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August 20, 2019

By Electronic Submission to Dr. Thomas Armitage, armitage.thomas@epa.gov

Dr. Thomas Armitage
Designated Federal Officer (DFO)
EPA Science Advisory Board (1400R)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Written Statement for SAB Public Teleconference on EPA's Proposed Rule, "Strengthening Transparency in Regulatory Science"

Dear Dr. Armitage,

We write on behalf of 32 concerned medical and public health experts, scientists, researchers, and clinicians to urge the Science Advisory Board ("SAB") to conduct a full review of the Environmental Protection Agency's ("EPA") proposal "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18,768 (Apr. 30, 2018) ("the Proposal"). The narrow review that Administrator Wheeler has requested is not adequate to address the many troubling implications of the Proposal for the scientific integrity of EPA's decision-making. As explained in a comment letter we submitted to EPA on August 7, 2018 (which we have attached to this letter), the Proposal will result in the exclusion of crucially important public health data from the agency's consideration when setting regulatory standards and will therefore undermine—not strengthen—EPA's decision-making. Given that EPA has stated that it intends to finalize the Proposal by the end of this year, it is critically important that the SAB weigh in on all aspects of the Proposal as soon as possible.

The Proposal, if finalized, would prohibit EPA from basing important regulatory actions on reliable, significant, responsibly-conducted, and best available scientific studies merely because the raw data are not "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773. EPA qualifies this requirement, however, by providing that "[w]here the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." *Id.* This qualification does not address our concerns.

In the comment letter we submitted to EPA last year, we explained that:

> The proposed rule will undermine EPA's ability to fulfill its mission to protect human health, safety, and the environment by using the best available information and science. First, the proposed rule would exclude from EPA's consideration any reports, studies, analyses, and models that rely on confidential, inaccessible, or unavailable data but that historically have been considered the best available science and therefore used to support regulations and standards designed to protect public health and safety. Second, in so doing, the rule also eliminates EPA's access to fundamental information necessary for identifying and calculating the "health benefits" of rules and standards needed to protect public health. Finally, it threatens to impose significant costs on both the federal government and independent scientists. Worst of all, the proposed rule creates these multiple problems without providing any significant countervailing benefits.

Other major figures in the scientific community reiterated these criticisms of the Proposal. For example, the editors-in-chief of *Science*, *Nature*, *PLOS*, *PNAS*, and *Cell* published a joint statement explaining that:

> 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.[1]

Similarly, a coalition of sixty-nine public health, medical, academic, and scientific groups commented that:

> If EPA excludes studies because the data cannot be made public, people may be exposed to real harm. The result would be decisions affecting millions based on inadequate information that fails to include well-supported studies by expert scientists. These efforts are misguided and will not improve the quality of science used by EPA nor allow the agency to fulfill its mandate of protecting human health and the environment.[2]

Since our original submittal, EPA has taken every opportunity to diminish the role of science and scientists in its decision-making. For example, the agency has disbanded the particulate matter review panel, which in the past advised the Clean Air Scientific Advisory Committee on the establishment of National Ambient Air Quality Standards for particulate matter and fine particulates. EPA also terminated the Integrated Risk Information System ("IRIS") assessment for formaldehyde. Of immediate relevance to the Proposal, EPA recently decided not to revoke the existing food tolerances for chlorpyrifos under the Federal Food, Drug, and Cosmetic Act. In

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[1] Jeremy Berg, et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data*, Science, Vol. 360, Issue 6388, eaau0116 (2018), https://science.sciencemag.org/content/360/6388/eaau0116.

[2] Public Health, Medical, Academic, and Scientific Groups Oppose EPA Transparency Rule (July 16, 2018), https://mcmprodaaas.s3.amazonaws.com/s3fs-public/EPA%20Transparency%20Rule%20FINAL.pdf?oNbdIjRo8Ick2LxdMeWaqWuYu4NM3unc.

reaching this decision, EPA identified "the lack of any meaningful raw data from the epidemiologic data that are the centerpiece of this area of inquiry" as the "most significant[]" reason for refusing to act.[3] As demonstrated by this decision, even without finalizing the Proposal, EPA is already implementing its principles in its regulatory decisions.

