically rejected some calls to narrow the definition of "navigable waters," stating:

> The objective of the 1972 act is to protect the physical, chemical, and biological integrity of the Nation's waters. Restriction of jurisdiction to those relatively few waterways that are used or susceptible to use for navigation would render this purpose impossible to achieve. Discharges of dredged or fill material into lakes and tributaries of these waters can physically disrupt the chemical and biological integrity of the Nation's waters and adversely affect their quality. The presence of toxic pollutants in these materials compounds this pollution problem and further dictates that the adverse effects of such materials must be addressed where the material is first discharged into the Nation's waters. To limit the jurisdiction of the Federal Water Pollution Control Act with reference to discharges of the pollutants of dredged or fill material would cripple efforts to achieve the act's objectives. The committee amendment does not redefine navigable waters. Instead, the committee amendment intends to assure continued protection of all the Nation's waters.

Legislative History of the Clean Water Act of 1977, H.R. Rep. 95-139 at 75 (March 29, 1977); *see also id*. at 54, 63, 70-71. Further, as part of the decision to allow states to be delegated the authority to do some permitting under § 404, Congress reserved navigable-in-fact waters, making it abundantly clear that Congress considered § 404 and the Clean Water Act to protect all waters, not just those that are navigable in fact. *Id*. The proposed rule's narrowing of the term "navigable waters" and emphasis on navigability is thus contrary to the statutory scheme, as the Agencies themselves admit.

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[3] In fact, the Agencies concede as much elsewhere in the proposed Dirty Water Rule when they admit "[t]his suggests that Congress had in mind a broader scope of waters subject to CWA jurisdiction than waters traditionally understood as navigable." 84 Fed. Reg. at 4164.

3. States Are Still Not Attaining The Goals And Purposes Of The CWA.

States continue to struggle to implement (and some actively resist) their Clean Water Act responsibilities to set standards, assess water quality, and issue and enforce permits to limit pollutants, with the result that our waters still do not attain basic standards of cleanliness and protection. EPA's most recent summary of states' reported water quality data shows not only that states have a poor record of assessment with only a fraction of waters assessed, but also that 53% of assessed rivers and streams, 68% of assessed lakes, reservoirs, and ponds, and 78% of assessed bays/estuaries are failing to meet one or more water quality standards.[4] Toxics are still discharged into our waters and agricultural discharges are almost wholly unregulated, accounting for almost half of the pollution entering waterways, and accounting for a significant portion of the waters that currently fail to meet basic standards of cleanliness (including the hypoxia problem in the Gulf and toxic algae blooms in lakes, including Lake Erie). *See, e.g.*, Michael Wines, "Behind Toledo's Water Crisis, a Long-Troubled Lake Erie," *New York Times* (Aug. 4, 2014), https://www.nytimes.com/2014/08/05/us/lifting-ban-toledo-says-its-water-is-safe-to-drink-again.html (discussing Toledo's closure of water supply due to toxic algal blooms in 2014).

Wetlands also continue to suffer, and have been declining more rapidly in recent years. In 1989, the U.S. Fish and Wildlife Service informed Congress that since the 1700s, twenty-two states had lost more than 50% of their wetland acreage, ten states in the Midwest and coastal areas had lost more than 70%, and California had lost 91%, with attendant disastrous results for clean water. *See* Dahl T.E., Wetland Losses Since the Revolution, U.S. Fish and Wildlife Service at 16-17 (1990), https://www.fws.gov/wetlands/Documents%5CWetlands-Loss-Since-the-Revolution.pdf. Against this historical backdrop of substantial losses, we are currently witnessing even more rapid declines in our wetland acreage. In the last comprehensive report for wetlands published in 2011, the U.S. Fish and Wildlife Service reported that the rate of annual wetland loss increased between 2004 and 2009, reversing the decades-long trend of decreases in annual wetland loss, and representing a 140% increase in the wetland loss rate compared with the prior reporting period. *See* Dahl T.E., *Status and Trends of Wetlands in the Coterminous United*

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[4] EPA, National Summary of State Information (last updated April 8, 2019), http://ofmpub.epa.gov/waters10/attains_nation_cy.control. *See also* EPA, Nat'l Rivers and Streams Assessment 2008-2009: A Collaborative Survey, Draft at 23 (Feb. 2013) (attached as Ex. A), where EPA reports that as of 2013, their data from 2008-2009 indicated 55% of the waters assessed exhibited poor conditions and only 21% were classified as "good." The results by region were even more disappointing with 63% of the waters in the eastern highlands classified as poor and 58% classified as poor in the plains and lowlands states. *Id*. These numbers continue to disappoint, even though EPA lowered these numbers slightly in the final report published in March 2016, reporting that 46% of waters were in poor condition and 28% in good condition, and 50% of waters were in poor condition in eastern highlands and plains and lowlands states. EPA, Nat'l Rivers and Streams Assessment 2008-2009: A Collaborative Survey at 25 (March 2016) (attached as Ex. B).

States 2004-2009, Report to Congress, U.S. Dep't of Interior, Fish and Wildlife Service, at 45 (2011) (attached as Ex. C). Our coastal wetlands, which filter contaminated runoff from urban areas and agriculture and protect coasts from storms, experienced a 25% increase in the rate of wetland loss from 2004-2009, compared with the previous reporting period. USFWS, Status and Trends of Wetlands in the Coastal Watersheds of the Conterminous United States, 2004 to 2009 at 1-2 (2013) (attached as Ex. D). Even when wetland acres are not lost, they are often degraded, losing functions as wildlife habitat, flood control and water quality control.

EPA and Congress are well aware that the state of our waters is poor. In 2017, EPA reported to Congress that over 46% of the nation's rivers and streams were in poor biological condition (with the percentage even higher in some regions) and 32% of remaining wetlands were in poor biological condition. EPA, *National Water Quality Inventory: Report to Congress* at 2 (Aug. 2017) (attached as Ex. E). These figures call for an increase in CWA protections, not a decrease.

4. The Agencies' Claim That The Clean Water Act's Regulatory Mechanisms Are Divorced From Its Purpose Have No Foundation In The Law.

There is no support in the law for the Agencies' attempt to create a false distinction between the Clean Water Act's stated purpose and its regulatory mechanisms. 84 Fed. Reg. at 4163-64, 4169. Congress' stated intent and purpose for the Act is to preserve and protect the chemical, physical and biological integrity of the Nation's waters. 33 U.S.C. § 1251. The Act's regulatory mechanisms are designed to fulfill that purpose and to do so across waters. *See, e.g.*, 33 U.S.C. § 1313(c)(2)(A) (water quality standards must take into consideration waters' "use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also tak[e] into consideration their use and value for navigation"); *id*. § 1311(a) (prohibiting the discharge of any pollutant).

The Agencies' attempt to strip the overall objective of any meaning by re-defining it as a mere "goal" for non-regulatory programs, 84 Fed. Reg. at 4169; *see also id*. at 4163-64 and n.18, is contradicted by the Clean Water Act itself and by the Clean Water Act's legislative history. *See, in particular,* Senator Edmond Muskie linking the overall purpose of the Act to its regulatory programs: "The Federal Water Pollution Control Act Amendments of 1972, for example, charge the Administrator of EPA with a direct mandate to regulate the discharge of pollutants into the waters of the United States. The sole purpose of the Act is to establish a detailed regulatory mechanism for restoring and maintaining the chemical, physical, and biological integrity of the Nation's waters." CWA Legislative History, Senate Consideration of the Report of the Conference Committee at 181 (Oct. 4 1972) (statement of Sen. Muskie). In justifying anticipated costs associated with the then bill, Senator Muskie also explained that the objective to restore the chemical, physical, and biological integrity of the Nation's waters is substantive and serious, stating that the objectives "are not merely the pious declarations that Congress so often makes in passing its laws; on the contrary, this is literally a life or death proposition for the Nation." *Id*. at 164. The Agencies' false distinction between the objective to restore the Nation's waters via non-regulatory programs on the one hand, and the restoration of

navigable waters via regulatory programs on the other hand, contradicts the text and legislative history of the Clean Water Act and is simply a naked attempt to justify the cramped and illegal restrictions on the application of the Clean Water Act through the Dirty Water Rule.

5. Cooperative Federalism Requires A Federal Floor For Protecting The Nation's Water Resources, Allowing States To Be More, But Not Less, Stringent.

While Congress preserved and directed a role for states in carrying out the intent and requirements of the Clean Water Act, giving them the first obligation and authority to develop water quality standards and the ability to be delegated permit authority, Congress made plain that state obligations and authorities are *always* subject to the backstop of EPA review. Congress also was clear that the federal law sets the Clean Water Act minimum for water quality standards, permitting, and effluent limits in the effort to address previous shortcomings in state-based clean water efforts. *See* 33 U.S.C. §§ 1313, 1314, 1316, and 1342. The cooperative federalism concept was based in minimum federal requirements and standards for all the Nation's waters, overseen by a strong federal agency backstop. States are required to adopt water quality standards, subject to EPA review and approval, for all waters that are protective of fishing, swimming, public health, aquatic life, and all the uses to which we put our waters. *Id*. § 1313(c) and (d). States may be delegated authority over permitting programs in the Clean Water Act, but again they are subject to certain federal minimums and oversight by the federal agencies. *See id*. §§ 1342(b)-(d) and 1344(g)-(j). As to any one of these requirements, states can always be more protective than the federal minimums. *See Montgomery Envtl. Coal. v. Costle*, 646 F.2d 568, 574-575 (D.C. Cir. 1980).

The Agencies' and states' arguments that broad protections under the Clean Water Act are an intrusion on that structure and/or on states' rights, and that states can absorb losses in federal protections by strengthening their state protections, is also shown to be false by examination of the applicable state laws themselves. Seven to nine states have laws that prohibit the state from adopting any protections more broadly applicable or more protective than federal law.[5] Another approximately nineteen states would allow more stringent or broad protections, but erect barriers to doing so with the result that no more protective requirements are adopted (or likely to be adopted).[6] Five states do not even adopt the "no net loss" goal for wetlands that has been an integral part of attempts to protect our wetland resources under the Clean Water Act since the first President Bush.[7] Most states (thirty) have no program for permitting in so-called "isolated" wetlands, meaning any wetland that is carved out of the Clean Water Act by virtue of the Dirty Water Rule will no longer be protected by any permitting program in those states.[8]

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[5] EPA and Dep't of the Army, *Appendices to the Resource and Programmatic Assessment for the Proposed Revised Definition of "Waters of the United States,"* (Dec. 11, 2018).
[6] *See id*.
[7] *See id*.
[8] *See id*.

Most states (thirty-three) have no wetland monitoring or assessment program.[9] Even a cursory look at the applicable state laws shows that without the Clean Water Act, wetland and waters protections will be greatly reduced with significantly more waters and wetlands at risk of pollution, destruction, and/or degradation. The federal component of "cooperative federalism" is critical to the protection of the Nation's water resources.

B. The Agencies Will Foster Further Uncertainty With This Action.

The Agencies claim that many of the new definitions and exclusions in the Dirty Water Rule will lead to more "regulatory certainty" and/or ease of application of the rule. *See, e.g.*, 84 Fed. Reg. at 4169, 4194, 4197. However, the Agencies' claims are empty when one reviews the details of the Dirty Water Rule. As discussed in detail below, a number of the new definitions (*e.g.*, "typical year") are non-scientific and utterly opaque. Further, in its effort to push more waterbodies out from the protections of the Clean Water Act, the Agencies have created the need to assess rain and snow records, records of multiple years, and to make subjective judgments about whether a dry water body is intermittent or just ephemeral, or maybe even a perennial water in a dry year. All of these individual judgments, based on data that may not even yet exist, will create substantial new uncertainty about which waters are protected.[10]

Further, the Agencies' abrupt about-faces regarding the definition of "waters of the United States," are dizzying. In less than four years, the Agencies have finalized the Clean Water Rule, announced an intent to repeal and replace the Clean Water Rule, proposed to repeal the Clean Water Rule outright and recodify the pre-2015 regulations, proposed and finalized a two-year inapplicability period instead of a repeal (which has been found illegal by two federal

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[9] *See id*.

[10] The Agencies' idea of allowing states, tribes, and other federal agencies to create new geospatial datasets identifying all waters of the U.S. and all excluded waters, *id*. at 4155-56, 4198, would fail to remedy the uncertainty and would lead to the loss of protections for waters that Congress intended to protect. Even if such datasets are theoretically possible (which is unclear due to gaps in national hydrology mapping), they could categorically list all waters as either included or excluded, which would destroy the ability of the Agencies to make science-based judgments regarding the connectivity of waters. Furthermore, because jurisdictional determinations under the Dirty Water Rule are based in the permanence of surface water, but such permanence is constantly changing due to alterations in local climates (especially in this time of climate change), any databases purporting to identify waters of the U.S. would constantly become out of date. In addition, the entire process of making jurisdictional determinations could become obsolete, leaving our waters subject to polluting activities without any individualized review of the nature of the waters on a site. The absence of a water body on a dataset could potentially be used as a defense to a claim of an unpermitted discharge. Finally, if states are permitted to create their own datasets within their borders, there would almost certainly be a race to the bottom, with states competing to "delist" as many water bodies as possible in order to attract industry. The Clean Water Groups are strongly opposed to the Agencies' proposal of a future effort to create geospatial datasets identifying waters of the U.S.

courts), and now have created an entirely new rule which abandons the significant nexus test that has been adopted by all courts that have addressed it as well as by the Agencies. The Agencies have done nothing but sow regulatory chaos with these numerous reversals of position, leaving the Nation's waters significantly less protected as the outcome.

C. There Was No "Confusion" Over The Clean Water Rule.

In addition, the Agencies' claim that there is stakeholder confusion regarding the scope of the 2015 Rule is unsupported by the record. 84 Fed. Reg. at 4197. In an attempt to support this assertion, the Agencies cull a handful of statements from litigation over the 2015 Rule. However, most of these statements actually demonstrate *disagreement* with the 2015 Rule, not uncertainty. As an example, the Agencies point to a statement made by certain states in a brief before the Sixth Circuit, in which the states argued that the 2015 Rule extends "'jurisdiction to virtually every potentially wet area of the country.'" 84 Fed. Reg. at 4197. The Agencies' attempt to twist this hyperbolic statement into an assertion of regulatory uncertainty is misleading and incorrect. The statement actually demonstrates a level of certainty (albeit an incorrect certainty) regarding how the 2015 Rule applies, as it expresses discontent with the purportedly broad scope of that application. Furthermore, in other portions of the proposed rule, the Agencies point to confusion with the *pre*-2015 regulatory regime, without acknowledging that the 2015 Clean Water Rule was promulgated in large part to address that uncertainty and did in fact create substantially more certainty regarding the scope of protected waters. *See, e.g., id.* at 4170, 4179.

Finally, the Agencies continue to assert the confusion caused by litigation over the 2015 Rule is a reason supporting the proposed rule. *Id.* This is not a reason for replacing a rule. There is often litigation over rules, but that litigation is not and cannot be a reason, on its own, to simply abandon a rule and replace it with a dramatic policy reversal. Facts and issues that arise in litigation may contribute to an agency reconsidering a position, but the existence of litigation alone cannot serve that purpose. If that were the case, then the best-funded entity who may have the most to gain from forestalling legitimate regulation (or the most litigious and belligerent party) would have incentive and be rewarded for highly obstructionist actions. This is not how the APA works, nor should it. Moreover, the Agencies ignore the likelihood that their proposed actions will prompt new litigation and all the uncertainties that may flow from there.

The Ninth Circuit held that an agency action violated the APA in a similar case involving a challenge to the agencies' move to exempt the entire Tongass National Forest in Alaska from the Roadless Rule, *Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 970 (9th Cir. 2015), cert. denied sub nom. *Alaska v. Organized Vill. of Kake, Alaska*, 136 S. Ct. 1509 (2016). In promulgating the "Tongass exemption" the U.S. Department of Agriculture claimed that its rule would "reduce[] the potential for conflicts regardless of the disposition of the various lawsuits" over the Roadless Rule. *Id.* But this claim was easily belied by the subsequent turn of events: the Tongass Exemption "predictably led to [another] lawsuit, and did not even prevent a separate attack by Alaska on the Roadless Rule itself." *Id.* "At most," the Ninth Circuit found, "the Department deliberately traded one lawsuit for another." *Id.* The same is true here. The

foregoing and forthcoming discussions demonstrate that the proposed actions are, at a minimum, contrary to the APA and other statutes and are likely to be challenged in court. The initiation of new litigation would again subject the nationwide interpretation of the "waters of the United States" to procedural uncertainty and confusion. In light of these uncertainties, the Agencies' purported goal of reducing uncertainty appears to be a pretext for simply repealing and replacing 2015 Clean Water Rule without bothering to provide a substantive, rational justification for that decision.

II. THE DIRTY WATER RULE IS CONTRARY TO CASE LAW THAT DICTATES BROAD APPLICATION OF THE CLEAN WATER ACT WITH A GROUNDING IN SCIENCE.

The Dirty Water Rule is inconsistent with long-standing case law interpreting the scope of the Clean Water Act. Consistent with Congress' vision, for nearly three decades the Agencies followed this case law and implemented the Clean Water Act to fully and broadly protect the Nation's waters, including tributaries and wetlands. Yet, the Agencies are now reversing their years of broad protection and proposing a rule that conflicts with case law.