In sum, over the past year, the role of science and reason at EPA have not been strengthened; they have been dismissed. Scientists, public health experts, and the medical community have all been marginalized in EPA's ongoing effort to roll back rules, undermine regulatory standards, and promote business interests over public health and environmental protection.

We urge you to use the August 27, 2019 meeting to push back and remind EPA of its statutory obligations to base its decisions on science—not on business interests or the interest of the President in promoting coal and other fossil fuels. In your capacity as expert advisors, you should urge EPA to withdraw the Proposal and engage in meaningful discussions with you and other experienced members of the scientific and public health communities who have nearly unanimously opposed the proposed rule.

EPA has unlawfully and inappropriately curtailed the role of the SAB. EPA did not consult with the SAB before publishing the Proposal. Only now, more than a year later, after much protest, is EPA allowing limited SAB input. But EPA has wrongfully restricted the SAB's input to one narrow aspect of the Proposal: "mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) as discussed in the proposed rule consistent with existing laws and policies that protect PII and CBI."[4] The SAB's statutory role is significantly broader. Given the central importance of the Proposal to SAB's mission and EPA's ability to fulfill its statutory duties, and because the Proposal departs from scientific norms, the SAB should weigh in on all aspects of the Proposal.

Thank you for considering these comments and raising these issues with EPA.

Sincerely yours,

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[3] Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35,555, 35,563 (July 24, 2019).

[4] Strengthening Transparency in Regulatory Science: Notification of a Public Teleconference of the Chartered Science Advisory Board, 84 Fed. Reg. 38,894, 38,895 (Aug. 8, 2019).

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August 7, 2018

By Electronic Submission to www.regulations.gov

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Docket ID No. EPA-HQ-OA-2018-0259

Re: COMMENTS ON PROPOSED RULE, STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE, 83 FED. REG. 18,768 (Apr. 30, 2018)

Dear Acting Administrator Wheeler:

The Emmett Environmental Law & Policy Clinic at Harvard Law School submits this letter on behalf of a distinguished group of experts committed to the advancement of research to improve the health and safety of Americans and people around the world. The signatories include the President of Harvard University, the Presidents and a number of Department Chairs and Chiefs of four of the world's foremost research and teaching hospitals (Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Massachusetts Eye and Ear, and Massachusetts General Hospital), the Deans of Harvard's T.H. Chan School of Public Health and Harvard Medical School, preeminent faculty at the Harvard T.H. Chan School of Public Health, the Harvard Medical School, and the Harvard School of Engineering and Applied Sciences, and numerous esteemed research and clinical doctors affiliated with Harvard and its research hospitals. Work done by the signatories and/or their institutions addresses a broad spectrum of health impacts on infants, children, and adults from exposures to chemicals and activities that are regulated by the U.S. Environmental Protection Agency ("EPA") under various statutes including the Safe Drinking Water Act, the Toxic Substances Control Act, the Comprehensive Environmental Response, Compensation, and Liability Act, the Resource Conservation and Recovery Act, the Clean Water Act, and the Clean Air Act, collectively referred to herein as "the Statutes."

Specifically, signatories of this letter have conducted research to determine whether and how exposures to chemical substances such as lead and mercury in food, water, soil, and air affects the development of fetuses, infant mortality, children's development, and children's educational performance. They have also studied the health effects of indoor and outdoor chemical exposures on adult health and safety, including worker productivity and well-being.

Some of the signatories' research is used to develop vaccines and cures for cancer, improve the medical care of infants, children and adults, improve public and private building design, and plan

responses to emergencies. The results are also used to demonstrate the benefits of proposed regulatory actions in accordance with statutory and regulatory requirements.[1]

Their research is routinely relied upon by international, federal, and state agencies—including EPA—when they set standards and establish rules and best practices for the protection of human health, safety, and the environment. As explained below, the proposed rule would—for no rational reason—prevent EPA from relying on much of the research that the signatories, their institutions, and other public health and environmental exposure researchers have conducted and continue to conduct. The rule will cripple EPA's ability to implement the aforementioned Statutes and will jeopardize the health and safety of infants, children, and adults in the United States and beyond.[2]

Without the ability to protect and respect patient/human subject privacy and confidentiality, signatories and other researchers would not be able to conduct the studies that are pivotal to their work and to EPA's ability to fulfill its statutory duty to protect public health. The proposed rule ignores a host of existing methods and best practices already established—and adhered to—by the research community to ensure the transparency, reproducibility, replicability, objectivity, and validity of studies, analyses, models, and reports.[3] The proposed rule thus does not serve its stated purpose to ensure that regulatory decisions are based on "valid" science.[4]

Signatories teach graduate and undergraduate students and doctors-in-training about best practices in the conduct of public health, medical, and scientific research. They publish their research results in the most reliable, highest-quality, peer-reviewed medical and scientific

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[1] Signatories' research—which analyzes the human health and environmental impacts of the presence of chemicals in air, soil, drinking water, food, and consumer products—is relevant to EPA's required determinations under the Statutes that its regulations provide societal benefits by reducing harm to human health and the environment. Such research is also critically important to identifying the benefits of EPA regulations when the agency is required by the Statutes or Executive Order to conduct a formal cost-benefit analysis. *See* Exec. Order No. 13783, 82 Fed. Reg. 16,093, §1(e) (Mar. 31, 2017) ("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.").

[2] David Cutler & Francesca Dominici, *A Breath of Bad Air: Cost of the Trump Environmental Agenda May Lead to 80 000 Extra Deaths per Decade*, JAMA NETWORK (June 12, 2018), https://jamanetwork.com/journals/jama/fullarticle/2684596.

[3] *See* Section IV, below, for a discussion of best practices. EPA already has detailed policy and procedural guidance for ensuring and maximizing the quality of information the agency disseminates. *See* EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency* (Oct. 2002), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf. Note further that the proposed rule incorrectly uses the terms "reproducibility" and "replicability" as though they are interchangeable. In fact, they have different meanings. Typically, in the scientific community, "*reproducibility* refers to the ability of a researcher to duplicate the results of a prior study using the same materials as were used by the original investigator." Steven N. Goodman, et al., *What does research reproducibility mean?*, 8 SCIENCE TRANSLATIONAL MEDICINE 341ps12 (2016). By contrast, "replicability" refers to the ability of a researcher to duplicate the results of a prior study following the same procedures but collecting new data. *Id*.

[4] *See* 83 Fed. Reg. 18,768, 18,773 (Apr. 30, 2018) (stated purpose "to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation"); *see also id.* at 18,770 ("It is the charge of regulators to ensure that key findings [of science that informs regulatory actions] are valid and credible.").

journals, including Lancet, Nature, Science, New England Journal of Medicine, Journal of the American Medical Association, Cell, and Environmental Health Perspectives. They conduct peer reviews of the work of other researchers. The approach advocated in the proposed rule is inconsistent with professional best practices in their respective disciplines for conducting, reviewing, and confirming the results/findings of studies, especially those based on confidential personal health data of study participants. As will be shown below, the proposed rule will wreak havoc on public health, medical, and scientific research and undermine the protection of public health and safety.

Accordingly, the signatories strenuously object to the proposed rule and urge EPA to withdraw it.

I. THE PROPOSED RULE WOULD PREVENT EPA FROM RELYING ON THE BEST AVAILABLE INFORMATION AND SCIENCE

In the proposed rule, EPA acknowledges that it must use the "best available science" in all of its regulatory actions.[5] The signatories agree that is the correct starting point for EPA. They disagree, however, with EPA's new position in this proposed rule that science is not the "best" unless the associated raw data are released to the public.[6] As an initial matter, releasing raw data will not improve the quality of the resulting report/study/analysis, and therefore will do nothing to render any individual study "better." EPA itself affirmed this point as recently as 2016.[7] Moreover, while it might be helpful in some situations to make raw data publicly available, it is neither practical nor desirable to impose this requirement as a one-size-fits-all approach.

Instead, there are a variety of other best practices that already exist to test and ensure the rigor, quality, and validity of research. These include the peer review process, which evaluates whether the work is based on the best available scientific understanding, and scientists' detailed description of their research methods, code and non-confidential data in their published articles. That detail allows other researchers not only to challenge the study results, but also to reproduce or validate them using the original data, and/or replicate them via other studies using different data sets. The scientific community considers results valid if they are or can be replicated by other researchers conducting studies using new data, but the same method.[8]

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[5] 83 Fed. Reg. at 18,769 (citing Exec. Order No. 13563, 76 Fed. Reg. 8,321 (Jan. 21, 2011)).