Immediately following passage of the Act, the Corps adopted regulations protecting only tidal and navigable-in-fact waters previously regulated, but a court quickly rejected that narrow interpretation, *Nat. Res. Def. Council, Inc. v. Callaway*, 392 F. Supp. 685, 686 (D.D.C. 1975), holding that the Corps was "without authority to amend or change the statutory definition of navigable waters," ordering regulations "recognizing the full regulatory mandate" of the Act. Courts have consistently found, both before and after the Supreme Court's decision in *Rapanos v. U.S.*, 547 U.S. at 779-81, that Congress intended to "occupy the field" of protecting waters; that the Clean Water Act was intended to wholly supplant the law that came before; that Congress intended to regulate the discharge of pollutants into non-navigable tributaries and adjacent wetlands because anything less leaves even traditionally navigable waters unprotected; and that Congress "knew exactly what it was doing" when it defined "navigable waters" broadly to mean the "waters of the United States." *U.S. v. Ashland Oil & Transp. Co.*, 504 F.2d 1317, 1321,1324-25 (6th Cir. 1974); *see also, e.g., City of Milwaukee v. Illinois and Michigan*, 451 U.S. 304, 317-19 (1981); *Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 22 (1981) (existing statutory scheme of state control and incentives was completely revised by Clean Water Act); *U.S. v. Hubenka*, 438 F.3d 1026, 1030-1032 (10th Cir. 2006); *U.S. v. HVI Cat Canyon, Inc.*, 213 F. Supp. 3d 1249, 1268 (C.D. Cal. 2016) (citing *Leslie Salt Co. v. Froehlke*, 578 F.2d 742, 754-55 (9th Cir. 1978), wherein the Circuit Court held that "navigable waters" must be given the broadest possible constitutional interpretation). The Supreme Court recognized the Clean Water Act's broad scope when it upheld the Act's application to adjacent wetlands in *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 132 (1985), observing that the Clean Water Act incorporates a "broad, systemic view of the goal of maintaining and improving water quality." The Court also noted Congress' determination that "[p]rotection of aquatic ecosystems . . . demanded broad federal authority to control pollution, for '[w]ater moves in hydrologic cycles and it is essential that discharge of pollutants be controlled at the source.'" *Id.* at 132-33 (quoting S. Rep. No. 92-414 at 77).

Thirty years later, after decades of successful Clean Water Act implementation and improving the status of the Nation's waters, two cases created some confusion over the scope of the Act's coverage. In *Solid Waste Agency of Northern Cook County* ("*SWANCC*") *v. United States Army Corps of Engineers*, 531 U.S. 159, 162, 164 (2001), the Court ruled that the Agencies' "Migratory Bird Rule" could not be used to extend the reach of the Act to "an abandoned sand and gravel pit." Then, in *Rapanos*, the Court issued a fractured opinion with no majority. A four-Justice plurality authored by Justice Scalia proposed one test for determining whether a water body is a "water of the United States"; Justice Kennedy, concurring in the judgment, proposed another, commonly referred to as the "significant nexus" test; and four dissenting Justices would have left the Agencies' definition in place, but also said they would uphold protection for waters satisfying *either* the plurality's or Justice Kennedy's test. *Rapanos*, 547 U.S. at 810 (Stevens, J., dissenting). More specifically, Justice Kennedy concluded that the Clean Water Act protects wetlands with a "significant nexus" to waters traditionally considered navigable. *Id*. at 759, 787. Such nexus exists where the water, including wetlands, "either alone or in combination with similarly situated lands in the region, significantly affect the chemical, physical, and biological integrity of other covered waters more readily understood as 'navigable.'" *Id*. at 780. Justice Scalia took a much narrower view of Clean Water Act jurisdiction, but in a few respects, his approach would find jurisdiction in instances where Justice Kennedy might not. *Id.* at 732-36 (discussing continuously flowing waters). The four justices in the *Rapanos* dissent held that they would uphold Clean Water Act jurisdiction in any case that satisfied *either* Justice Kennedy's or Justice Scalia's tests. *Id.* at 807, 810, n.14. This meant that waters that satisfied either of those tests would have the votes of five or more justices to support jurisdiction. Despite the disagreement on specifics, even the narrowest provisions in Justice Scalia's opinion in *Rapanos* recognizes that in passing the Clean Water Act, Congress intended to cover a much broader set of waters than had earlier been the case or than was traditionally considered "navigable." *Id.* at 731. The Court remanded, for further review, the Corps' application of the Act to four wetlands "lying near ditches or man-made drains that eventually empty into traditional navigable waters." Neither *SWANCC* nor *Rapanos* invalidated any specific regulatory provision.

All of the Circuit Courts that have addressed the issue of Clean Water Act jurisdiction following *Rapanos* have applied Justice Kennedy's significant nexus analysis or have adopted an even broader application of the Clean Water Act's protections: that waters that meet *either* Justice Kennedy's or Justice Scalia's approach must be considered waters of the U.S., protected by the Clean Water Act. *U.S. v. Bailey*, 571 F.3d 791, 799 (8th Cir. 2009); *see also U.S. v. Cundiff*, 555 F.3d 200, 210 (6th Cir. 2009) and *U.S. v. Johnson*, 467 F.3d 56, 65 (1st Cir. 2006) (if either plurality or Justice Kennedy's test is met, there is a "water of the United States"); *U.S. v. Gerke*, 464 F.3d 723, 724 (7th Cir. 2006) (Court looks to "significant nexus" standard as precedent); *U.S. v. Robison*, 505 F.3d 1208, 1222 (11th Cir. 2007) (same); *N. Cal. River Watch v. City of Healdsburg*, 496 F.3d 993, 999-1000 (9th Cir. 2007) (same) (followed by *N. Cal. River Watch v. Wilcox*, 633 F.3d 766, 781 (9th Cir. 2011) where court described Justice Kennedy's concurrence as the "controlling rule of law"); *U.S. v. Lucas*, 516 F.3d 316, 327 (5th Cir. 2008) (same); *U.S. v. Donovan*, 661 F.3d 174, 182 (3d Cir. 2011) (same); *see also Precon Dev. Corp.*,

Inc. v. U.S. Army Corps of Engineers, 633 F.3d 278, 289-90 (4th Cir. 2011) (parties agree and court adopts Justice Kennedy significant nexus test, approving of Corps definition of "adjacent") and *Upstate Forever v. Kinder Morgan Energy Partners, L.P.*, 887 F.3d 637, 649 n.10 (4th Cir. 2018) (characterizing Justice Kennedy's *Rapanos* concurrence as "controlling"). Yet, irrationally and unlawfully, the Agencies here propose a rule that is based on Justice Scalia's approach in order to follow an industry-motivated Executive Order signed by the newly inaugurated Trump administration. *See* 84 Fed. Reg. at 4154 ("This proposal is . . . intended to review and revise the definition of ''waters of the United States'' consistent with the Executive Order signed on February 28, 2017"); Executive Order 13778, 82 Fed. Reg. 12497 (March 3, 2017) (stating "the Administrator and the Assistant Secretary shall consider interpreting the term "navigable waters," as defined in 33 U.S.C. 1362(7), in a manner consistent with the opinion of Justice Antonin Scalia in *Rapanos v. United States*, 547 U.S. 715 (2006)."). The Agencies' new exclusive reliance on Justice Scalia's narrow application of the Clean Water Act is contrary to all of these Circuit Courts of Appeals' decisions that have interpreted and applied *Rapanos* since 2007.

Furthermore, the Agencies' reliance on Justice Scalia's opinion is contrary to the decision in *Marks v. United States*, 430 U.S. 188, 193 (1977). In *Marks v. United States*, the Supreme Court attempted to develop a doctrine for interpreting and implementing Supreme Court cases where a majority agreed only on the outcome of the case, but not on the grounds for the outcome. The *Marks* doctrine dictates that the holding of the Court, in those fractured circumstances, must be viewed as the narrowest position taken on the result of the case by concurring members of the Court. *Id.* This works fairly well in a situation where a subset of justices' reasoning fits within a broader decision of other concurring members; the narrower subset should control. In *Rapanos*, however, there is no subset of reasoning fitting neatly within another, but rather a set of overlapping opinions in the nature of a Venn diagram which concurred in the result that the matter must be remanded for further examination of jurisdiction with an eye to narrowing the test that the Corps had used previously. Either Justice Kennedy's or Justice Scalia's approach would narrow the test the Corps had been using, meaning that to have the least far-reaching or least extreme result on the existing application of Clean Water Act jurisdiction, under the *Marks* doctrine, future courts find jurisdiction where either test is met. Alternatively, it is the opinion of the dissent that stitches the whole together, allowing a five or more justice majority to find jurisdiction if either test is satisfied. These approaches have been applied by a number of Circuit Courts to find jurisdiction if either test is met. The remaining courts have determined that Justice Kennedy's significant nexus test is the narrowest holding in that it overlaps with Justice Scalia's holding (that is, it remands the matter to the Corps on the least extreme change or "narrowest grounds") and it is this test that the Agencies previously applied for the 2015 Clean Water Rule.

Therefore, under no application of *Marks* can Justice Scalia's test alone be considered the narrowest grounds on which the Court ruled in *Rapanos*, because Justice Scalia's test was the most extreme form of curtailment of jurisdiction under the Clean Water Act. This is consistent with the manner in which all of the Circuit Courts confronted with the question have addressed and implemented *Rapanos*. The *Marks* doctrine plainly stands for the principle that fractured decisions of the Court should not be read to have the furthest reaching or most extreme change in

the law or result, the matter before the Court. Yet that is the Agencies' argument here. The Agencies' sole reliance on Justice Scalia's opinion to significantly constrain and reduce Clean Water Act protections should be rejected as inconsistent with the overwhelming precedent from throughout the Circuit Courts of Appeal. It should also be rejected as inconsistent with the Agencies' adoption of a rule based on the significant nexus test just four years ago. This unsupported reinterpretation of case law is an arbitrary and capricious "'[u]nexplained inconsistency' in agency policy." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (internal citation omitted).

III. THE DIRTY WATER RULE IS CONTRARY TO THE SCIENCE AND THE RECORD BEFORE THE AGENCIES.

A. The Agencies Disregarded The Unrefuted Science Report And Irrationally Dictated A Rule Directly Contrary To The Science and Their Prior Policy.

The task of the Agencies in promulgating the 2015 Clean Water Rule, 80 Fed. Reg. 37,054 (June 29, 2015), was to demonstrate, through scientific evidence, which waters significantly influence traditionally navigable waters. They did so with an unprecedented review of the scientific literature with additional advice and comment of experts on topics from biology to hydrology to geology to oceanography to soil science, describing the many vital connections between tributaries, wetlands, and downstream waters. The report titled "Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence" (hereinafter the "Science Report") EPA-HQ-OW-0880-20858,[11] found extensive evidence that tributaries and wetlands play critical roles in maintaining the physical, chemical, and biological integrity of downstream waters. The Science Report was a state-of-the-art review and synthesis of the extensive scientific literature describing the numerous important connections between tributaries, adjacent waters, wetlands, and downstream waters. The Science Report synthesized the published, peer-reviewed scientific literature (*see, e.g.*, more than 70 pages of peer-reviewed literature references at end of Science Report) discussing the physical, chemical, and/or biological connectivity between various kinds of streams, wetlands, and other waters, and downstream water bodies. The final Science Report provides the scientific foundation for much of the final Clean Water Rule. 80 Fed. Reg. at 37,057, 37,065. The Agencies based the 2015

[11] Attached as Ex. F-1.

Clean Water Rule—the Rule the Agencies now seek to replace with this Dirty Water Rule—on the extensive evidence of the Science Report and its underpinnings.[12]

To justify the proposed replacement here of the 2015 Clean Water Rule (the Rule that is grounded in the Science Report), the Agencies must first disclose whether they intend to reverse the factual findings made in support of the 2015 Rule, and then provide a rationale for that choice. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("the requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position. An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books." (emphasis in original)). The public notice for the proposed rule does not satisfy this requirement.

The Agencies made extensive factual and legal findings in support of the Clean Water Rule, using what the Agencies found to be the "best available peer-reviewed science, public input, and the agencies' technical expertise and experience in implementing the statute." 80 Fed. Reg. at 37,055. The Agencies first affirmed their conclusion that the "significant nexus" standard is the appropriate test for determining which waters are "waters of the United States," based upon consensus case law and extensive scientific analysis and input. *Id.* at 37,056. Then, because "[t]he relevant science on the relationship and downstream effects of waters has advanced considerably in recent years," EPA's Office of Research and Development prepared the Science Report and the Agencies used this analysis to "characterize the nature and strength of the chemical, physical, and biological connections between upstream and downstream waters," and to develop a rule that would "greatly reduce[] the extent of waters subject to this individual review." *Id*. at 37,057.

The Science Report contained five major conclusions which the Agencies set forth in support of the Clean Water Rule: (1) that all tributary streams "exert a strong influence on the chemical, physical, and biological integrity of downstream waters"; (2) "that wetlands and open waters in riparian areas and floodplains are chemically, physically, and biologically integrated with rivers via functions that improve downstream water quality"; (3) that "[w]etlands and open waters in non-floodplain landscape settings ('non-floodplain wetlands') [also] provide numerous functions that benefit downstream water integrity"; (4) that connectivity between tributary

[12] Enclosed with these comments as Exhibits F1-F11 are copies of several key scientific and technical documents that were part of the record for the 2015 Clean Water Rule, and which are relevant to the present rulemaking as well, but which were excluded from the docket at EPA-HQ-OW-2018-0149. Exhibits F1-F11 do not include copies of the few 2015 Clean Water Rule scientific and technical documents that are included in the docket at EPA-HQ-OW-2018-0149. Our comments here include the entirety of the scientific and technical record for the Clean Water Rule including the work of the Science Advisory Panel and all drafts and the final published Science Report (including the documents published in the docket at EPA-HQ-OW-2018-0149 and those excluded but attached here in Exhibits F1-F11), as well as all widely available publications incorporated in the 2015 rulemaking docket by EPA's memorandum from Rose Kwok to the Water Docket (attached as Ex. F-10).

streams and wetlands and downstream jurisdictional waters "occurs along a gradient that can be described in terms of the frequency, duration, magnitude, timing, and rate of change of water, material, and biotic fluxes to downstream waters," and that, while the connectivity of stream channels and riparian/floodplain wetlands to downstream waters is unequivocal, "[t]he connectivity and effects of non-floodplain wetlands and open waters are more variable and thus more difficult to address solely from evidence available in peer-reviewed studies" (emphasis added); and (5) that the "incremental effects of individual streams and wetlands are cumulative across entire watersheds, and therefore, must be evaluated in context with other streams and wetlands" in the same watershed. *Id*. at 37,063-64.

Based on these conclusions in the Science Report, the Agencies went on to make specific findings in support of their decision to categorically define certain waters as jurisdictional in the 2015 Rule, and to define additional separate categories of waters that should be subject to case-specific significant nexus analysis to make a jurisdictional determination. They "conclude[d] that it is appropriate to assess the effects of [similarly situated] waters in combination based on the similarity of the functions they provide to the downstream water and their location in the watershed," *id*. at 37,065-66, and further found that the appropriate region for assessing "similarly situated" waters is "the watershed draining to the nearest traditional navigable water, interstate water, or the territorial sea." *Id*. at 37,067. They made findings as to a list of specific ecological functions that provide a nexus between upstream tributaries, wetlands, and other surface waters and downstream jurisdictional waters. *Id*. at 37,067-68.

Building on that foundation, the Agencies concluded that all tributaries (as specifically defined in the 2015 Rule) and all "adjacent" wetlands and surface waters (as specifically defined in the 2015 Rule) have a significant nexus to downstream jurisdictional waters. *Id*. at 37,068-70. The Agencies then identified two "exclusive circumstances" in which, based on the scientific literature, the Agencies should undertake a case-specific analysis of significant nexus. *Id*. at 37,071. One category comprises five types of wetlands: Prairie potholes, Carolina and Delmarva bays, pocosins, western vernal pools in California, and Texas coastal prairie wetlands. *Id*. The second category comprises all waters located within certain specific distances from downstream jurisdictional waters.

When an agency spends years studying a topic and developing an extensive factual record to support a selected policy, it cannot simply reverse course without identifying flaws in that previous analysis. In a similar case regarding the Bureau of Land Management's recent suspension of the methane "Waste Prevention Rule," the U.S. District Court for the Northern District of California explained the type of "detailed justification" that is necessary to support this type of policy reversal. The court explained that the agency

> must provide at least some basis – indeed, a "detailed justification" – to explain why it is changing course after its three years of study and deliberation resulting in the Waste Prevention Rule. New facts or evidence coming to light, considerations that BLM left out in its previous analysis, or some other concrete basis supported in the record – these are the types of "good reasons" that the law

> seeks. Instead, it appears that BLM is simply "casually ignoring" all of its previous findings and arbitrarily changing course.

Sierra Club v. Zinke, 286 F. Supp. 3d 1054, 1068 (N.D. Cal. 2018) ("*Zinke*") (internal citation omitted).

Here, the Agencies similarly "casually ignor[e]" their previous science-based findings and four years of study and deliberation that led to the passage of the 2015 Clean Water Rule. The Agencies point to no new scientific facts, no mistakes, and no considerations the Agencies neglected to include in their previous analysis. The Agencies only briefly reference the Science Report, acknowledging that EPA's Scientific Advisory Board ("SAB") "found that '[t]he literature review provides strong scientific support for the conclusion that ephemeral, intermittent, and perennial streams exert a strong influence on the character and functioning of downstream waters and that tributary streams are connected to downstream waters,'" 84 Fed Reg. at 4175-76, but then quickly dismissing these findings on the grounds that the SAB also recognized there is a hydrologic "gradient of connectivity" between tributaries, making ephemeral tributaries less likely to affect downstream waters. *Id*.; *see also id*. at 4187. This treatment of the science ignores the context of the SAB's remarks regarding the gradient of connectivity, which was to explain that connectivity is not a binary, presence/absence concept, but rather is a multidimensional function of the magnitude, duration, and frequencies of three different types of connections: surface water, subsurface groundwater, and the movement of biological organisms.[13] The Agencies' unstated implication that ephemeral tributaries are less deserving of protections because they are less connected also ignores the SAB's conclusions that even infrequent, small surface flows or subsurface flows from ephemeral tributaries can have important impacts on the biological and chemical integrity of downstream waters.[14] The Agencies do not dispute this scientific fact. In fact, the Agencies' economic analysis accompanying the proposed rule relies on the Science Report and a few of its sources for several sections of the economic analysis devoted to the importance of the ecosystem services provided by ephemeral streams. The economic analysis explains that ephemeral streams are important for replenishing groundwater for irrigation and drinking water supplies for communities in the arid western U.S.[15] It also includes details regarding how the shallow groundwater in ephemeral stream channels supports dense corridors of biologically diverse species even when the streams are dry, including Endangered Species Act-listed species and species that depend on the streams' microclimates and therefore cannot move to another habitat if their ephemeral stream home is

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[13] Letter to Gina McCarthy, SAB Review of the Draft EPA Report Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence at 53-54 (Oct. 17, 2014).
[14] *Id*. at 34.
[15] EPA and Dep't of the Army, *Economic Analysis for the Proposed Revised Definition of "Waters of the United States"* at 195-96 (Dec. 14, 2018), https://www.epa.gov/sites/production/files/2018-12/documents/wotusproposedrule_ea_final_2018-12-14.pdf.

destroyed.[16] Because the Agencies propose to remove Clean Water Act protections for ephemeral streams in spite of this reiteration of their import, it is clear the Agencies are simply ignoring their prior scientific findings without disputing their validity.

Finally, the Agencies also suggest that the Science Report's conclusions are unimportant because they are scientific, not legal. 84 Fed Reg. at 4175-76; *see also id*. at 4187. The Agencies even suggest they previously relied on scientific conclusions too extensively in developing the 2015 Rule. *Id*. at 4,197 and n. 34. This dismissal of science makes a mockery of the Clean Water Act's science-based objective to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a). Moreover, the Agencies did in fact interpret the Clean Water Act and Supreme Court rulings alongside the Science Report in the 2015 Rule; therefore, the Agencies must now explain why that legal interpretation based in sound science was impermissible or unreasonable.

In sum, as in *Zinke*, the Agencies failed to provide any concrete support in the record that would justify their policy reversal without reversing their careful scientific analysis. The Agencies must substantively address their prior scientific findings, and cannot simply pretend they never happened or are not highly relevant to the Agencies' proposed action here. The Science Report established the connectivity of many waters of the United States, even those that appear on the surface to be "isolated" or "ephemeral," and their importance to the overall "biological, chemical, and physical integrity of the Nation's waters." The Science Report is thorough and based upon the best, well-established principles of hydrology, geology, biology, chemistry and climate. It was developed with the assistance and review of the best scientists and researchers in these fields in the nation. Yet the Agencies throw this aside in a rush to satisfy polluters and the states that want to cater to them.

B. <u>The Agencies Ignored Relevant Scientific Developments Since The Science Report That Further Demonstrate The Dirty Water Rule Is Wholly Contrary To Science And Is Arbitrary and Capricious.</u>

In addition to the Agencies' dismissal of the 2015 Science Report and accompanying years of scientific research in the proposed rule, the Agencies have also ignored the wealth of

[16] *Id*.; *see also id*. at 183-184, 163-164 (describing adverse impacts to many species which rely on temporary, ephemeral waters, including specific threatened and endangered species).

relevant data, peer-reviewed scientific articles, and government reports published since 2015.[17] In so doing, the Agencies ignored "'an important aspect of the problem.'" *See State v. U.S. Bur. Of Land Mgt*., 2017 WL 4416409 at *11 (Oct. 4, 2017) (citing *Motor Vehicle Mfs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983)).

According to a 2017 peer-reviewed book entitled *Intermittent Rivers and Ephemeral Streams*, research into these non-perennial aquatic ecosystems has "burgeoned," in part due to the threats to the extremely rich biodiversity represented in these waters and the increasing commonality of them due to climate change.[18] These recent hydrology publications reinforce and strengthen our knowledge of the importance of ephemeral and intermittent streams, "isolated" wetlands, headwaters, groundwater, and fragile features like prairie potholes and vernal pools. They also reveal that in the face of increasing effects from climate change, more and more streams are going dry part of the year, wetlands are drying, and pollutant loads to waters are increasing. The studies reiterate that intermittent and ephemeral streams, as well as seasonal and "isolated" wetlands, also provide critical habitat for a diverse array of species, including endangered and threatened species. The Agencies' proposal to entirely remove protections for ephemeral streams (and to some extent intermittent streams), "isolated" wetlands, and other smaller but critically important waters not only ignores these studies, but affirmatively takes the opposite policy approach to what the science compels, excluding enormous percentages of waters from Clean Water Act protection without even using available national geodatabases to quantify the extent of their proposed jurisdictional changes.

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[17] The *only* scientific document cited in the Dirty Water Rule is the Science Report, which is ironic given that the Dirty Water Rule ignores or acts contrary to the Science Report's conclusions and recommendations. The Agencies do include a small number of scientific and technical articles in their "supporting documents" in the rulemaking docket – mostly economic studies, without any indication of how they were considered. While the titles of these articles and studies are listed in the docket, nineteen of the actual documents themselves are absent as of April 15, 2019, making it impossible for the public to consider these documents which are purportedly part of the record (list attached as Ex. K-1). The Agencies' failure to put the documents on which they relied into the record violates notice-and-comment under the APA. *See, e.g., Am. Radio Relay League v. FCC*, 524 F.3d 227, 236-240 (D.C. Cir. 2008) (finding that under APA § 553, an agency may not cherry-pick documents on which it relies for public review and that it must allow the public to review the technical studies upon which it relied). The Clean Water Groups were able to obtain copies of these missing documents, and attach them here (attached as Ex. K-2 – K-20). Moreover, the few scientific articles that are included in the docket would support a policy approach and rule directly opposite to the one chosen by the Agencies. For example, the Agencies include an article entitled *Temporary Streams in Temperate Zones: Recognizing, Monitoring and Restoring Transitional Aquatic-Terrestrial Ecosystems*, which explains that temporary streams are home to rare and endemic species and can even host more biodiversity than perennial streams. Such scientific knowledge calls for *more* protection of temporary streams, not less.

[18] *Intermittent Rivers and Ephemeral Streams: Ecology and Management*, Eds. Thibault Datry, Núria Bonada, and Andrew Boulton, Academic Press (2017).

Since 2015, numerous studies have been published, each one adding to the scientific evidence that smaller upstream waters are critical to the health of downstream waters. The following summaries include government reports, peer-reviewed hydrology studies, and related assessments that examine the state of our waters, predicted changes to waters due to climate change, connectivity between waters, or the critical ecological services provided by smaller and intermittent or ephemeral waters, all published between 2015 and 2019.[19] The publications do not represent a comprehensive scientific literature review, but rather comprise a sampling of the kinds of readily-available studies the Agencies failed to search for and failed to consider, which the Clean Water Groups found through a few hours of searching.

- **Fourth National Climate Assessment[20]**

The Fourth National Climate Assessment is a collection of scientific studies and assessments that summarizes the effects of climate change in the United States. With respect to water, the assessment outlines several ongoing adverse effects to water quantity and quality due to climate change, including increases in extreme and more intense storms, which in turn increases pollutant loads to surface waters and greater risk of algal blooms; greater risk of drought and increases in groundwater depletion rates in many areas due to higher temperatures, lack of precipitation, and expanded irrigation needs; decreases in snowmelt and streamflow in many areas; and increased flood risks due to either more extreme rains or sea level rise, or both. Agriculture and drinking water supplies rely on groundwater for more than 40% of their needs, yet aquifers in the U.S. have already been depleted over the last several decades and climate change is currently worsening these groundwater losses.

- **Marsh bird response to hydrologic alteration and restoration of wetlands in the boreal hardwood transition[21]**

This report summarizes the findings of a study of marsh bird use of boreal hardwood transition wetlands in Michigan, which provide significant breeding grounds for at-risk marsh birds.

- **Challenges, developments and perspectives in intermittent river ecology[22]**

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[19] These scientific articles and reports are attached to this comment letter in Exhibits G-1 – G-31. Our comments here include all of the attached documents in Exhibits G-1 – G-31.
[20] U.S. Global Change Research Program, 2018: *Impacts, Risks, and Adaptation in the United States: Fourth National Climate Assessment, Volume II*, Ch. 3, at 146-157 (attached as Ex. G-1).
[21] Michael J. Monfils and R. Gregory Corace, *Marsh bird response to hydrologic alteration and restoration of wetlands in the boreal hardwood transition*, Michigan Natural Features Inventory (2018) (attached as Ex. G-2).
[22] Thibault Datry et al., *Challenges, developments and perspectives in intermittent river ecology*, Freshwater Biology, 1171-1180 (2016) (attached as Ex. G-3).

This front matter article is an introduction to a special issue of *Freshwater Biology* which compiled thirteen articles focused on intermittent river ecology. The authors observe that "…more than half the channels comprising river networks globally cease to flow or dry periodically." Among other things, the articles note that climate change is increasing the prevalence of intermittent waters as more and more perennial waters begin to dry and become intermittent waters.

- **Regional climate change projections of streamflow characteristics in the Northeast and Midwest U.S.[23]**

This article predicts future streamflow changes in the Northeast and Midwest due to climate change. Specifically, the authors predict increases in winter precipitation (with more rain than snow) and to a lesser extent summer precipitation. The authors also explain there will be more intense storm events, with various accompanying changes for streamflows in different parts of the region, including increases in both low flow days and peak flow days.

- **Landscape metrics as predictors of hydrologic connectivity between Coastal Plain forested wetlands and streams[24]**

This article describes the seasonally changing nature of surface water connectivity of wetlands with nearby streams, using forested Delmarva bay wetlands as a case study.

- **Dissolved organic matter variations in coastal plain wetland watersheds: The integrated role of hydrological connectivity, land use, and seasonality[25]**

This study examines the importance of transport of dissolved organic matter from "geographically isolated" wetlands in the Delmarva peninsula to perennial streams via temporary, seasonal, surface water connections between the wetlands and streams.

- **A comparison of biotic groups as dry-phase indicators of ecological quality in intermittent rivers and ephemeral streams[26]**

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[23] Eleonora M.C. Demaria et al., *Regional climate change projections of streamflow characteristics in the Northeast and Midwest U.S.*, Journal of Hydrology: Regional Studies, 309-323 (2016) (attached as Ex. G-4).
[24] Steven M. Epting et al., *Landscape metrics as predictors of hydrologic connectivity between Coastal Plain forested wetlands and streams*, Hydrological Processes, 516-532 (2017) (attached as Ex. G-5).
[25] Jacob D. Hosen et al., *Dissolved organic matter variations in coastal plain wetland watersheds: The integrated role of hydrological connectivity, land use, and seasonality*, Hydrological Processes, 1664-1681 (2018) (attached as Ex. G-6).
[26] Rachel Stubbington et al., *A comparison of biotic groups as dry-phase indicators of ecological quality in intermittent rivers and ephemeral streams*, Ecological Indicators, 165-174 (2019) (attached as Ex. G-7).

This study analyzed the extent of dry-phase biological organisms in intermittent and ephemeral streams, including diatoms, aquatic plants, and aquatic fauna present during dry phases of these streams, in order to assess the health of the streams.

- **Ecological research and management of intermittent rivers: and historical review and future directions**[27]

This article summarizes major findings of scientific research on intermittent rivers and streams, including a "boom" in research demonstrating the important connections between these waters and downstream navigable waters in the U.S. after the Supreme Court's *Rapanos* decision.

- **U.S. Environmental Protection Agency Report on the Environment, Stream Flows**[28]

This report examines changes in stream flows in the U.S. from 1961–2016 at streams with U.S. Geological Survey stream gauge data throughout the country (which tend to be larger, perennial rivers and streams). The report finds that stream flows varied considerably since 1961, with wet and dry periods lasting for years at a time, and with more streams experiencing low flow volumes compared with a baseline of 1941–1960. EPA states that changes in flows can be caused by a number of factors including dams, water withdrawals and pumpings, land use changes, and climate and weather.

- **The National Rivers and Streams Assessment Fact Sheet**[29]

This EPA fact sheet summarizes the conditions of rivers and streams in the U.S., including the fact that 46% of river and stream miles are in poor biological condition and that this measure has been worsening in recent years with a 9% decline since a 2004 assessment, due to excess nutrient pollution among other stressors.

- **Modeling the potential impacts of climate change on the water table level of selected forested wetlands in the southeastern United States**[30]

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[27] Catherine Leigh et al., *Ecological research and management of intermittent rivers: an historical review and future directions*, Freshwater Biology, 1181-1199 (2016) (attached as Ex. G-8).
[28] EPA, Report on the Environment, Stream Flows (2018) (attached as Ex. G-9).
[29] EPA, The National Rivers and Streams Assessment 2008/2009 Fact Sheet (2016) (attached as Ex. G-10).
[30] Jie Zhu et al., *Modeling the potential impacts of climate change on the water table level of selected forested wetlands in the southeastern United States*, Hydrology and Earth System Sciences, 1-17 (2017) (attached as Ex. G-11).

This article examines the impacts of climate change on the hydrology of five kinds of forested wetlands in the southeastern U.S., including cypress ponds/swamps, Carolina bays, pine flatwoods, drained pocosins, and natural bottomland hardwood ecosystems. The authors found that climate change will cause drying in all five types of forested wetlands in the southeastern U.S.

- **An Evaluation Of Agricultural Tile Drainage Exposure And Effects To Wetland Species And Habitat Within Madison Wetland Management District, South Dakota**[31]

This Fish and Wildlife Service report evaluates the effects agricultural tile drainage is having on the U.S. prairie pothole region, including wetland loss and pollution of wetlands. The study assessed the levels of nutrients, pesticides, and other pollutants in the wetlands, as well as biological diversity and abundance, at Service-managed prairie pothole sites in South Dakota. The study results indicate agricultural tile drains can discharge pollutants to the wetlands in amounts that are likely harming wildlife, including waterfowl reproduction. The study authors encourage stronger regulation of tile drainage in order to protect these wetlands which are critical for waterfowl, waterbird, and other species, including Endangered Species Act-listed species. The acreage of wetlands in the prairie pothole region has already declined by 61%, and wetland losses continue due to tile drainage.

- **Geographically Isolated Wetlands: Rethinking a Misnomer**[32]

This article explains why the term "geographically isolated wetlands" is a scientifically inaccurate and confusing term, as wetlands surrounded by uplands are not isolated from other waters in a hydrological, chemical, or ecological sense.

- **Identification of Putative Geographically Isolated Wetlands of the Conterminous United States**[33]

This study used mapping tools to identify geographically isolated wetlands in the U.S., and found more than 8.3 million putative geographically isolated wetlands, representing about 16% of freshwater wetlands in the conterminous U.S.

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[31] USFWS Region 6, *An Evaluation Of Agricultural Tile Drainage Exposure And Effects To Wetland Species And Habitat Within Madison Wetland Management District, South Dakota* (2018) (attached as Ex. G-12).
[32] David Mushet et al., *Geographically Isolated Wetlands: Rethinking a Misnomer*, Wetlands, 423-431 (2015) (attached as Ex. G-13).
[33] Charles R. Lane and Ellen D'Amico, *Identification of Putative Geographically Isolated Wetlands of the Conterminous United States*, Journal of the American Water Resources Association, 705-722 (2016) (attached as Ex. G-14).

- **Geographically isolated wetlands are part of the hydrological landscape[34]**

This paper focuses on the effects of geographically isolated wetlands on flows in downstream waters. The authors note that geographically isolated wetlands "perform lag, sink, and source functions that can influence the chemical, physical, and/or biological integrities of downgradient waters, especially when considered in aggregate."

- **Department of Defense Strategic Environmental Research and Development Program Reports[35]**

This collection of three Department of Defense reports analyze the functions of intermittent and ephemeral streams to improve management and restoration of them on southwestern Department of Defense lands, and concludes it is important to conserve ephemeral streams in order to protect ecological diversity.

- **Bidirectional stream-groundwater flow in response to ephemeral and intermittent streamflow and groundwater seasonality[36]**

This article examines the connections between streams and groundwater and, among other conclusions, states that intermittent and ephemeral streams are important groundwater recharge and discharge areas.

- **Montana Prairie Wetlands and Intermittent/Ephemeral Streams: Hydrologic Needs Assessment for Healthy Watersheds[37]**

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[34] M.C. Rains et al., *Geographically isolated wetlands are part of the hydrological landscape*, Hydrological Processes, 153-160 (2016) (attached as Ex. G-15).
[35] David Cooper et al., *Watershed to Local Scale Characteristics and Function of Intermittent and Ephemeral Streams on Military Lands*, Department of Defense Strategic Environmental Research and Development Program (2015); Julian Olden and David Lytle, *Hydroecology of Intermittent and Ephemeral Streams: Will Landscape Connectivity Sustain Aquatic Organisms in a Changing Climate?*, Department of Defense Strategic Environmental Research and Development Program (2015); Juliet Stromberg et al., *Structure and Function of Ephemeral Streams in the Arid and Semiarid Southwest: Implications for Conservation and Management*, Department of Defense Strategic Environmental Research and Development Program (2015) (attached as Ex. G-16, parts 1, 2, and 3).
[36] Margaret A. Zimmer and Brian L. McGlynn, *Bidirectional stream-groundwater flow in response to ephemeral and intermittent streamflow and groundwater seasonality*, Hydrological Processes, 1-10 (2017) (attached as Ex. G-17).
[37] RTI International, *Montana Prairie Wetlands and Intermittent/Ephemeral Streams: Hydrologic Needs Assessment for Healthy Watersheds* (July 2015) (attached as Ex. G-18).

This study, prepared for EPA, tested how our alterations of prairie wetlands in Montana affect amphibians, and found that increases in human disturbance were correlated with decreases in amphibian diversity.

- **Delineation and Quantification of Wetland Depressions in the Prairie Pothole Region of North Dakota[38]**

This article describes a new method using high resolution light detection and ranging ("LiDAR") technology to quantify prairie pothole wetland depressions, including more advanced information about the depressions' ability to store water. This improved method for measuring prairie potholes will assist with conservation efforts centered around their ecological and hydrological import, including for flood mitigation.

- **New mapping techniques to estimate the preferential loss of small wetlands of prairie landscapes[39]**

This article presents a new method using LiDAR data and other techniques to improve the mapping of prairie potholes, which have historically been difficult to accurately map due to their small size and other factors. The authors note that accurate mapping is important for improving wetland policies, and prairie potholes provide critical ecosystem services just like more permanent and surface-connected wetlands do, including serving as groundwater sinks and sources, removing excess nutrient pollution, sequestering carbon, and providing floodwater control.

- **Midcontinent Prairie-Pothole Wetlands and Climate Change: An introduction to the Supplemental Issue[40]**

This introductory article for a special edition of *Wetlands* magazine devoted to prairie potholes and climate change summarizes a collection of research on the topic. The author notes that the prairie pothole region is one of the largest wetland complexes in North America, although 60–65% of the basins were lost to agriculture drainage by the mid-1980s. Wetland losses continue in this region despite knowledge of the importance of this area as waterfowl breeding habitat and knowledge of the many other ecosystem services these wetlands provide. The multiple threats to prairie potholes include climate change.