[6] *See* 83 Fed. Reg. at 18,772 (rule would require that "dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.").

[7] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research*, at 4-5 (2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf ("Whether 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.").

[8] *See, e.g.*, Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science 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)* 4 (May 12, 2018), https://perma.cc/MM3J-CHEA [hereinafter "SAB Memo"]; Bernard Goldstein, Op-Ed., *This is Why EPA's "Secret Science" Proposal Alarms Public Health Experts*, THE

Contrary to EPA's stated goal of improving the basis for its regulatory decisions, requiring the public availability of all raw data will instead undermine EPA's ability to make reasonable decisions. This requirement will effectively prohibit EPA from considering studies that by design are based on data that *cannot* be made publicly available due to laws and contracts designed to protect patient and human subject privacy and ensure willingness of people to participate in research by sharing their private information with researchers. The proposed rule precludes consideration of studies based on confidential data, even when those results have been confirmed by other studies.[9] Hence, the proposal would in many instances *prohibit* EPA from relying on the best available science relevant to many of the regulatory issues that the agency faces.

Moreover, this proposed requirement contravenes five decades of EPA practice. EPA has repeatedly affirmed that its mission requires it to rely on the best available scientific evidence, without ever asserting that it should exclude from consideration studies for which the underlying data were not publicly available. For example, in its 1997 strategic plan, EPA declared one of its seven overall purposes was to ensure that "efforts to reduce environmental risk are based on the best available scientific information."[10] In 2002, EPA issued Information Quality Guidelines in which it took the position that the standard set forth in the Safe Drinking Water Act — "the best available, peer-reviewed science"[11] — should apply to all of the agency's risk assessments.[12]

EPA's historic position is consistent with the Statutes. For example, one of EPA's core duties under the Clean Air Act is to set and periodically review the National Ambient Air Quality Standards ("NAAQS") for six common air pollutants. In carrying out this responsibility,

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CONVERSATION (May 18, 2018), https://theconversation.com/why-the-epas-secret-science-proposal-alarms-public-health-experts-96000.

[9] One example is the Six Cities Study, Douglas W. Dockery, et al., *An Association between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENGLAND J. MED. 1753 (1993), whose results were subsequently confirmed by independent reanalysis, Health Effects Institute, *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality* (2000), https://www.healtheffects.org/system/files/HEI-Reanalysis-2000.pdf. Indeed, both the Six Cities Study and the American Cancer Study of Particulate Air Pollution and Mortality have each been reproduced and replicated. The findings are consistent with the original studies. *See, e.g.*, Qian Di, Francesca Dominici, Joel D. Schwartz, et al., *Air Pollution and Mortality in the Medicare Population*, 376 NEW ENGLAND J. MED. 2513-2522 (2017), *available at* https://www.nejm.org/doi/full/10.1056/nejmoa1702747.

[10] EPA, EPA/190-R-97-002, *EPA Strategic Plan*, at 16 (1997), https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=400009JX.PDF Earlier, in a March 1992 report titled *Safeguarding the Future: Credible Science, Credible Decisions*, an independent committee convened by EPA declared that "science is one of the soundest investments the nation can make for the future. Strong science provides the foundation for credible environmental decision making. With a better understanding of environmental risks to people and ecosystems, EPA can target the hazards that pose the greatest risks, anticipate environmental problems before they reach a critical level, and develop strategies that use the nation's, and the world's, environmental protection dollars wisely." EPA, *Safeguarding the Future: Credible Science, Credible Decisions*, at 15 (Mar. 1992), https://nepis.epa.gov/Exe/ZyPDF.cgi/30001ZWJ.PDF?Dockey=30001ZWJ.PDF.

[11] 42 U.S.C. § 300g-1(b)(3)(A)(i).

[12] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, at 21-23 (2005), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf.