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[38] Qiusheng Wu and Charles R. Lane, *Delineation and Quantification of Wetland Depressions in the Prairie Pothole Region of North Dakota*, Wetlands (2016) (attached as Ex. G-19).
[39] J.N. Serran and I.F. Creed, *New mapping techniques to estimate the preferential loss of small wetlands of prairie landscapes*, Hydrological Processes (2015) (attached as Ex. G-20).
[40] David M. Mushet, *Midcontinent Prairie-Pothole Wetlands and Climate Change: an Introduction to the Supplemental Issue*, Wetlands, S223-S228 (2016) (attached as Ex. G-21).

- **Preparing for an uncertain future; migrating shorebird response to past climate fluctuations in the Prairie Potholes[41]**

This article uses past migratory shorebird data in the prairie pothole region to predict how shorebirds may react to future climate extremes in this region during migration. The article concludes that because migrating shorebirds have demonstrated a willingness to travel to different parts of the region to find their necessary habitat, one way we can mitigate the effects of climate change is to preserve a diverse array of wetlands throughout the entire prairie pothole region.

- **Interannual Water-level Fluctuations and the Vegetation of Prairie Potholes: Potential Impacts of Climate Change[42]**

This article examines how small changes in water depths, such as those caused by climate change, can shift prairie pothole wetlands to different "classes," or groups that are characterized by types of vegetation.

- **Abiotic habitat thresholds for salmonid over-summer survival in intermittent streams[43]**

This study highlights the importance of intermittent stream habitat for Endangered Species Act-listed salmonids, and addresses factors that can limit the fishes' survival in these intermittent waters. Specifically, the study finds that salmonid survival in intermittent waters is impacted by dissolved oxygen levels, the types and depths of pools left in dry times, and water temperature, among other things.

- **Clean Water Rule Spatial Analysis: A GIS-based scenario model for comparative analysis of the potential spatial extent of jurisdictional and non-jurisdictional wetlands[44]**

This report models the extent of Clean Water Act jurisdiction under three differing scenarios, using GIS technology and nationally available geodatabases. The three scenarios are: most restrictive (protects wetlands directly adjacent to perennial waters only), very restrictive

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[41] Valerie Steen et al., *Preparing for an uncertain future: migrating shorebird response to past climate fluctuations in the Prairie Potholes*, Ecosphere (2018) (attached as Ex. G-22).
[42] Arnold G. van der Valk and David M. Mushet, *Interannual Water-level Fluctuations and the Vegetation of Prairie Potholes: Potential Impacts of Climate Change*, Wetlands, 397-406 (2016) (attached as Ex. G-23).
[43] Cleo Woelfle-Erskine et al., *Abiotic habitat thresholds for salmonid over-summer survival in intermittent streams*, Ecosphere (2017) (attached as Ex. G-24).
[44] Roger Meyer and Andrew Robertson, *Clean Water Rule Spatial Analysis: A GIS-based scenario model for comparative analysis of the potential spatial extent of jurisdictional and non-jurisdictional wetlands*, St. Mary's University of Minnesota (2019) (attached as Ex. G-25).

(protects wetlands directly adjacent to perennial and intermittent waters only), and less restrictive (protects wetlands directly adjacent to perennial, intermittent, or ephemeral waters, or ditched or channelized streams). The report includes modeling results for three watershed case study sites: Cottonwood River Watershed, MN; South Platte Headwaters Watershed, CO; and Cimarron River Watershed, NM. In the Cottonwood River Watershed, 36% of wetland acreage would become non-jurisdictional under the most restrictive scenario, which is a 125% increase in non-jurisdictional wetland acreage compared with the less restrictive scenario. Under the very restrictive scenario, 21.9% of wetland acreage would become non-jurisdictional. In the South Platte Headwaters Watershed, 54.5% of wetland acreage would become non-jurisdictional under the most restrictive scenario, which is a 1,774% increase in non-jurisdictional wetland acreage compared with the less restrictive scenario. Under the very restrictive scenario, 15.3% of wetland acreage would become non-jurisdictional. In the Cimarron River Watershed, 68.8% of wetland acreage would become non-jurisdictional under the most restrictive scenario, which is a 502% increase in non-jurisdictional wetland acreage compared with the less restrictive scenario. Under the very restrictive scenario, 17.7% of wetland acreage would become non-jurisdictional.

- **An ecohydrological stream type classification of intermittent and ephemeral streams in the southwestern United States[45]**

This article presents an ecohydrological stream type classification tool for intermittent and ephemeral streams on arid and semi-arid Department of Defense lands in the southwestern U.S. Approximately 89% of the streams in this study of four military reservations had "permanent" flow for less than twelve days per year; as a result, the stream classifications were based not on flow permanence, but rather on the timing and magnitude of streamflow events, vegetation type, and geomorphology. The classification system is intended to be useful for Department of Defense land managers.

- **Characterizing the dynamics of surface water-groundwater interactions in intermittent and ephemeral streams using streambed thermal signatures[46]**

This study uses temperature measurements to garner information about the interactions between surface water and groundwater during temporary flow events in intermittent and ephemeral streams.

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[45] Lainie Levick et al., *An ecohydrological stream type classification of intermittent and ephemeral streams in the southwestern United States*, Journal of Arid Environments, 16-35 (2018) (attached as Ex. G-26).
[46] Gabriel C. Rau et al., *Characterizing the dynamics of surface water-groundwater interactions in intermittent and ephemeral streams using streambed thermal signatures*, Advances in Water Resources (2017) (attached as Ex. G-27).

- **Southwestern Intermittent and Ephemeral Stream Connectivity**[47]

This article provides a summary of the various kinds of connectivity between ephemeral and intermittent streams and perennial or intermittent rivers. The paper summarizes scientific research on the evidence of connectivity between these waters and the factors affecting the connectivity in the southwestern U.S., including an in-depth case study of the San Pedro River Basin. The authors note that intermittent and ephemeral streams function in many of the same ways as perennial streams, and are biodiversity hotspots with abundant and diverse flora and fauna along their corridors, serving as biological connectors for migration and movement of wildlife and plant matter both during dry and wet phases. In addition to this biological and ecological connectivity, ephemeral and intermittent streams supply water and nutrients to larger waters, have long-distance sediment and chemical connections to perennial stream reaches, and connect to groundwater through water infiltration for groundwater recharging during wet times. These important functions and kinds of connectivity are especially critical in the southwestern U.S. where, according to recent data from the National Hydrography Dataset, "94%, 89%, 88%, and 79% of the streams in Arizona, Nevada, New Mexico, and Utah, respectively, are intermittent or ephemeral."

- **Hydrologic Influences on Plant Community Structure in Vernal Pools of Northeastern California**[48]

This study, based in northeastern California, quantified the roles that water depth and inundation time periods in vernal pools play with respect to plant distribution. This improved understanding of the relationships between water and plants in these seasonal wetlands is intended to promote management of the wetlands for diverse plant communities, including plants that are specially adapted to vernal pools.

- **Headwater Streams and Wetlands are Critical for Sustaining Fish, Fisheries, and Ecosystem Services**[49]

This article collects scientific research and knowledge that demonstrates the ecological importance of headwater streams and wetlands, meaning portions of a river basin that contribute to downstream navigable waters – a category that comprises 79% of river length in the conterminous U.S. The authors explain why threatened and endangered fish and other aquatic species will become more imperiled if the proposed 2018/2019 definition of Waters of the U.S. is finalized. The authors summarize: "some examples of headwaters that would not meet Scalia's definition and could lose protection under the new rule include the karst

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[47] D.C. Goodrich et al., *Southwestern Intermittent and Ephemeral Stream Connectivity*, Journal of the American Water Resources Association, 1-23 (2018) (attached as Ex. G-28).
[48] Meredith C. Gosejohan et al., *Hydrologic Influences on Plant Community Structure in Vernal Pools of Northeastern California*, Wetlands (2017) (attached as Ex. G-29).
[49] Susan A.R. Colvin et al., *Headwater Streams and Wetlands are Critical for Sustaining Fish, Fisheries, and Ecosystem Services*, American Fisheries Society (2018) (attached as Ex. G-30).

features critically important to threatened and endangered cavefish (Figure 5), intermittent streams used by imperiled fish for spawning and early rearing (Figure 8), and intermittent side channels and floodplains that provide critical habitat for juvenile salmon." The loss of fisheries and other ecosystem services would carry adverse economic and cultural consequences, as well as biological ones. The ecosystem services of headwaters are estimated to have a $15.7 trillion/year value in the conterminous U.S. and Hawaii, and headwaters provide recreation, ecotourism, aesthetic, spiritual and socio-cultural value, including for many Native American tribes which have integral cultural and spiritual ties with salmon or other fish. In conclusion, the authors recommend that the Agencies conduct a "formal ecological and economic risk assessment" in order to quantify the expected effects of the proposed rule.

- **Mapping of Non-Perennial and Ephemeral Streams in the Santa Ana Region**[50]

This report notes that ephemeral streams are common in southern California and that they significantly impact the quantity and quality of downstream waters, yet existing maps are insufficient to identify them. In modeling non-perennial streams in southern California, the authors noted that stream flow varies substantially over seasons within a single year and with climate changes over multiple years; as a result, "[s]tatic classes of flow duration (e.g., 'perennial,' 'non-perennial') are unlikely to characterize a stream accurately."

C. The Agencies Wholly Disregarded The Effects Of Climate Change On Waters Of The U.S. And Have Therefore Failed To Ensure Full Protections In The Face Of Climate Change and Ignored an Important Aspect of the Problem.

The Agencies also entirely ignore the effects of climate change on waterways throughout the country in their proposed rule. The Agencies do not even acknowledge the existence of climate change in the proposed rule, much less apply the known effects to their policy analysis. The words "climate change" do not appear in the proposed rule, economic analysis, or resource and programmatic assessment. Yet, the effects of climate change will substantially affect the flow conditions, pollution levels, and temperatures of waters in the United States, which will in turn impact the extent of adverse ecological and economic effects of the proposed rule.

First, the Agencies' reliance on a thirty-year rolling period to measure a "typical year" for purposes of classifying tributaries as perennial, intermittent, or ephemeral,[51] will skew the regulation of tributaries under the Clean Water Act towards past conditions that are much different than the ones we are currently experiencing and will continue to experience due to the effects of climate change. Specifically, scientists predict increasing numbers of perennial

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[50] Marcus Beck et al., *Mapping of Non-Perennial and Ephemeral Streams in the Santa Ana Region*, Southern California Coastal Water Research Project (Dec. 2017) (attached as Ex. G-31).
[51] *See, e.g.*, 84 Fed Reg. at 4219.

streams will become intermittent or ephemeral due to the effects of climate change,[52] meaning more streams would lose protections under the Agencies' proposed rule as time passes. At the same time, in the northeastern and midwestern U.S., precipitation levels are projected to rise.[53] These predicted changes to average annual precipitation are not insignificant; therefore, a jurisdictional definition of tributaries that relies on past precipitation averages will inevitably not reflect the current, on the ground, circumstances. None of these highly relevant considerations regarding changes to precipitation and stream flow were considered in the Agencies' proposed rule.

Second, the Agencies failed to consider or address the additive adverse ecosystem effects caused by removing Clean Water Act protections for many waters at a time when those waters are already facing grave threats due to climate change. These threats include increases in pollution loads, higher water temperatures, more frequent algal blooms, greater groundwater depletion rates, more frequent droughts, increases in irrigation needs, and other consequences of climate change.[54] Nearly half of the river and stream miles in this country are already biologically impaired,[55] and the effects of climate change will exacerbate these impairments unless greater protections are implemented. In addition, the kinds of wetlands that are most at risk from the Agencies' proposed rule are also at increased risk from climate change. For example, all five types of forested wetlands in the southeastern U.S. are susceptible to drying due to climate change.[56] In addition, prairie potholes may experience changes in water depths due to climate change, with accompanying threats to habitat for waterfowl and migrating shorebirds.[57] However, instead of increasing protections due to the extra burdens of climate change, the Agencies irrationally here propose the opposite approach.

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[52] Thibault Datry et al., *Challenges, developments and perspectives in intermittent river ecology*, Freshwater Biology, 1171-1180 (2016) (attached as Ex. G-3).
[53] Eleonora M.C. Demaria et al., *Regional climate change projections of streamflow characteristics in the Northeast and Midwest U.S.*, Journal of Hydrology: Regional Studies, 309-323 (2016) (attached as Ex. G-4).
[54] U.S. Global Change Research Program, 2018: *Impacts, Risks, and Adaptation in the United States: Fourth National Climate Assessment, Volume II*, Ch. 3, at 146-157 (attached as Ex. G-1).
[55] EPA, *National Water Quality Inventory: Report to Congress* (2017) (attached as Ex. E).
[56] Jie Zhu et al., *Modeling the potential impacts of climate change on the water table level of selected forested wetlands in the southeastern United States*, Hydrology and Earth System Sciences, 1-17 (2017) (attached as Ex. G-11).
[57] David M. Mushet, *Midcontinent Prairie-Pothole Wetlands and Climate Change: an Introduction to the Supplemental Issue*, Wetlands, S223-S228 (2016) (attached as Ex. G-21); Valerie Steen et al., *Preparing for an uncertain future: migrating shorebird response to past climate fluctuations in the Prairie Potholes*, Ecosphere (2018) (attached as Ex. G-22); Arnold G. van der Valk and David M. Mushet, *Interannual Water-level Fluctuations and the Vegetation of Prairie Potholes: Potential Impacts of Climate Change*, Wetlands, 397-406 (2016) (attached as Ex. G-23).

IV. SPECIFIC PROVISIONS OF THE DIRTY WATER RULE ARE CONTRARY TO THE CLEAN WATER ACT AND TO SCIENCE, ARE ARBITRARY AND CAPRICIOUS, AND ARE BAD POLICY.

This section of the comments will address specific provisions of the Dirty Water Rule and how each is contrary to law and/or the record. Each of these illustrate that, by rejecting significant nexus as the applicable measure of jurisdiction and by adopting the much narrower Justice Scalia test, the Dirty Water Rule is contrary to established law and science.

A. Human Alterations.

One comment applies almost across the board: the Agencies' repeated efforts to allow human alterations to waters (often alterations made with the permission of the Corps) will start a chain reaction of cutting these waters off from their status as waters of the U.S., which will have cascading effects of many connected waters losing all protections under the Clean Water Act. This effect, which cuts across multiple categories of waters in the Dirty Water Rule, is perhaps the most insidious, most cynical, and most contrary to the intent and purpose of the Clean Water Act. It will continue to drive down protections for waters, squeezing them out of the coverage of the Clean Water Act for decades to come.

For example, the Dirty Water Rule provides that wetlands that have been "cut off" from other waters by a road will lose Clean Water Act protection. Or, tributaries that might otherwise qualify as a water of the U.S. will lose that protected status if they are cut off by a human alteration such as a ditch or levee or dam that disrupts visible surface flows. In fact, under the Dirty Water Rule, levees or dams or similar impediments can cut any number of waters out of the Act by disrupting surface flows; even if flows plainly continue through groundwater or seepage or overtopping in floods, if those flows are not visible or frequent enough, the human alteration will have served to eliminate Clean Water Act protections for waters cut off by those alterations. This is unacceptable and contrary to the Clean Water Act and any interpretation of that Act by any court that has addressed the matter since its passage. The Clean Water Groups oppose this attempt at creeping elimination of waters from protections of the Clean Water Act through human alterations.

B. Test for Delineating Traditional Navigable Waters.

The Agencies briefly request comment on whether Appendix D to the *Rapanos* Guidance and other existing guidance regarding the scope of traditional navigable waters should be updated "to help improve clarity and predictability of the agencies' regulatory program." The Clean Water Groups would oppose any alteration, and certainly any narrowing, of the existing guidance and tests for determining whether a water is a traditional navigable water. As an initial matter, the proposed rule simply does not provide sufficient detail to allow members of the public to provide informed comments. Moreover, the existing guidance and tests have developed over many years in response to court rulings and advancements in the scientific

understanding of hydrology, and therefore revisions are not justified absent a specific proposal and explanation in a fully articulated proposed rulemaking. 84 Fed. Reg. at 4170-71.

C. Interstate Waters.

The Dirty Water Rule proposes to eliminate interstate waters from the list of waters that are categorically considered waters of the U.S., protected by the Clean Water Act. The Agencies propose to include such waters only if they meet the definitions provided elsewhere in the rule, (*e.g.*, for tributaries), going out of their way to actually reinterpret longstanding law. 84 Fed. Reg. at 4171. There is no support for the Agencies' reinterpretation in order to eliminate protections for interstate waters and such elimination will do significant damage.

Overall, this reinterpretation will result in the lowest common denominator driving down protections for waterbodies that cross state lines or that form a border between states, with the less-protective states controlling the regulation and protections, or lack thereof, for those waters. This is a formula for state-to-state conflicts and further degradation of waters, favoring less protection overall, the apparent goal of the Dirty Water Rule. This drive to favor the least protective conditions, even where a water is shared with a potentially more-protective state, ignores important national and federal considerations and the stated intent and purpose of the Clean Water Act to move away from the conditions where states competed to allow more pollution and degradation in an attempt to curry favor with business and development. Congress intended the Clean Water Act to eliminate (or at least very sharply curtail) that kind of state competition and race to the bottom and plainly, throughout the Clean Water Act, provided that waters should always move toward protection and increased cleanliness, not less. The Dirty Water Rule turns that on its head, including by eliminating interstate waters as categorically protected.

D. Impoundments.

The Dirty Water Rule's treatment of impoundments fosters and advances the decrease in protections for waters under the Clean Water Act primarily through the "human alteration" method of cutting waters off from federal protections, as generally discussed above. The Dirty Water Rule does this several ways.

First, the Dirty Water Rule provides that an impoundment of a water of the U.S. will not change the water's jurisdictional status "unless jurisdiction has been affirmatively relinquished." 84 Fed. Reg. at 4172. There is no description in the proposed rule of what this means, but on its face, it violates the law. When Congress has instructed the Agencies to apply the Clean Water Act to waters of the U.S. and ensure that activities in those waters are regulated and controlled, an agency cannot simply "affirmatively relicnquish" its jurisdiction and attendant obligations to apply and enforce the law as Congress intended. If a water is jurisdictional then it must remain jurisdictional and no "affirmative action" of the agency can change that. *See Callaway*, 392 F. Supp. at 686 (court held that the Corps was "without authority to amend or change the statutory definition of navigable waters," and had "acted unlawfully and in derogation of [its]

responsibilities under" the Act by defining "navigable waters" narrowly); *cf. MCI Telecomm. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 230-32 (1994) (ruling that an agency's loosening of tariff filing requirements was an unlawful failure to exercise authority and implement regulatory requirements integral to the governing statute).[58] The Agencies' obligation to protect these waters is a core legal requirement of the Clean Water Act, not merely a technical or factual determination. While the Agencies can adopt rules to provide details about how to determine which waters meet the significant-nexus standard, they lack authority to exclude from the Act's reach waters that do meet that standard. *See Callaway*, 392 F. Supp. at 686. The Clean Water Act is a "tough law," *NRDC v. Costle*, 568 F.2d at 1375, and the Agencies charged with implementing it must do so—they are not free to reduce their administrative burden, for example, by creating exemptions from the Act's requirements, *id.* at 1374, 1377, 1379. An agency that "affirmatively relinquishes" jurisdiction over a water of the U.S. acts arbitrarily and capriciously, abuses its discretion, and acts *ultra vires* under the Clean Water Act.

Second, the Dirty Water Rule provides that discharge of dredged or fill material into a water of the U.S. then "transforms" that jurisdictional water into an "upland," making it no longer jurisdictional. This is completely contrary to the Clean Water Act and again, is a blatant example of the "human alteration" off-ramp that will allow the Agencies to continue to strip Clean Water Act protections from the nation's waters, even where those waters are jurisdictional. In no rational reading of Congress' statements and actions in passing the Clean Water Act can the Agencies find authority to remove entire swatches of waters of the U.S. from protections with the issuance of a single, project-specific permit that has cascading effects.

Similarly, the Agencies' request for comment on whether impoundments that "release water downstream only infrequently" or that make downstream flow "less than intermittent" should be cut off from Clean Water Act protections is simply a more egregious variation on the chipping away at jurisdictional waters through human alterations. 84 Fed. Reg. at 4173. The answer from the Clean Water Groups is no, these conditions in an impoundment do not and should not change the condition of the water to non-jurisdictional. Impoundment and/or human alteration of a jurisdictional water should never change the jurisdictional character of that water. To allow it to do so violates the Clean Water Act and the Agencies' obligations under the Act.

E. <u>Tributaries.</u>

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[58] Similarly, courts have required EPA to implement the full mandate of the Act. Time and again, courts have rejected EPA's attempts to exempt certain categories of "point sources" from the Act's permitting requirements. *See Nat'l Cotton Council of Am. v. EPA*, 553 F.3d 927, 940 (6th Cir. 2009); *Nw. Envtl. Advocates v. EPA*, 537 F.3d 1006, 1012 (9th Cir. 2008); *N. Plains Res. Council v. Fidelity Expl. & Dev. Co.*, 325 F.3d 1155, 1164 & n.4 (9th Cir. 2003); *League of Wilderness Defs./Blue Mountains Biodiversity Project v. Forsgren*, 309 F.3d 1181, 1190 (9th Cir. 2002); *NRDC v. EPA*, 966 F.2d 1292, 1304-06 (9th Cir. 1992); *NRDC v. Costle*, 568 F.2d 1369, 1377 (D.C. Cir. 1977).

The Dirty Water Rule severely restricts the protections of tributaries under the Clean Water Act by imposing a definition of tributary that is divorced from science and from the obligation to protect and preserve the chemical, physical, and biological integrity of the nation's waters. It is further contrary to Justice Kennedy's decision in the *Rapanos* case, which itself narrowed the categories of waters to which the Clean Water Act applied.

The Dirty Water Rule restricts the definition of a tributary water to a river, stream, or "naturally occurring surface water channel" that contributes what amounts to visible surface flow, directly or indirectly through another tributary or jurisdictional water, on a perennial or intermittent (but not "ephemeral") basis to a traditional navigable water or territorial sea. 84 Fed. Reg. at 4155. The Clean Water Groups strongly oppose this severe narrowing of the definition and constrained focus on permanence of surface flows, which contradicts Congress' directive to protect all waters of the U.S. with the broadest possible interpretation of the term (*see supra* part I.A. of this letter), entirely ignores the statutory obligation to protect the chemical and biological integrity of the Nation's waters (33 U.S.C. § 1251(a)), and also violates the significant nexus test and accompanying science demonstrating the importance of ephemeral and more temporary streams to the health of downstream waters.

Tributaries serve as the lifeblood and conduits for all of our nation's waters and the health of those waters. Justice Kennedy, in formulating the "significant nexus" test for waters of the U.S.—a test that has been adopted by all of the Circuit Courts of Appeal that have addressed this question—has explained that the Corps was free under the Clean Water Act, to "identify categories of tributaries that, due to their volume of flow. . . their proximity to navigable waters, or other relevant considerations, are significant enough that wetlands adjacent to them are likely, in the majority of cases, to perform important functions for an aquatic system incorporating navigable waters." *Rapanos*, 547 U.S. at 780-81. Justice Kennedy also pointed out that ephemeral waterways, which may be dry much of the time, as well as wetlands without a surface connection to tributaries, can still meet the significant nexus standard. He described Justice Scalia's attempt to impose a continuous flow requirement as making little sense, because "torrents thundering at irregular intervals through otherwise dry channels," which could *significantly affect downstream waterways*, would not be covered. *Id*. at 769. The Agencies mischaracterize the *Rapanos* decision by asserting that the significant nexus standard was the opinion of a "single justice." *Id.* at 4196. In fact, the four justices in the dissent in *Rapanos* stated that they would agree with Justice Kennedy and find Clean Water Act jurisdiction where there was a significant nexus between the water in question and a water of the U.S. *Rapanos*, 547 U.S. at 810 (Stevens, J., dissenting). While it is correct that the standard was articulated in Justice Kennedy's opinion, five justices of the Supreme Court agreed that jurisdiction was proper with a significant nexus.

The Agencies have now irrationally and arbitrarily abandoned their prior use of the significant nexus standard, based on the science of the connectivity of waters. In applying and implementing Justice Kennedy's decision (as well as that of the Circuit Courts) as part of development of the 2015 Clean Water Rule, the Agencies engaged in a searching and thorough examination of various relevant scientific disciplines drawing from the decades of clean water

work at the Agencies, as well as a significant body of published research from outside the Agencies, and by employing experts from all relevant fields, including hydrology, stream and wetland science, geology, biology, chemistry, and climate, culminating in the Science Report. The Science Report found ***unequivocal and consensus evidence*** *that all tributaries*, including perennial, intermittent, and ephemeral streams, "exert a strong influence on the integrity of downstream waters," at ES-2, and that all tributaries have a significant nexus to traditional navigable waters, interstate waters, and the territorial seas.

The Science Report demonstrates that tributaries, and waters adjacent to tributaries and/or jurisdictional waters, play fundamental roles in determining both the course a river takes and its contents. Tributaries supply initial flow (from snowmelt collecting or channeling area precipitation, or from springs or upwellings), as well as the materials that form the river's bed and banks, such as sediment, and the materials that fill it, such as water, nutrients, and organisms. *See, e.g.*, Science Report at 3-47 tbl.3-1, 4-40 tbl.4-3. In some cases, they do this by filtering or settling out, or delaying the delivery of, other materials like contaminants or floodwaters. *Id*. at 3-47 tbl.3-1, 4-40 tbl.4-3. Tributaries can also serve as nurseries or spawning areas during certain times of the year for species that then migrate downstream later in their life stages, for example, as part of migrating salmon lifecycles on both coasts. *See, e.g.*, *id*. at ES-5, ES-13, 1-9, 2-40, and 2-44.

One reason tributaries are so important to downstream waters is that, to a large degree, tributaries determine the characters of the water downstream—physically, chemically, and biologically. *Id*. at 3-45 to 3-46. A watershed is like a funnel: tributaries cover a broader expanse than rivers do, and they collect water and other materials across that broad area and deliver it toward a concentrated point downstream. *Id*. at 3-5. In the arid and semiarid Southwest, where the majority of tributaries are seasonally dry, *id*. at 2-29, flows from ephemeral tributaries are still a "major driver" of flows in downstream rivers, even despite their "ephemeral" nature (which simply means that they do not have *visible* surface water at all times. Visibility, however, is never considered a sole determinative factor in whether a water body is a water body and/or whether it has "flow"). *Id.* at B-59. Ephemeral channels supply substantial amounts of surface water to rivers during infrequent, but very influential, flood events. *Id*. For instance, during a high-intensity storm in New Mexico that dropped up to one-quarter of the area's annual rainfall over the course of two days, flood flows from the Rio Puerco, an ephemeral tributary to the Rio Grande River, accounted for *76% of the flood flow downstream in the Rio Grande*. *Id*. at 3-7 to 3-8; Vivoni et al., *Analysis of a monsoon flood event in an ephemeral tributary and its downstream hydrologic effects*, Water Resources Research (2006). Those flows plainly physically affect downstream waters, but also play critical roles in replenishing sediments or nutrients or building aquatic habitat.

Fig. 1: Floodwaters in the Rio Puerco, an ephemeral tributary. Source: Vivoni 2006.

Even when water in ephemeral tributaries sinks into the ground before reaching downstream rivers, it plays a critical role in replenishing shallow groundwater flows. These flows, in turn, are a vital source of surface water in the downstream rivers through springs or base flow. *Id*. at B-59, 5-8 (ephemeral tributaries supply roughly half of the San Pedro River's "baseflow"), B-39 (most perennial and intermittent rivers in the Southwest are groundwater dependent). As noted by the SAB and the independent comments of panel experts on the 2015 Clean Water Rule, shallow groundwater is a vital connection between waterbodies and serves important physical and biological functions for rivers. *See, e.g.*, *id.* at ES-2 to ES-3, ES-8 to ES-9, 2-11 (incl. Fig. 2-5), 2-34, 4-11, 4-14, 4-22 to 4-23 and 4-28, 5-2.

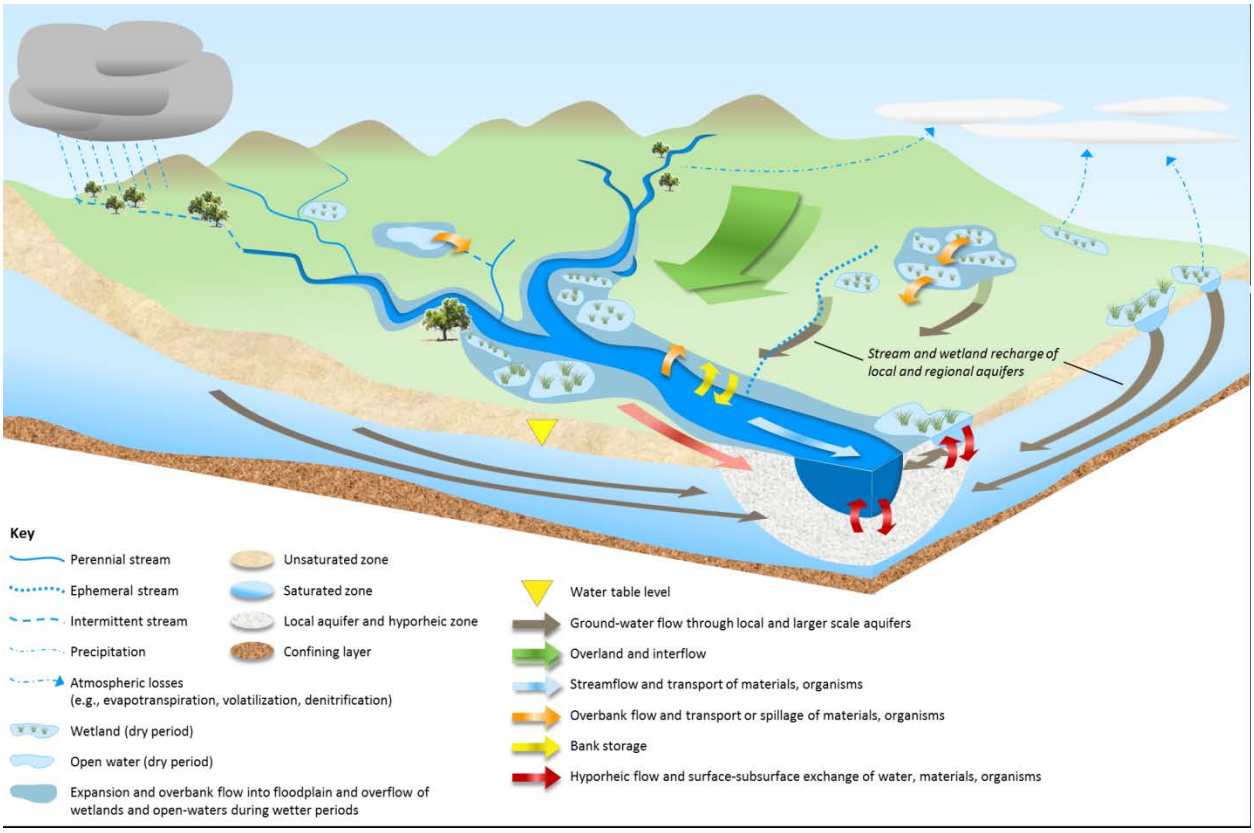

Fig. 2: Illustration of subsurface exchanges of water between a river and its floodplain wetlands (*i.e.*, wetlands in the light blue band bordering the river). Source: Science Report at 1-5 fig.1-1A.

Tributaries also have a major influence on the chemical composition of downstream waters. *Id*. at 3-46, 6-1 to 6-2. Tributaries supply a large proportion of the water in rivers, and that water carries chemicals—good and bad. *Id*. at 3-22. For example, in the Southwest, organic material that is important for biological productivity accumulates in ephemeral channels during dry periods and is carried downstream in great quantities when those channels fill with water. *See id*. at 3-29, B-48 (in the San Pedro River, dissolved organic carbon doubled or tripled during storm events from a flush of terrestrial organic matter and nutrients). Tributaries also affect the chemical makeup of downstream waters by contributing, removing, transforming, or delaying the delivery of harmful chemicals discharged upstream. *Id*. at 3-47 tbl.3-1.

Tributaries are essential to living organisms downstream, whether in perennial, intermittent, or ephemeral streams. *Id*. at 3-46, 3-38, 6-3. In the Southwest, fish may not travel ephemeral channels to a large degree, but water flowing down those channels has a significant influence on fish downstream. Native fish are adapted to the variable flows that ephemeral tributaries provide, and these adaptations allow them to outcompete invasive species. *Id*. at B-38, B-58. Many western rivers are fed significantly by snowmelt from tributaries high in the watershed, and the large snowmelt-fed flows in tributaries leading to rivers like the Columbia

provide the means for salmon to travel to and from spawning areas to the ocean. *Id*. at 2-40, 3-1, 3-41, 6-3 (noting salmonids' reliance on headwater streams); EPA, About EPA's Work in the Columbia River Basin, https://www.epa.gov/columbiariver/about-epas-work-columbia-river-basin (noting the headwaters of the Columbia are fed by snowmelt and spring waters).

Finally, to understand the significance of connections between waters, one must consider the combined effect across the watershed and over time. *Id*. at 6-10. The illustration below shows the same river during wet and dry periods. If you look only at connections between the river and its visibly adjacent wetlands during the dry period, you would underestimate the chemical, physical, and biological significance of those connections overall on waters of the U.S. As the Science Report concluded, the effects of tributaries and adjacent wetlands on downstream waters are cumulative, and the connections between those waters must be analyzed together over time and must be protected as a whole under the Clean Water Act in order to effectuate its purpose and intent and the direction of Congress. *Id*. at 6-10.

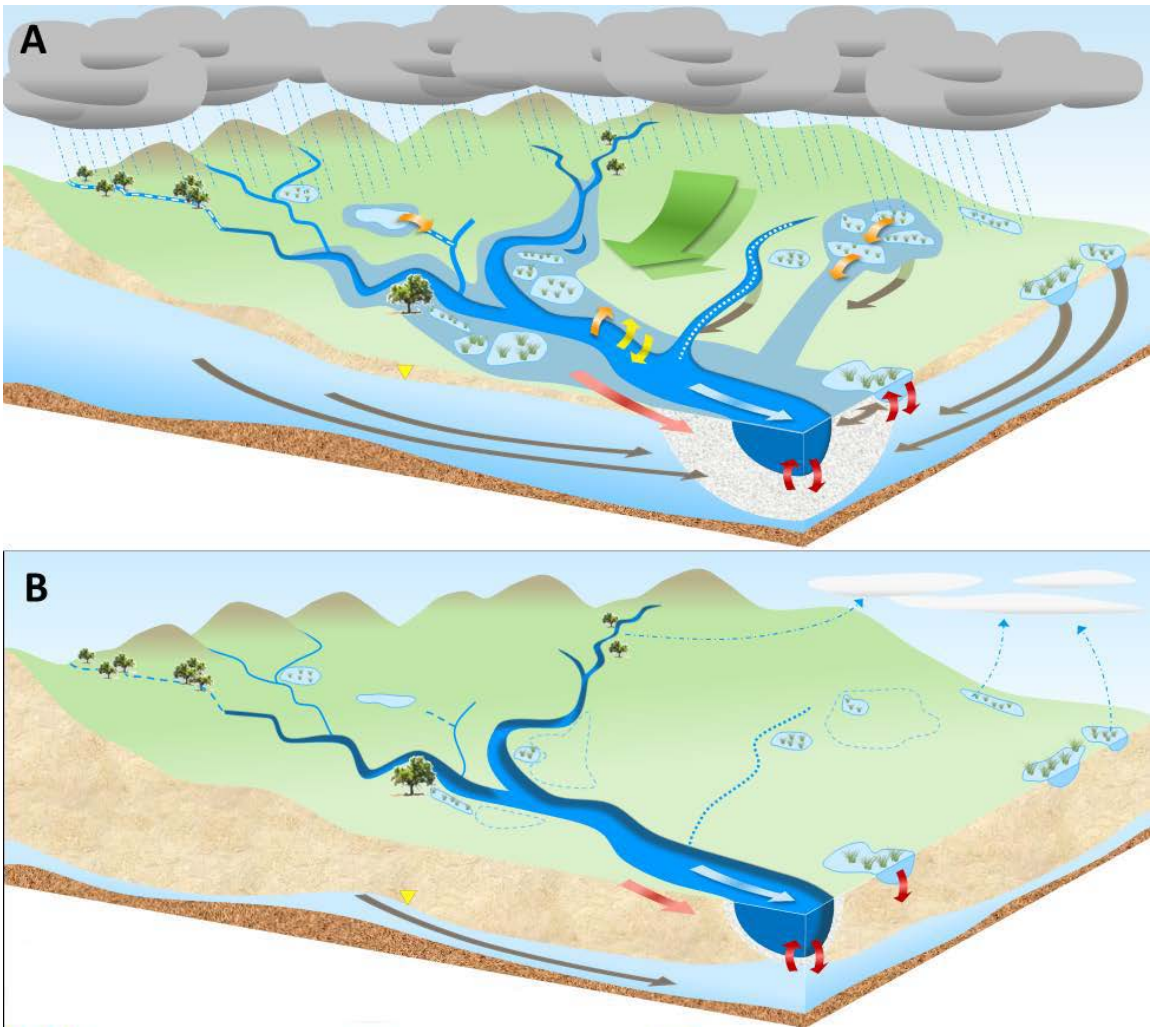

Fig. 3: A river system during wet and dry periods. Source: Science Report 1-7 fig.1-2.