Congress commanded EPA to use "the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects [of air pollution] on public health or welfare."[13] Similarly, the Safe Drinking Water Act commands EPA in general to use "the best available, peer-reviewed science" and when deciding whether to regulate a particular contaminant to consider the "best available public health information."[14] The Toxic Substances Control Act requires that regulation of chemical substances be "consistent with the best available science" and that EPA make decisions "based on the weight of the scientific evidence."[15] The water quality criteria that EPA develops under the Clean Water Act must "accurately reflect[] the latest scientific knowledge" on a variety of factors.[16]

Furthermore, because EPA is required under the Statutes to assess the public health benefits of its regulations, it must take into account all relevant science and cannot arbitrarily exclude certain studies demonstrating those benefits. Under the Clean Air Act, EPA must set the NAAQS at a level "requisite to protect the public health."[17] Under the Safe Drinking Water Act, EPA must determine whether a contaminant "may have an adverse effect on the health of persons" before deciding to regulate it.[18]

Many of the fundamental public health studies on which EPA has based key rules and standards under the Statutes are studies for which the raw data were not or could not have been released. Attachment 1 to this letter contains a partial list of studies that likely contain confidential data; these are all studies on which EPA has relied and cited as the basis for its actions under some of the Statutes. Until now, release of the underlying raw data was not an EPA criterion for determining the "best available" reports, studies, analyses, or models. Indeed, none of the Statutes invoked by EPA as support for the proposed rule limits EPA in this fashion; none of the Statutes requires EPA to make raw data publicly available.[19]

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[13] 42 U.S.C. § 7408(a)(2).

[14] 42 U.S.C. §§ 300g-1(b)(3)(A)(i), 300g-1(b)(1)(B)(ii)(II).

[15] 15 U.S.C. § 2625(h), (i).

[16] 33 U.S.C. § 1314(a)(1).

[17] 42 U.S.C. § 7409(b).

[18] 42 U.S.C. § 300g-1(b)(1)(A)(i).

[19] When litigants in the past argued that EPA could not rely on studies for which the raw data had not been publicly available, the D.C. Circuit soundly rejected their argument. As the court explained in one case:

> Claiming neither that they were unable to obtain the studies, nor that the studies were improperly published or peer reviewed, Petitioners instead urge us to impose a general requirement that EPA obtain and publicize the data underlying published studies on which the Agency relies. The Clean Air Act imposes no such obligation. . . . More generally, we agree with EPA that requiring agencies to obtain and publicize the data underlying all studies on which they rely "would be impractical and unnecessary."
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> […]
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> As EPA persuasively stated in denying Petitioners' original request for information:
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>> 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

EPA's proposed new approach, which conflicts with the agency's obligations and curtails its authority, is irrational at best and detrimental to public health and safety at worst.

II. THE PROPOSED RULE WOULD EXCLUDE CRITICAL STUDIES FROM CONSIDERATION IN FUTURE EPA RULEMAKING

There are at least two categories of critically-important, health-based studies for which it will be impractical or illegal to make the underlying data publicly available. Within each category are studies that have already formed the basis for decades of EPA regulatory actions producing enormous public health and safety benefits. The proposal would require that EPA stop relying on these studies and prohibit automatic consideration of, or reliance on, others like them in the future for no other reason than that the raw data cannot be released to the public.[20] This result would be extremely harmful to human health, safety, and the environment.

A. THE PROPOSAL WOULD PREVENT EPA FROM RELYING ON STUDIES BASED ON CONFIDENTIAL HUMAN HEALTH DATA

For many studies, disclosure of the raw data would violate researchers' statutory or contractual duties to protect patient or human research participant confidentiality. Many types of crucial health impact studies cannot be conducted without human participants. For any research carried out by healthcare providers that involves the handling of individually identifiable health information, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Privacy Rule imposes strict confidentiality requirements.[21] Federally-funded research involving human subjects is governed by the Federal Policy for the Protection of Human Subjects, also

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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. . . . Such data are often the property of scientific investigators and are often not readily available because of ... proprietary interests ... or because of [confidentiality] arrangements [with study participants].

Am. Trucking Associations, Inc. v. E.P.A., 283 F.3d 355, 372 (D.C. Cir. 2002) (quoting Particulate Matter NAAQS, 62 Fed. Reg. 38,652, 38,689 (July 18, 1997)). The court reiterated this holding six years later in a challenge to the 2008 lead NAAQS. *Coal. of Battery Recyclers Ass'n v. E.P.A.*, 604 F.3d 613, 622 (D.C. Cir. 2010). In that case, the litigants had sought access to the raw data underlying Bruce P. Lanphear, et al., *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, 113 ENVTL. HEALTH PERSP. 894 (2005).

[20] The proposal allows EPA to decide to consider such studies on a case-by-case basis. *See* 83 Fed. Reg. at 18,772. The factors EPA identifies for providing individual exemptions—that such disclosure cannot be done "in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security"—merely reiterates the main reasons that data are not currently made publicly available. *Id.* at 18,773. If EPA always allows data to be withheld for those reasons, the rule is meaningless and has no effect. On the other hand, if EPA instead picks and chooses when to allow data to be withheld for those reasons, it will be doing so based on no meaningful standards. *Cf. Pearson v. Shalala*, 164 F.3d 650, 660 (D.C. Cir. 1999) ("It simply will not do for a government agency to declare—without explanation—that a proposed course of private action is not approved. To refuse to define the criteria it is applying is equivalent to simply saying no without explanation.").

[21] 45 C.F.R. Part 160 and Subparts A and E of Part 164.

known as the Common Rule.[22] The Common Rule requires that researchers obtain Institutional Review Board ("IRB") approval and informed consent of research subjects, during which process the researcher will typically need to make promises regarding confidentiality.[23] Most institutions have committed to comply with the Common Rule for all of their research,[24] even when it is not federally-funded.[25]

EPA's suggestion in the proposed rule that "simple data masking, coding, and de-identification," 83 Fed. Reg. at 18,771, will be able to overcome these confidentiality concerns is incorrect. As explained by the EPA's own Science Advisory Board ("SAB"), "[i]n some cases, the data cannot be released simply by redacting portions of it. For example, data may have been collected with an assurance to the participating individuals that their data would be kept confidential."[26] Researchers cannot violate those promises after the fact, particularly if they want to be able to continue to find participants for their studies. In addition, "[i]n the case of clinical trials, there are studies in which removal of all identifying data negates its scientific value."[27]

The understanding of what counts as identifying data is continually expanding: true de-identification of the data may not be possible for some studies, such as those in which the participants come from a small geographical area and/or a specific profession. One study found that the researchers could re-identify approximately one-quarter of the records in a subset of a

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[22] 45 C.F.R. 46 subpart A is the U.S. Department of Health and Human Services ("HHS") citation for the Common Rule. A total of 18 federal agencies have adopted it; each agency has its own separate entry in the Code of Federal Regulations. This federal rule governs ethical constraints that federally funded studies must follow, including academic research, responding to earlier concerns of ethical lapses in medical research. *See, e.g.*, Jerry Menikoff, *Could Tuskegee Happen Today?*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 311, 312-16 (2008) (describing the Congressional response to public outcry when the details of the Tuskegee experiment were brought to light). The thrust of the Common Rule is to address such matters of research ethics as informed consent, informational risk, and institutional oversight when research involves human subjects. *See* 82 Fed. Reg. 7,149-7,274.

[23] For example, under its "Basic elements of informed consent" provisions, the Common Rule provides that "in seeking informed consent the following information shall be provided to each subject: . . . A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained." 45 C.F.R. § 46.116(b)(5). The Common Rule also requires that the IRB ensure that the researchers make "adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." 45 C.F.R. § 46.111(a)(7).

[24] *See Federalwide Assurance (FWA) for the Protection of Human Subjects*, HHS, https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html (describing Common Rule policy for institutions performing government-funded human subject research) (last visited August 3, 2018).

[25] Harvard University, for example, has established policies for all university research that go beyond the requirements of the Common Rule. *Statement of Policies and Procedures Governing the Use of Human Subjects in Research at Harvard University*, HARVARD UNIVERSITY, https://provost.harvard.edu/use-human-subjects-research (last visited August 3, 2018).

[26] SAB Memo, *supra* note 8, at 4.

[27] Lynn R. Goldman & Ellen K. Silbergeld, *Assuring Access to Data for Chemical Evaluations*, 121 ENVTL. HEALTH PERSP. 149, 150 (2013).

HIPAA-compliant environmental health data set.[28] For some studies, it may not be possible to de-identify the data set while still protecting patient or research subject confidentiality.