The Dirty Water Rule also sows significant confusion and uncertainty about which tributaries are protected. For example, it qualifies that perennial or intermittent flow means those conditions are met in a "typical year." *Id.* The Dirty Water Rule provides that "typical year" means "within the normal range of precipitation over a rolling thirty-year period for a particular geographic area." *Id*. at 4204. The Dirty Water Rule does not define "normal range" for determining precipitation normalcy, and it does not define the scope or type of range for determining a "particular geographic area." Customarily, scientists and statisticians do not use the word "normal" to identify something that must be defined. Customarily, these experts will use median, mean, or even average, or, most precisely, will define a particular percentile within a precise period of time (*e.g.*, occurring within the 90th percentile of precipitation events over a rolling thirty-year period). With the unclear and unscientific definition provided in the Dirty Water Rule, it appears that any precipitation falling within the thirty-year period can be defined as normal, because it occurred within that period. If a level of precipitation does not occur in that rolling thirty-year period then, seemingly, it cannot be considered "normal" for that period. The proposed rule seems to assume, but does not address, whether thirty-year precipitation is even available for all individual sites. This substantial uncertainty about the meaning of a typical year, and the enormous range of possible levels of precipitation that could be considered typical, demonstrate the unworkability and arbitrariness of this standard.[59]

The Dirty Water Rule's definition of "ephemeral" as meaning "surface water flowing or pooling only in direct response to precipitation (*e.g.*, rain or snow fall)" is also contrary to science and results in contorted reasoning and arbitrary results. 84 Fed. Reg. at 4204. Rain and snow are in fact part of the hydrologic cycle that produces waters of the U.S. (*see* Figure 3 on the preceding page which plainly shows the impact of precipitation within a watershed). The Dirty Water Rule defines "snowpack" as "layers of snow that accumulate over extended periods of time in certain geographic regions and high altitudes." 84 Fed. Reg. at 4204. There is no attempt in the Dirty Water Rule to identify when snow actually becomes snow pack—whether it is a month, a year, or multiple years. Presumably, a winter in the Midwest results in snowpack even in a low snow year. The Dirty Water Rule does not state when in the hydrologic cycles rain or snow becomes stream flow and snowmelt. In order to gain protections, the proposed rule appears to require rain or snow to soak into the ground first, at which point it is no longer visible and not protected, but then come to the surface in a spring or groundwater fed stream—and if the stream flows often enough or visibly enough, it is protected. These confusing and contorted requirements further highlight the fact that the proposed rule has no grounding in hydrological science.

[59] In addition, as explained in *supra* part III.C of this letter, the Agencies fail to address the fact that increasing numbers of waters will become ephemeral as climate change continues to reduce many stream flows.

The Dirty Water Rule's treatment of tributaries also utilizes the human alteration scheme to excise and, over time decrease, the number of otherwise jurisdictional waters from Clean Water Act protections. While a tributary will not lose jurisdictional status if it flows through an impoundment or ditch or culvert or a natural break such as a boulder field or debris pile, the break must continue to convey intermittent or perennial flow from the tributary to another jurisdictional water at the downstream end of the break. If, however, the human or natural alteration causes the water to recede from visible flow (*e.g.*, to flow into groundwater for a period of time or become more diffuse in, *e.g.*, a wetland), then the Dirty Water Rule appears to dictate that the entirety of the tributary will lose Clean Water Act protection from the area of the break to its source. 84 Fed. Reg. at 4174. This suggests that the Corps or EPA can grant a permit for an alteration to a stream, which can then make the entirety of the water flowing to the alteration, and/or from the alteration, non-jurisdictional. This approach is completely contrary to the law and nakedly serves as a vehicle for the Agencies and the Dirty Water Rule proponents to cut as many waters as possible, now and into the future, out of the protections that Congress intended for all waters of the U.S.

Finally, the Agencies request comment on some additional items that are not part of the Agencies' current proposed Dirty Water Rule. In this section of the proposed rule the Agencies seek comment on whether both intermittent and ephemeral streams should be wholly excluded from the definition of Waters of the U.S., and only perennial streams should be protected. 84 Fed. Reg. at 4177. As discussed in further detail in *infra* section V of this letter, ephemeral and intermittent streams represent approximately 60% of the nation's streams, and more than 80% or 90% of streams in some arid western states. The proposal to eliminate protections for ephemeral streams will already hold catastrophic impacts for the health of our waters, but increasing those losses to include the majority of streams in this country would quicken and deepen these adverse impacts to our water quality. The Clean Water Groups strongly oppose any further narrowing of the definition of tributary to only perennial streams as contrary to case law, the Clean Water Act, and the extensive scientific record. The Clean Water Groups also strongly urge the Agencies to return ephemeral streams to the definition of tributaries based on the extensive scientific record and the law, as explained in the above discussion of the effects that even ephemeral streams have on the chemical, physical, and biological integrity of the nation's waters. And because neither the law nor the science supports allowing any "break," physically or in surface flow, whether natural or human-caused, to result in a waterbody losing jurisdictional status and the protections of the Clean Water Act, the Clean Water Groups oppose any decision to allow breaks to eliminate protections.

F. <u>Ditches.</u>

The Agencies have solicited comment on whether ditches that are "constructed in upland" should be non-jurisdictional regardless of flow. 84 Fed. Reg. at 4182. That is, even if the ditch otherwise meets all the requirements for being defined as a tributary (*e.g.*, it has perennial flow to a water of the U.S.), if it is "constructed in upland" it will not receive Clean Water Act protections. The Clean Water Groups oppose this additional exclusion of waters from protection. If a ditch, regardless of where it was excavated in the first instance, has perennial or

intermittent flow such that it meets the proposed definition of tributary (a definition that itself is so narrow and constrained that it does not meet the requirements of law and is not based in science), then that ditch is certainly having a significant influence on the chemical, physical, and biological integrity of waters of the U.S. and it must be protected as a jurisdictional water under the Clean Water Act.

The Clean Water Groups also oppose the new proposed exclusion of ditches that are ephemeral and that are relocated tributaries or constructed out of tributaries. *Id*. at 4179. The Agencies again here propose to allow individuals to destroy Clean Water Act protections for a natural stream by altering or relocating it, provided the newly created "ditch" only has ephemeral flows after the alterations. As we explained in *supra* section IV.E of this letter, these natural ephemeral streams provide critical connections to downstream waters and must be protected under the mandates of the Clean Water Act.

G. Wetlands.

The Dirty Water Rule proposes that only wetlands that "abut" (physically touch on at least one side) a water of the U.S. or that have a "direct hydrologic surface connection" to a water of the U.S. in a "typical year" may be considered protected by the Clean Water Act. 84 Fed. Reg. at 4184. This constrained application of the Clean Water Act to wetlands is wholly divorced from the science and will result in important wetland resources losing protections.

Wetlands naturally absorb flood waters, filter pollutants, and recharge groundwater reserves, as well as provide habitat for fish, amphibians, insects, birds, and mammals. Because they attract such a diverse array of species and provide many kinds of food, EPA has elsewhere called wetlands "biological supermarkets."[60] Wetlands also are connected to other waters of the U.S. in a variety of ways. The Science Report found clear evidence that wetlands and open waters in floodplains are "highly connected" to tributaries and rivers "through surface water, shallow groundwater, and biological connectivity." Science Report at ES-2, and 4-1 *et seq*., especially 4-39. Relying on these findings, the Agencies previously concluded that all waters adjacent to foundational waters, impoundments, and tributaries have a significant nexus to foundational waters.

The connections between wetlands and other waters may not always be visibly obvious. For example, northern boreal patterned peatlands have been shown to have flow characteristics which are visible on the surface of the peatlands (even if the water flow itself is not always visible), and these peatlands are crucial to flood control, water quality and the chemical, physical and biological integrity of waters of the U.S.[61] Moreover, floods, even if infrequent, have significant, lasting, and beneficial impacts because they allow rivers and wetlands to exchange

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[60] EPA, Why Are Wetlands Important?, https://www.epa.gov/wetlands/why-are-wetlands-important.

[61] Minnesota Department of Natural Resources, Minnesota Scientific and Natural Areas Patterned Peatlands, https://www.dnr.state.mn.us/snas/peatlands.html.

water and other materials, in both directions. Science Report at 4-1, 4-39. For example, sediment released from wetlands during a flood can help shape a river's channel and therefore affect its physical integrity. *Id*. at 4-39. Floodplain wetlands also reduce floods by storing water that overflows from rivers or that may flow from the landscape into a river (thereby helping to control and slow flooding downstream). *Id*. at 4-1, 6-4. Wetlands can effectively act like a large sponge on the landscape in times of flood. The subsurface or flood-stage flows connecting floodplain wetlands to rivers also convey chemicals. *Id*. at 4-11. One of the most important functions of floodplain wetlands is to intercept contaminants, such as excess fertilizer and pesticides from agricultural operations, by filtering them through the roots of wetland plants. The plants absorb the contaminants and prevent them from reaching the river. *Id*. at 4-11, 4-14.

Even when there is no surface-water connection between a river and a neighboring wetland, shallow groundwater flows may provide a connection. *Id*. at 4-39. Tributaries and rivers are not "pipes" that simply carry water from one place to another in discrete containers. *Id*. at 2-21. They are porous, and water from a river's channel regularly enters the shallow subsurface, where it may mix with other subsurface water (including water from neighboring wetlands) before returning to the channel or even to other surface waters. *Id*. at 2-12, 4-7. Floodplains are frequently composed of alluvium—a combination of silt, sand, or other matter deposited over time—that tends to be "highly permeable" and particularly well suited to conveying shallow groundwater flows. *Id*. at 2-12; *see* fig.2 (above). These shallow subsurface flows can connect rivers to floodplain wetlands during both high-flow and low-flow periods. *Id*. at 2-12, 4-7; *see* fig.2. Although the word "floodplain" may give the impression that these connections occur primarily during times of flooding, in fact, many important connections between rivers and floodplain wetlands persist at other times as well. *Id*. at 4-39. The Agencies misrepresent the scientific record when they suggest that a river is connected to the wetlands in the 100-year floodplain only once every hundred years. *See, e.g.*, 84 Fed. Reg. at 4188.

Justice Kennedy noted that wetlands separated by land from another waterway can be vital to the waterway, for if such a wetland is destroyed, "floodwater, impurities, or runoff that would have been stored or contained in the wetlands" could instead "flow out to major waterways." *Rapanos*, 547 U.S. at 775. The very absence of a hydrological connection could thus make protection of the wetland critical. *Id*. Justice Kennedy acknowledged that isolated wetlands may be protected by the Act, singly or in combination with similarly situated wetlands, as they can significantly affect other covered waters "more readily understood as 'navigable,'" and the Corps may properly determine that proximity, volume of flow (annually or on average), or other relevant considerations may form the foundation for protecting a wetland under the Act. *Id*. at 780. The Science Report similarly found that wetlands and open waters located outside of floodplains also provide numerous functions, such as storage of floodwater, that benefit downstream water integrity. *Id*. at ES-3, 4-20, 4-38.

In spite of the extensive evidence in the record regarding the connectivity of wetlands, the Dirty Water Rule further narrows the definition of a connected wetland by excluding some events that would and do result in visible surface connections between a wetland and a water of the U.S. For example, the Dirty Water Rule provides that hydrologic connections through

"directional sheet flow" during storm events or a "mere hydrologic connection" where a wetland lies in the 100-year floodplain, "flooding, on average, once every 100 years," will not satisfy the definition of an adjacent wetland. 84 Fed. Reg. at 4186, 4188. The Clean Water Groups oppose the categorical rejection of sheet flow and floodplain connections to wetlands from the protections of the Clean Water Act.

First, if "sheet flow" (whatever that means) during a rain storm event connects a wetland to a water of the U.S., then that connection will substantially influence part of the ecology of that water of the U.S. Connections during rain storm events and in a floodplain are part of the normal cycles for wetlands such as Carolina or Delmarva bays, for example, or for pothole wetland regions or floodplains with wetlands that do not appear visibly connected to a river. Again, the Dirty Water Rule's exclusions in this regard are not based on any science regarding hydrology, river and wetland systems, or aquatic biology.

Second, the manner in which the Dirty Water Rule references or describes the 100-year floodplain is misleading, at times simply incorrect, and always disingenuous. As the Agencies well know, references such as a "100-year flood" or "100-year floodplain" are not a reference to frequency of flooding. Rather, these are statistical references. A "100-year flood" can happen three or four years in a row, or twice in ten years, or twice in thirty years. The "100" measure, instead, is a reference to the probability of a flood of a particular magnitude in any given year. Therefore, the 100-year flood or the 100-year floodplain means that the specific geographic extent of the floodplain has a statistical 100:1 chance of being inundated in *any* given year. A smaller sized floodplain could have a 50:1 chance, for example, of being inundated in any given year (the so-called "50-year flood"). Further, these references cannot be divorced from the effects of climate change, something the Agencies have made no attempt to consider or factor into decisions regarding the Dirty Water Rule (*see supra* part III.C. of this letter). With climate change, as amply demonstrated by Hurricane Harvey and Houston, the 100-year floodplain is changing and in many instances may be becoming a 50- or 25-year floodplain. The only legally and scientifically supportable approach to defining wetlands that are protected by the Clean Water Act must include all wetlands within a floodplain (at least to the 100-year floodplain) and all wetlands that are connected to a water of the U.S. by "sheet flow during storm events."

Finally, as with other parts of the Dirty Water Rule, the Agencies propose that human alterations such as dikes, barriers, or other structures that cut off direct, visible surface flows between a wetland and a water of the U.S. will serve to then eliminate Clean Water Act protections for the wetland that would otherwise be jurisdictional. 84 Fed. Reg. 4184, 4188. This will be the case even if there is a demonstrated chemical, physical, and/or biological impact from the wetland to the water of the U.S. through a hydrological connection that does not meet the narrow definitions of connected waters within the Dirty Water Rule. Again, this results in a purposeful chipping away of waters that will be protected under the Clean Water Act. Moreover, the arbitrariness and scientific inaccuracy of this proposal is illustrated by a comparison of the 2015 rule language with the language in the Dirty Water Rule. Without any supporting science or citations, the Dirty Water Rule states: "Wetlands separated from other 'waters of the United States' by upland or by dikes, barriers, or similar structures would not be adjacent and would not

be jurisdictional wetlands under the proposed rule, unless there is a direct hydrologic surface connection between the wetland and those waters through or over such structures during a typical year. *This is because upland or dikes, barriers, or similar structures typically block most surface water flow*." 84 Fed. Reg. at 4188 (emphasis added). This language stands in stark contrast to very similar language in the 2015 Clean Water Rule, which reached the exact opposite conclusion, explaining: "Such waters continue to have a hydrologic connection to downstream waters. *This is because constructed dikes or barriers, natural river berms, beach dunes, and the like typically do not block all water flow*." 80 Fed. Reg. at 37,084 (emphasis added). It appears that the Agencies simply took the same concept and switched out the conclusion by ignoring the science. This is arbitrary and capricious. Moreover, the Agencies seek comment on whether they should remove protections for wetlands separated from other waters by dikes or other barriers, "even if they have a direct hydrologic surface connection in a typical year to an otherwise jurisdictional water." 84 Fed. Reg. at 4189. The Clean Water Groups strongly oppose such an expanded and unlawful view of human alterations that would ignore even visible direct surface water connections.

H. Groundwater.

The Agencies wholly exclude groundwater from protection under the Dirty Water Rule, regardless of whether the water has a significant nexus to a water of the United States. 84 Fed. Reg. at 4190. In doing so, the Agencies adopt an approach contrary to the record, science, the purpose and intent of the Clean Water Act, and case law.

First, as several courts have noted, legislative history only addresses the unremarkable proposition with which all courts have so far agreed—that the Clean Water Act would not regulate "isolated/nontributary groundwater" which has no effect on surface water." *Idaho Rural Council v. Bosma*, 143 F. Supp. 2d 1169, 1180 (D. Idaho 2001) (citing *Wash. Wilderness Coal. v. Hecla Mining Co.*, 870 F. Supp. 983, 990 (E.D. Wash. 1994)). But the Agencies take this concept much further than the Clean Water Act or case law dictates or allows, exposing waters of the U.S. to contamination or degradation through groundwater. The Agencies have again voluntarily refused to exercise their statutory authority and obligations to protect groundwater that is in significant nexus with waters of the U.S.