The proposed rule would prohibit the continued and future use of these studies by EPA thereby obstructing EPA's statutory duty to consider the "best," "reasonably" available information in its decision-making processes. The resulting information vacuum would occur for no other reason than that the underlying human subject data is private and cannot be publicly disseminated.[29]

The proposed rule would also impede EPA's ability to address new and emerging public health risks in future rulemakings. For example, former Administrator Pruitt announced on May 22, 2018, that EPA will begin to develop maximum contaminant levels under the Safe Drinking Water Act for two fluorochemicals, perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonate ("PFOS").[30] EPA also plans to designate PFOA and PFOS as hazardous chemicals, potentially under the Comprehensive Environmental Response, Compensation, and Liability Act.[31] If finalized, however, the proposed rule would prevent these EPA actions.[32]

When EPA issued health advisories for these two chemicals in 2016, the Health Effects Support Documents relied extensively on epidemiological studies generated by the C8 Health Project.[33] A key component of the evidence for the harmfulness of these chemicals consists of epidemiological studies based on data that are not publicly available. Researchers published more than three dozen papers based on these data, identifying probable links between PFOA

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[28] Latanya Sweeney, et al., *Re-identification Risks in HIPAA Safe Harbor Data: A Study of Data from One Environmental Health Study*, TECH. SCI., 2017082801 (Aug. 28, 2017), https://techscience.org/a/2017082801.

[29] Note that some of the Statutes require EPA to use the "best" available information and others have a lower standard. For example, the Toxic Substances Control Act compels EPA to take "reasonably" available information into account. 15 U.S.C. § 2625(k).

[30] Amena H. Saiyid, *Pruitt Plans to Declare Two Fluorochemicals Hazardous*, BLOOMBERG BNA (May 22, 2018), https://news.bloombergenvironment.com/environment-and-energy/pruitt-plans-to-declare-two-fluorochemicals-hazardous.

[31] Press Release, EPA, *Administrator Pruitt Kicks Off National Leadership Summit on PFAS* (May 22, 2018), https://www.epa.gov/newsreleases/administrator-pruitt-kicks-national-leadership-summit-pfas.

[32] Epidemiological studies, which were essential to discovering the immunotoxicity of perfluorinated alkylate substances, including PFOA and PFOS, were based on confidential human health data. *See* Philippe Grandjean, *Delayed discovery, dissemination, and decisions on intervention in environmental health: a case study on immunotoxicity of perfluorinated alkylate substances*, 17:62 ENVTL. HEALTH 1 (2018), *available at* https://ehjournal.biomedcentral.com/articles/10.1186/s12940-018-0405-y.

[33] EPA, EPA 822-R-16-003, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)*, at 3-1 to 3-60 (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_hesd_final-plain.pdf; EPA, EPA 822-R-16-002, *Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)*, at 3-1 to 3-49 (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfos_hesd_final_508.pdf. The C8 Health Project was funded through the settlement agreement in a lawsuit brought over drinking water contaminated by PFOA from the DuPont Washington Works facility near Parkersburg, West Virginia. The study involved close to 70,000 participants, for each of whom "demographic data, medical diagnoses (both self-report and medical records review), clinical laboratory testing, and determination of serum concentrations of 10 perfluorocarbons (PFCs)" were collected. Stephanie J. Frisbee et al., *The C8 Health Project: Design, Methods, and Participants*, 117 ENVTL. HEALTH PERSP. 1873, 1876 (2009) ("To protect participant privacy, the presiding judge subsequently sealed the data set.").

(also known as C8) exposure and "diagnosed high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer, and pregnancy-induced hypertension."[34]

This situation underlines the arbitrariness and irrationality of the proposed rule. On the one hand, EPA is proposing to take regulatory action to protect the American people from emerging health threats. On the other—through the proposed rule—it is simultaneously undermining its own ability to follow through on those proposals.