Second, the Agencies are well aware of groundwater's importance to the integrity of the nation's waters, and the record is replete with evidence demonstrating that groundwater may in many cases be critical to preserving water quality in down-gradient navigable waters. *See, e.g.*, Science Advisory Board (SAB) Consideration of the Adequacy of the Scientific and Technical Basis of the EPA's Proposed Rule titled "Definition of Waters of the United States under the Clean Water Act" at 3, EPA-HQ-OW-2011-0880-7531 (Sept. 30, 2014) ("groundwater connections, particularly via shallow flow paths in unconfined aquifers, can be critical in supporting the hydrology and biogeochemical functions of wetlands and other waters"). The record provides no scientific basis for treating groundwater differently than tributaries, wetlands, and other surface waters that may significantly affect the chemical, physical, and biological

integrity of navigable waters. *Id.* (noting that the groundwater exclusion "do[es] not have scientific justification").

I. Waste Treatment Exemption.

The so-called waste treatment exemption, which allows waters of the U.S. that have been used for waste treatment systems to be excluded from any further protections of the Clean Water Act, is unlawful. Although an exclusion for waste treatment systems was originally promulgated in 1980, the 2019 proposed Dirty Water Rule expands it in a manner far more sweeping than the original, rendering permanent an interpretation of the exclusion that was originally intended to be temporary. In 1980, EPA limited the exclusion to "manmade bodies of water" that "neither were originally created in waters of the United States (such as a disposal area in wetlands) nor resulted from the impoundment of waters of the United States." 45 Fed. Reg. 33,290, 33,424 (May 19, 1980). When industry objected, obviously desirous of using the Nation's waters for free waste disposal, EPA suspended the language limiting the exclusion to manmade systems, without opportunity for public comment, but explaining that the *suspension was temporary* and that EPA would *"promptly" amend the rule or "terminate the suspension."* 45 Fed. Reg. 48,620, 48,620 (July 21, 1980) (emphasis added). It never did, and the Agencies now propose to treat the suspension of the limiting language as a settled matter, refusing even to take comment on their action. 84 Fed. Reg. at 4190 (stating that "[w]aste treatment systems have been excluded from this definition since 1979, and they would continue to be excluded under this proposal...."); *id.* at 4192 ("when an applicant receives a permit to impound a water of the United States in order to construct a waste treatment system (as excluded under (b)(11)), the agencies are affirmatively relinquishing jurisdiction over the resulting waste treatment system as long as it is used for this permitted purpose, consistent with longstanding practice."); *see also id.* at 4194 (stating that "the agencies propose to not change the longstanding approach to implementing the waste treatment exclusion,") and *id*. at 4195 (soliciting comment only on "whether greater clarity is needed by including in the rule text that the exclusion only applies to 'lawfully constructed waste treatment systems.'").

The Agencies have also affirmed an interpretation of the exclusion that authorizes new impoundments of natural waters, such as streams and wetlands, so that they can be pressed into service as industrial waste dumps. *Id.* at 4190. In the Dirty Water Rule, the Agencies propose a definition for waste treatment systems for the first time, but continue the improper exclusion of those waters from protection under the Clean Water Act. *Id.* at 4205. It is now fully apparent that the act of "suspending" the original limiting language in the Waste Treatment System Exclusion is nothing more than a subterfuge; the Agencies have abandoned all pretense that the suspension is temporary, or that they intend to correct the problem through rulemaking.

Congress spoke clearly: the Clean Water Act would apply to "the waters of the United States," 33 U.S.C. § 1362(7), regardless of how those waters were used. *See supra* pp. 6-7. The law contains no exceptions to that rule, much less for natural water bodies artificially converted into repositories for industrial waste. Indeed, that is the very practice Congress meant for the Act to end. *See* S. Rep. No. 92-414 at 7 ("The use of any river, lake, stream or ocean as a waste

treatment system is unacceptable."). The Waste Treatment System Exclusion violates the plain language of the Act. Nowhere does the Act empower the Agencies simply to remove waters of the United States from the Act's protections. *Cf. Nat'l Ass'n of Mfrs. v. Dep't of Labor*, 159 F.3d 597, 600 (D.C. Cir. 1998) ("There is, of course, no such 'except' clause in the statute [at issue in that case], and we are without authority to insert one."); *NRDC v. Costle*, 568 F.2d at 1377 (invalidating a rule on the basis that, under the Clean Water Act, EPA lacked discretion to exempt entire categories of point sources from certain permitting requirements).

Even assuming for the sake of argument that Congress actually intended to delegate to the Agencies the discretion to allow the Nation's waters to be used as waste dumps – though it did not – the Agencies have failed to exercise that discretion in a reasoned and consistent manner, have failed to explain their interpretation of the Waste Treatment System Exclusion, and have changed what was originally adopted as a temporary measure into a permanent exclusion without explanation. Their latest action on the exclusion is thus arbitrary and capricious. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Permanently adopting the Waste Treatment System Exclusion, and now adding a definition, without the language limiting it to manmade systems, is arbitrary and capricious in two ways. First, the exclusion flies in the face of the Agencies' own statements in the Rule that impoundments of waters of the United States emphatically remain waters of the United States, based on their significant nexus to foundational waters. The Agencies provide no explanation—scientific, technical, or otherwise—for their decision to treat so-called "waste treatment systems" differently from other impoundments of waters of the United States. Second, EPA has never explained the shift from its 1980 position that only manmade waste treatment systems should be excluded from the definition of "waters of the United States," to its present position permanently extending the exclusion to systems created in natural waters. When EPA promulgated the exclusion in 1980, it explained that the Act "was not intended to license dischargers to freely use waters of the United States as waste treatment systems," 45 Fed. Reg. at 33,298, and that the exclusion was limited to manmade waters "to ensure that dischargers did not escape treatment requirements by impounding waters of the United States and claiming the impoundment was a waste treatment system, or by discharging wastes into wetlands." 45 Fed. Reg. at 48,620. Then, when EPA suspended the language limiting the exclusion to manmade systems, the agency said it was responding to complaints that the limitation would otherwise cover "existing waste treatment systems . . . *which had been in existence for many years*."[62] *Id.* (emphasis added). The Agencies' failure to explain their decision to convert a temporary, narrow suspension to a permanent, wholesale exclusion makes their action arbitrary.

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[62] For some time following the temporary suspension, the exclusion was not interpreted to authorize newly created waste impoundments in natural waters. *See W. Va. Coal Ass'n v. Reilly*, 728 F. Supp. 1276, 1289-90 (S.D. W. Va. 1989) (deferring to EPA's interpretation that treatment ponds were regulated "impoundments," not excluded "waste treatment systems"). Over time, however, the Agencies adopted a new interpretation that allowed newly created waste impoundments in natural waters. *See Ohio Valley Envtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 211-16 (4th Cir. 2009) (upholding the Agencies' interpretation in the context of a permit challenge).

Also missing is any explanation of why the proposed Waste Treatment System Exclusion is necessary or appropriate, assuming for the sake of argument that it could comply with the Clean Water Act. The fact that the Agencies have always done it this way is not an explanation. As explained above, the only time this issue was ever actually subject to notice and comment (in 1980), the Agencies came to the opposite conclusion. If some sort of lagoon or pond is needed as a waste treatment system, there is no reason such a system cannot be constructed outside of natural waters. If natural waters are prevalent and difficult to avoid in the area, it is possible to use diversions and liners constructed of clean fill material to create a wholly human-made feature segregated from natural waters of the U.S. It is simply not necessary to use waters of the U.S. as waste treatment systems, and the proposed rule offers no explanation to the contrary.

Even if the Agencies were to find it necessary to locate waste treatment systems in waters of the U.S. in some circumstances, and again assuming for the sake of argument that it is lawful to do so, this option ought to be used only as a last resort. If the rule is going to permit such an option, the rule should make clear that every effort must be made to avoid waters of the U.S., including the use of human-made systems, diversions, and liners. The Army Corps or state agencies with delegated 404 authority should grant the needed permits for a waste treatment system in waters of the U.S. only if all other alternatives are exhausted.

The Agencies' action is also procedurally defective, insofar as it makes the exclusion permanent, as though the exclusion is already legitimately in place, without adhering to legally required procedures. By codifying the suspension and affirming an interpretation of the exclusion that covers newly created waste impoundments in natural waters, the Agencies propose to make the suspension a permanent part of the regulations.

Converting the temporary suspension to a permanent one and now adding a definition is an important substantive change to the waste treatment system exclusion itself, which requires the agencies to provide the public with an opportunity to comment on the underlying exclusion—not just the new definition. The Administrative Procedure Act's notice-and-comment requirements apply to amendments and repeals of rules. 5 U.S.C. § 553 (setting forth notice-and-comment requirements for rule making); *id.* § 551(5) (defining rule making to include amendment or repeal of a rule). Courts have, in other contexts, found that even temporary suspensions or delays in implementation of duly promulgated rules are substantive changes, subject to notice-and-comment requirements. *See, e.g.*, *NRDC v. Abraham*, 355 F.3d 179, 204-06 (2d Cir. 2004); *Envtl. Def. Fund, Inc. v. Gorsuch*, 713 F.2d 802, 816-17 (D.C. Cir. 1983) (holding that agency action that effectively suspended implementation of duly promulgated standards for waste management facilities was subject to notice-and-comment requirements, where the "substance of the decision was exemption of a whole class from prescribed obligations required by law for the protection of the public"). Even where courts have allowed agencies to promulgate temporary or interim measures without notice and comment, that permission has rested on the understanding that the agency will promptly issue permanent rules, informed by notice and comment. *See, e.g.*, *Mid-Tex Elec. Co-op., Inc. v. FERC*, 822 F.2d 1123, 1132 (D.C.

Cir. 1987); *Nat'l Fed'n of Fed. Emps. v. Devine*, 671 F.2d 607, 613 (D.C. Cir. 1982) ("The validity of the interim regulation . . . is conditioned on expeditious conduct of notice and comment procedures in good faith.").

In short, the waste treatment system exclusion is unlawful; but in any case, the Agencies must provide a full explanation for its decision to make permanent the exclusion, and to apply it explicitly to new systems built in waters of the United States, in addition to notice and comment on the proposed new definition.

V. THE AGENCIES IRRATIONALLY FAILED TO QUANTIFY THE PREDICTED REDUCTIONS IN CWA PROTECTION.

The Agencies repeatedly admit that "fewer waters would be subject to the CWA under the proposed rule than are subject to regulation under the 2015 Rule or pre-2015 practice"[63] and that they are "narrowing the scope of CWA regulatory jurisdiction over waters,"[64] yet they irrationally claim they are unable to quantify this reduced jurisdiction, stating that they "are not aware of any means to quantify changes in CWA jurisdiction with any precision."[65] However, a Freedom of Information Act-obtained slideshow prepared by the Agencies addresses the likely quantitative effects of excluding ephemeral streams and potentially intermittent streams, as well as wetlands that do not directly touch a water of the U.S. The slideshow contains an analysis based on National Hydrography Dataset and National Wetlands Inventory data, and reveals that at least 51% of wetlands will be excluded under the proposed rule and at least 18% of streams will be excluded as ephemeral (with an additional 52% of streams excluded as intermittent if the Agencies choose to exclude intermittent streams in the final rule).[66] In their public Resource and Programmatic Assessment for the proposed rule, the Agencies stated that due to limitations in these same databases, the rule's "potential effects are described qualitatively and are not quantified."[67] The Agencies cannot rationally claim they are unable to quantify the effects of the proposed rule using available national databases when the Agencies themselves performed a quantitative analysis outside of the public record. Moreover, it is highly irresponsible and arbitrary and capricious to propose a policy reversal with sweeping impacts for the health of our waters without even bothering to assess the impacts of the change.

The Agencies are well aware that the majority of streams in the country are ephemeral or intermittent. In EPA's 2018 rulemaking docket for the Agencies' proposed repeal of the 2015 Clean Water Rule, the Agencies included an EPA slide that calls ephemeral and intermittent streams the "workhorses of the watershed," and shows that, nationwide, 59% of stream miles are

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[63] 84 Fed. Reg. at 4202.
[64] *Id*. at 4201.
[65] *Id*. at 4200.
[66] EPA and Army Corps of Engineers, 2017 e-mails and PowerPoint presentation obtained via Freedom of Information Act (attached as Ex. H).
[67] EPA and Dep't of the Army, *Resource and Programmatic Assessment for the Proposed Revised Definition of "Waters of the United States"* at 10.

either ephemeral or intermittent.[68] They have also observed, without quantification, that "[b]ecause ephemeral streams represent a larger percent of waters in the arid West, any change in jurisdiction related to ephemeral features may be greater there than in other portions of the country."[69] In fact, widely available National Hydrology Dataset data reveals that "94%, 89%, 88%, and 79% of the streams in Arizona, Nevada, New Mexico, and Utah, respectively, are intermittent or ephemeral."[70] In order to quantify the projected effects on wetlands, scientists at the St. Mary's University of Minnesota used GIS technology and widely available national datasets to model the likely jurisdictional reductions under scenarios in which only wetlands adjacent to perennial streams are protected, or only wetlands adjacent to perennial and intermittent streams are protected.[71] In one case study watershed, the Cimarron River Watershed in New Mexico, 68.8% of wetland acreage would become non-jurisdictional if only wetlands adjacent to perennial streams are protected, and 17.7% of wetland acreage would become non-jurisdictional if only wetlands adjacent to perennial or intermittent streams are protected.[72] The Agencies performed no similar modeling, despite having access to the same underlying data. However, the Agencies did provide a few simple case study summaries of hydrography data in their economic analysis. The case study for two watersheds in the Rio Grande River Basin revealed that 85-91% of stream miles are ephemeral, and 34-62% of wetland acres are not abutting waters of the U.S. in those watersheds.[73] These startling figures underscore the need for comprehensive, nationwide modeling.

Finally, the Agencies failed to conduct the type of jurisdictional analysis they conducted only a few years before when proposing the 2015 Clean Water Rule, in which they reviewed 200 randomly selected approved jurisdictional determinations in order to predict jurisdictional changes under the 2015 Rule.[74] The Agencies did not explain why they declined to perform a similar analysis for this proposed rule.

VI. THE AGENCIES FAILED TO PERFORM THE ANALYSIS REQUIRED BY EXECUTIVE ORDER 12898.

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[68] EPA, Materials Shared at Outreach Meetings for Docket EPA-HQ-OW-2017-0203 at 332 (attached as Ex. I).
[69] EPA and Dep't of the Army, *Resource and Programmatic Assessment for the Proposed Revised Definition of "Waters of the United States"* at 11.
[70] D.C. Goodrich et al., *Southwestern Intermittent and Ephemeral Stream Connectivity*, Journal of the American Water Resources Association, 1-23 (2018) (attached as Ex. G-28).
[71] Roger Meyer and Andrew Robertson, *Clean Water Rule Spatial Analysis: A GIS-based scenario model for comparative analysis of the potential spatial extent of jurisdictional and non-jurisdictional wetlands*, St. Mary's University of Minnesota (2019) (attached as Ex. G-25).
[72] *Id*. at 26.
[73] EPA and Dep't of the Army, *Economic Analysis for the Proposed Revised Definition of "Waters of the United States"* at 189-90.
[74] 2015 Analysis of Jurisdictional Determinations for Economic Analysis and Rule (attached as Ex. F-11).

By their own admission, the Agencies ignore and fail to apply the requirements of Executive Order 12,898, Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 Fed. Reg. 7629 (Feb. 11, 1994). *See* 84 Fed. Reg. at 4203. The Agencies dismiss their environmental justice obligations based on the bare assertion that "there is no significant evidence of disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples." *Id.*[75] Yet the Agencies' own analysis in support of the proposed rule admits that the expected increases in water pollution caused by the rule will, among other things, increase sediment concentrations in waters, leading to increased needs for dredging of reservoirs and drinking water costs.[76]

Readily-available information and studies demonstrate that this increase will have exactly the type of disproportionate effects the Executive Order aims to prevent. In particular, drinking water and related water services are already disproportionately costly for lower-income consumers and people of color, particularly those who live in rural communities—thus, the adverse environmental effects of the rule will produce increased costs that fall disproportionately on already-overburdened communities. Accordingly, finalizing the proposed rule without identifying and addressing its serious environmental justice implications, as the Agencies propose to do here, contravenes Executive Order 12,898 and the Agencies' policy, and is arbitrary and capricious.

A. Environmental Justice Requirements Are Applicable To The Proposed Rule.

Executive Order 12,898 makes "each Federal agency," including the EPA and the Corps, responsible for "identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations." 59 Fed. Reg. at 7629, § 1-101 (Feb. 16, 1994).

Beyond that, EPA's own environmental justice plan "envision[s] an EPA that integrates environmental justice into everything" it does. EPA, *EJ 2020 Action Agenda, The U.S. EPA's Environmental Justice Strategic Plan for 2016-2020* at iii (Oct. 27, 2016) (attached as Ex. J-1). To accomplish this vision, EPA sets forth eight different priority areas, the first of which is "rulemaking." *Id.* Specifically, EPA aims to "[i]nstitutionalize environmental justice in

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[75] Neither did the Agencies apply the Executive Order in their proposals to repeal the 2015 Clean Water Rule and recodify the preexisting regime. *See* Definition of "Waters of the United States"—Recodification of Pre-Existing Rules, 82 Fed. Reg. 34,899, 34,904 (July 27, 2017); Definition of "Waters of the United States"—Recodification of Preexisting Rule, 83 Fed. Reg. 32,227, 32,252 (July 12, 2018) (both claiming that the "proposed rule maintains the legal status quo. The agencies therefore believe that this action does not have disproportionately high and adverse human health or environmental effects on minority, low-income populations, and/or indigenous peoples.").

[76] EPA and Dep't of the Army, *Economic Analysis for the Proposed Revised Definition of "Waters of the United States"* at 136-37.

rulemaking," including performance of "rigorous assessments of environmental justice analyses in rules," in order to "deepen environmental justice practice within EPA programs to improve the health and environment of overburdened communities." *Id*. Recognizing that "[r]ulemaking is an important function used by the EPA to protect human health and the environment for all communities," EPA devotes the second chapter of the plan to "Rulemaking," and through this chapter, aims to "ensure environmental justice is appropriately analyzed, considered, and addressed in EPA rules with potential environmental justice concerns, to the extent practicable and supported by relevant information and law." *Id*. at 13. Thus, EPA has regularly and purposefully focused on the need for environmental justice assessments of its rulemaking.

EPA has provided guidance to its rule-writers containing direction on how to incorporate environmental justice into the rulemaking process, noting that "it is critical that EPA rule-writers consider environmental justice (EJ) when developing a regulation." EPA, *Guidance on Considering Environmental Justice During the Development of Regulatory Actions* at 1 (May 2015) (attached as Ex. J-2) ("EPA EJ Guidance"). The Guidance defines an "environmental justice concern" as including "the actual or potential lack of fair treatment or meaningful involvement of minority populations, low-income populations, tribes, and indigenous peoples in the development ... of environmental ... regulations." *Id*. at 9. This can arise not only when a regulation would "[c]reate new disproportionate impacts," but also when it would "exacerbat[e] existing disproportionate impacts." *Id*. at 10. The assessment can include qualitative or quantitative elements. *Id*. And the Guidance directs rule-writers to begin the assessment by "first understand[ing] what an action is accomplishing and why it is necessary." *Id.*

Both the EPA and the Corps also have an obligation pursuant to Executive Order 13,175 to consult with tribes when they formulate policies that have tribal implications, as is the case with this proposed rule. Executive Order 13,175, Consultation and Coordination With Indian Tribal Governments, 65 Fed. Reg. 67,249, 67,250 (Nov. 6, 2000) (requiring that "[e]ach agency shall have an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications"). The Corps also has made specific commitments to indigenous peoples through its U.S. Army Corps of Engineers Tribal Policy Principles,[77] which grow in part from the Executive Order 13,175, and the Presidential Memorandum on Tribal Consultation (Nov. 5, 2009) (attached as Ex. J-3) (noting that "[h]istory has shown that failure to include the voices of tribal officials in formulating policy affecting their communities has all too often led to undesirable and, at times, devastating and tragic results.").

While the records in the proposed rulemaking docket indicate that the Agencies conducted some informal discussions with tribal leaders,[78] there is no indication that the Agencies disclosed the issue about increased sedimentation increasing the costs of drinking water treatment, or many other specific predicted impacts which would affect tribes. *See* EPA

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[77] Corps, Tribal Nations, https://www.usace.army.mil/Missions/Civil-Works/Tribal-Nations/ (last visited April 9, 2019).
[78] EPA, Materials Shared at Outreach Meetings for Docket EPA-HQ-OW-2017-0203 at 145, 156, 285-86 (attached as Ex. J-4).

and Dep't of the Army, *Summary Report of Tribal Consultation and Engagement for the Proposed Rule: Revised Definition of "Waters of the United States,"* and attachments, EPA-HQ-OW-2018-0149-0094. The Agencies therefore failed to provide the requisite opportunity for "meaningful and timely input" by tribal leaders. Executive Order 13,175, Sec. 5.

The proposed rule is likely to result in both the "lack of fair treatment" and a lack of "meaningful involvement of minority populations, low-income populations, tribes, and indigenous peoples." EPA EJ Guidance at 10-12. For example, the complete absence of a meaningful environmental justice analysis means that environmental justice communities have not been sufficiently alerted by the Agencies to the likely disproportionate effects of increased drinking water treatment costs that will flow from the proposed dramatic narrowing of Clean Water Act jurisdiction. Thus, by failing to "identify" the disproportionate effects of the proposed rule, as required by Executive Order 12,898, the Agencies have missed a significant opportunity to gather additional relevant evidence from the communities that will be most deeply affected by these increased costs. Moreover, the Agencies have failed to "address" these anticipated disproportionate effects at all as required by Executive Order 12,898, much less in a meaningful way that prevents unfair treatment of already overburdened water consumers.

B. The Proposed Rule Has Disproportionately High Environmental Effects On Minority Populations, Low-Income Populations, And Tribal Populations.

EPA is already aware of the issues surrounding drinking water affordability and disproportionate burdens of drinking water infrastructure and treatment costs on low-income communities and communities of color. A recent report affirmed that "[l]ow-income users' water bills account for a larger share of total low-income household expenditures than higher income households." National Academy of Public Administration, *Developing a New Framework for Community Affordability of Clean Water Services* at 38 (Oct. 2017) (attached as Ex. J-5). This is why EPA has provided information and guidance to states and municipalities, utilities, and permit writers, to help ensure that the people they serve have access to affordable drinking water, and to ensure that they are not disproportionately burdened with the costs of drinking water collection, treatment, and distribution infrastructure.[79] EPA's policy states that "[f]ederal… policies[] and actions should… promote affordable neighborhoods," among other things.[80]

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[79] *See, e.g.*, EPA, *Tools for Financing Water Infrastructure* (March 2007), https://www.epa.gov/sites/production/files/2016-01/documents/waterinfra2007.pdf; EPA, Sustainable Water Infrastructure, Financing Water Infrastructure, https://www.epa.gov/sustainable-water-infrastructure/financing-water-infrastructure (last updated March 20, 2017).

[80] EPA, *EPA's Clean Water and Drinking Water Infrastructure Sustainability Policy* (Oct. 4, 2010), https://www.epa.gov/sustainable-water-infrastructure/clean-water-and-drinking-water-infrastructure-sustainability-policy.

Readily-available public information confirms that a rule that causes increased drinking water treatment costs will disproportionately burden minority populations, low-income populations, and/or indigenous peoples.

Low-income households already pay higher water bills in relation to income. According to the United States Conference of Mayors:

> A serious concern for local government is the disproportionate financial impact on households at or below the poverty level, or with low, moderate and fixed income at the lower end of the income distribution because user fees command a greater percentage of their annual incomes. This disparate financial impact is regressive. Current public water cost allocation schemes that rely on uniform user class pricing place a tremendous financial burden on the lower median income households in a community. The financial burden is both substantial, and sometimes, widespread in a community

The United States Conference of Mayors, *Growth in Local Government Spending on Public Water and Wastewater – But How Much Progress Can American Households Afford?* at 11 (April 2013) (attached as Ex. J-6). Additional research by a University of Wisconsin-Milwaukee researcher exposed "the regressive character of water tariffs, since at lower levels of income we find much higher percentages of water costs over income." Oriol Mirosa, *Water affordability in the United States: An Initial Exploration and an Agenda for Research*, Sociological Imagination. Vol. 51. Iss. 2. at 2 (Dec. 2015) (attached as Ex. J-7).

Drinking water affordability is in crisis. One national assessment found "[a]nalytical results [that] highlight high-risk and at-risk households for water poverty or unaffordable water services." Elizabeth A. Mack and Sarah Wrase, *A Burgeoning Crisis? A Nationwide Assessment of the Geography of Water Affordability in the United States*, PLOS One (Jan. 11, 2017) (attached as Ex. J-8). The authors noted that "[m]any of these households are clustered in pockets of water poverty within counties, which is a concern for individual utility providers servicing a large proportion of customers with a financial inability to pay for water services." A 2016 study found that "one-third of customers in the lowest 20th percentile income level have had months where they could not pay all their utility bills on time and are three times more likely to have their service disconnected." U.S. Government Accountability Office, *Water Infrastructure: Information on Selected Midsize and Large Cities with Declining Populations*, at 13 (GAO-16-785) (Sept. 2016) (attached as Ex. J-8). Some analysts consider this a threat to human rights. *See, e.g.*, Georgetown Law Human Rights Institute Fact-Finding Practicum, *Tapped Out: Threats to the Human Right to Water in the Urban United States* (April 2013) (attached as Ex. J-9).

Drinking water rates are characterized by racial disparities. One set of researchers' findings "indicate that higher reported cost of water and sewer was associated most strongly with minority racial status." Rachel Butts and Stephen Gasteyer, *More cost per drop: Water rates,*

structural inequality, and race in the United States—The case of Michigan (attached as Ex. J-10). The researchers believe the effect can be explained by "post-industrial divestment and subsequent depopulation of particular urban areas," an effect that has fallen more severely on people of color. *Id*. Another study focused on Boston and mapped data about water shutoffs along with data on racial diversity across the city, finding the two factors are closely related. Kimberly Foltz-Diaz et al., Massachusetts Global Action, *The Color of Water: A Report on the Human Right to Water in the City of Boston* (July 2014) (attached as Ex. J-11). An in-depth investigation by the Chicago Tribune found similar effects in Chicago, helping explain why black and poor suburbs pay higher water rates, and why overall water rates in the metropolis are surging. Ted Gregory et al., "Same Lake, Unequal Rates; Why our water rates are surging – and why black and poor suburbs pay more," *Chicago Tribune* (Oct. 25, 2017) (attached as Ex. J-12).

As noted above, EPA's *Guidance on Considering Environmental Justice During the Development of Regulatory Actions* recognizes that environmental justice concerns can arise when the environmental effects of an agency action exacerbate an existing disproportionate impact for communities covered by Executive Order 12,898. The Agencies concede that their proposed rule will cause increased sedimentation and resulting increased costs of drinking water treatment, which will in turn exacerbate an environmental justice problem that is already at crisis proportions. For this and other reasons, the Agencies must therefore complete their environmental justice responsibilities before finalizing the proposed rule.

VII. THE AGENCIES FAILED TO COMPLY WITH THE ENDANGERED SPECIES ACT.

Section 7 of the Endangered Species Act ("ESA"), requires each federal agency to consult with USFWS and with National Marine Fisheries Service ("NMFS") as to any action authorized, funded, or carried out by the agency to ensure that such action is not likely to jeopardize the continued existence of any endangered or threatened species or result in destruction or adverse modification of a listed species critical habitat. 16 U.S.C. § 1536(a)(2). Further, for actions subject to consultation, the agency shall not make any irreversible or irretrievable commitment of resources with respect to the proposed agency action which has the effect of foreclosing measures necessary to ensure no jeopardy to listed species or destruction or adverse modification of critical habitat. *Id.* § 1536(d).

Here, the Agencies have failed to consult with the USFWS and NMFS regarding the Dirty Water Rule to ensure that the rule will not jeopardize endangered or threatened species nor destroy or adversely modify critical habitat. Given that the Dirty Water Rule will result in innumerable streams and wetlands (and possibly lakes, ponds, impoundments, ditches, etc.) to lose Clean Water Act protection from pollution, degradation and/or destruction, the potential for jeopardy to species and habitat is significant, indeed harm is likely. Numerous listed species of fish live and spawn in small headwaters of western streams and rivers, many of them in the desert in rivers and streams that are fed by so-called ephemeral desert washes. Many listed amphibian species spawn and/or live in ephemeral wetlands or streams such as vernal pools. Many listed bird species use desert washes, and many migratory waterfowl rely heavily on what will be considered "isolated" wetlands under this rule, during migration and/or for breeding and

feeding. And of course, all of these species live downstream of waters that the Dirty Water Rule will now fail to protect from pollution, degradation, or destruction with attendant negative effects downstream to all waters (because waters are connected in more ways than just visibly and perennially).

A review of recent hydrology publications reveals several examples illustrating the importance of ephemeral streams and other smaller water bodies for endangered and threatened species. For example, streams that are fragmented into pools during times of low flow provide critical habitat for endangered and threatened salmonids in the Pacific Northwest.[81] Seasonal vernal pools provide unique habitat for plants that are specially adapted to vernal pool wetlands.[82] Prairie potholes are a well-known prolific breeding ground for waterfowl, provide crucial migratory habitat for many shorebirds, and are generally hotspots for wildlife (at one prairie pothole district in South Dakota, at least a dozen threatened or endangered species are either known or possibly occur).[83] Karst water features and intermittent streams throughout the country are also known to be essential for fish like threatened and endangered cavefish, as well as many kinds of threatened salmon, trout, darters, minnows, suckers, and other fishes.[84] All of these waters are at risk of losing protections under the proposed rule, destroying vital habitats for innumerable species. The Agencies' own economic analysis predicts a "decline in wildlife habitat quantity and quality," "[w]ater quality degradation [that] may adversely affect species habitat," and "loss of wildlife and habitats" from more frequent and larger oil spills, among other things.[85] The economic analysis also elsewhere observes that various threatened and endangered species rely on ephemeral streams and pools, including the Pecos sunflower, streamside salamander, red salamanders, and Strecker's chorus frog.[86] In spite of these acknowledged impacts, the Agencies have puzzlingly taken no steps to analyze the extent and nature of these predicted effects. For species protected under the Endangered Species Act, the Agencies must consult with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service ("NMFS") under § 7 of the Endangered Species Act to determine whether the proposed removals

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[81] Woelfle-Erskine et al., *Abiotic habitat thresholds for salmonid over-summer survival in intermittent streams*, Ecosphere (2017) (attached as Ex. G-24).
[82] Gosejohan et al., *Hydrologic Influences on Plant Community Structure in Vernal Pools of Northeastern California*, Wetlands (2017) (attached as Ex. G-29).
[83] Steen et al., *Preparing for an uncertain future; migrating shorebird response to past climate fluctuations in the Prairie Potholes*, Ecosphere (2018) (attached as Ex. G-22); David M. Mushet, *Midcontinent Prairie-Pothole Wetlands and Climate Change: An introduction to the Supplemental Issue*, Wetlands (2016) (attached as Ex. G-21); U.S. Fish and Wildlife Service Region 6, *An Evaluation Of Agricultural Tile Drainage Exposure And Effects To Wetland Species And Habitat Within Madison Wetland Management District, South Dakota* at 6 (2018) (attached as Ex. G-12).
[84] Colvin et al., *Headwater Streams and Wetlands Are Critical for Sustaining Fish, Fisheries, and Ecosystem Services*, American Fisheries Society (2018) (attached as Ex. G-30).
[85] U.S. Environmental Protection Agency and Department of the Army, *Economic Analysis for the Proposed Revised Definition of "Waters of the United States"* at 136-37 (Dec. 11, 2018).
[86] *Id*. at 195-96, 164, 184.

of CWA protections for waters and the accompanying increases in pollution and filling of wetlands will adversely affect these species or their designated critical habitats.

Further, the Agencies have access to additional resources that reveal ranges and critical aquatic habitats for many federally listed species. For example, the U.S. Fish and Wildlife Service includes an active list of listed species on its website.[87] The list includes many fish species, shellfish species, amphibians, corals, birds, and aquatic insects that rely on water. The list also includes information on the species' historical and current range, and if critical habitat has been designated, that too is available. A GIS exercise would allow the Agencies to understand where waters will be stripped of Clean Water Act protections that overlap with range and habitat of the listed species. A graduate student could perform this analysis in a week. The Agencies could contact Professor Steve Roady at Duke University for assistance with this habitat analysis, for example. From that information, the Agencies could then determine which listed species depend on waters that may be adversely affected by the Dirty Water Rule, initiate consultation, and seek a biological opinion from USFWS and NMFS.

These are just a handful of examples of the extensive and potentially seriously damaging results on federally listed species and their habitat from the Dirty Water Rule necessitating consultation under Section 7 of the ESA. The Agencies made no attempt to comply with the ESA, yet they are committing resources to the finalization and implementation of the Dirty Water Rule. The Agencies are in violation of Section 7 of the ESA.

VIII. THE AGENCIES FAILED TO COMPLY WITH THE NATIONAL ENVIRONMENTAL POLICY ACT.

Finally, the Agencies utterly failed to comply with the requirements of the National Environmental Policy Act ("NEPA"). NEPA requires all federal agencies to prepare an environmental impact statement ("EIS") for any "major Federal actions significantly affecting the quality of the human environment." 42 U.S.C.A. § 4332(C). In fulfillment of its policy that "each person should enjoy a healthful environment and that each person has a responsibility to contribute to the preservation and enhancement of the environment," 42 U.S.C.A. § 4331(c), "NEPA 'establishes 'action-forcing' procedures that require agencies to take a 'hard look' at environmental consequences.'" *Ctr. for Biological Diversity v. U.S. Dep't of Interior*, 623 F.3d 633, 642 (9th Cir. 2010) (internal citations omitted). NEPA also requires federal agencies to "study, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." 42 U.S.C.A. § 4332(E).

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[87] USFWS, Environmental Conservation Online System, https://ecos.fws.gov/ecp0/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals.

Section 511(c) of the Clean Water Act creates a limited exemption which characterizes the actions of the Administrator of the EPA as not "major Federal action[s] significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969," 33 U.S.C.A. § 511(c), and thus not subject to the NEPA requirement to prepare an EIS. However, this exemption does not apply to other provisions and requirements of NEPA – all provisions other than the requirements for major federal actions significantly affecting the environment in § 4332(C), nor does it apply to the Corps or to the actions of the EPA when it is providing financial assistance for the construction of publicly owned treatment works or permitting new sources of discharges of pollutants under § 402 of the Clean Water Act. *See* 33 U.S.C.A. § 511(c). The Agencies' actions here are not fully exempt from NEPA. As a result, the Agencies have violated NEPA by failing to take any steps to consider the environmental impacts of their proposed rule or alternatives to the action.

CONCLUSION

We urge the Agencies to withdraw the current proposal because it is unsupported, contrary to science, and contrary to law. There is no legitimate need for this proposed rule, and the Agencies offered only irrational explanations for the Dirty Water Rule, in violation of the APA. The proposed rule's provisions directly contradict the mandates of the text of the Clean Water Act, its legislative history, federal case law, and settled science, all of which dictate broad protections for all of the Nation's waters. The Agencies cannot explain why they propose to reverse decades of clean water protections when the record irrefutably points to a need for increased, not decreased, protections of our waters as they continue to degrade each year. This policy reversal is contrary to the CWA and is arbitrary and capricious under the APA.

Moreover, the Agencies unlawfully failed to analyze the impacts of the Dirty Water Rule. The proposed rule would introduce many new exclusions and methods of removing protections via human alterations, gutting protections for huge percentages of waters. Yet, the Agencies failed to even roughly quantify the impacts of their proposal. Nor did they attempt to analyze the impacts on environmental justice communities that will disproportionately bear the adverse effects associated with more polluted water. The Agencies also failed to comply with their obligations under the ESA to analyze the impacts to threatened and endangered species. Finally, the Agencies did not consider the broader environmental impacts of their proposal, or alternatives to the proposal, under NEPA. Silence does not destroy the Agencies' legal obligations to analyze the many effects of their sweeping proposal. Their failure to perform critical analyses is not only irresponsible, but violates the APA, executive orders, and the ESA.

Any questions regarding these comments may be directed to Jennifer Chavez at (202) 667-4500, Janette Brimmer at (206) 343-7340, or Anna Sewell at (202) 797-5233.

Sincerely,

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