B. THE PROPOSAL WOULD PREVENT EPA FROM RELYING ON STUDIES CONDUCTED MANY YEARS AGO FOR WHICH DATA ARE NO LONGER AVAILABLE

Many key EPA regulatory decisions in effect today were based on studies conducted decades ago. Due to the passage of time, the raw data from these studies may no longer be available. Records may have been lost; researchers may have retired or passed away. Or, the data may have been stored in electronic media such as tapes that are no longer compatible with existing systems or otherwise difficult to access.[35] As noted by John Ioannidis, who is a strong advocate of data transparency,[36] "we should recognize that most of the raw data from past studies are not publicly available. . . . 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."[37]

C. STUDIES THAT EPA WILL BE PROHIBITED FROM CONSIDERING UNDER THE PROPOSAL HAVE SERVED AS THE BASIS FOR MULTIPLE RULEMAKINGS BY EPA AND OTHER AGENCIES

Studies that would be excluded from EPA consideration under the proposal form the basis for multiple regulatory actions that EPA and other agencies have taken over the course of many years. Consider, for example, early studies on the neurological effects of low-dose exposure to lead such as Herbert Needleman's 1979 paper finding a negative relationship between the level of lead in children's teeth and IQ scores.[38] EPA relied on this study in its 1986 Air Quality Criteria document for lead.[39] EPA's Lead and Copper Rule, which established the federal

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[34] *The Science Panel Website*, C8 SCIENCE PANEL, http://www.c8sciencepanel.org/index.html (last updated Jan. 4, 2017). Even the scientists selected to lead the research were provided with access only to de-identified data from the participants, except in the case of some participants who consented to provide additional data for follow-up studies.

[35] Goldman & Silbergeld, *supra* note 27, at 150.

[36] Ioannidis was one of the authors of Marcus R. Munafò et al., *A Manifesto for Reproducible Science*, 1 NATURE HUMAN BEHAVIOUR 1 (2017), DOI: 10.1038/s41562-016-0021, http://www.nature.com/articles/s41562-016-0021.pdf.

[37] John P.A. Ioannidis, *All Science Should Inform Policy and Regulation*, 15(5) PLOS MEDICINE 1, 1-2 (May 3, 2018), https://doi.org/10.1371/journal.pmed.1002576.

[38] Herbert L. Needleman, et al., *Deficits in Psychologic and Classroom Performance of Children with Elevated Dentine Lead Levels*, 300 NEW ENGLAND J. MED. 689 (1979).

[39] EPA, AIR QUALITY CRITERIA FOR LEAD, VOL. IV, 12-86 to 12-88, 12-95 (1986), https://nepis.epa.gov/Exe/ZyPDF.cgi/9101HLA1.PDF?Dockey=9101HLA1.PDF.

regulations for lead under the Safe Drinking Water Act, in turn relied on that Air Quality Criteria document to identify blood lead levels of concern.[40] EPA relied on both the 1986 Air Quality Criteria and on Needleman's research directly in establishing standards for lead-based paint hazards under the Toxic Substances Control Act.[41] Needleman's work, and subsequent studies building upon it, also supported EPA's decision to revise the NAAQS for lead in 2008.[42] The D.C. Circuit specifically ruled that the underlying data from one of the studies on which EPA relied in this rulemaking did not need to be publicly available for EPA to rely on the study.[43]

After 40 years, and with the principal investigator no longer alive, it is not clear that the raw data from the Needleman study is available. Even if the data were, they could not be made publicly available without invading the privacy of the study participants. Importantly, it would not be possible to conduct that same study at this time, because children no longer have blood or dental lead levels as high as they did in the 1970s as a result of EPA's implementation of the Statutes.

EPA's drinking water standard for arsenic under the Safe Drinking Water Act is similarly dependent on studies that the agency would now be compelled to ignore under the proposed rule. EPA established a drinking water standard of 10 ppb for arsenic in 2001.[44] The Food and Drug Administration ("FDA") then relied on EPA's determination.[45] In setting this standard, EPA relied on a National Research Council review of the scientific evidence, which "concluded that [certain epidemiological] studies from Taiwan provided the current best available data for the risk assessment of inorganic arsenic-induced cancer."[46] The Taiwanese papers looked at rates of skin cancer and blackfoot disease in villagers from southwestern Taiwan who were exposed to high levels of arsenic in their drinking water.[47] These studies were based on data from clinical

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[40] Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper, 56 Fed. Reg. 26,460, 26,468–26,469 (June 7, 1991).

[41] Lead; Identification of Dangerous Levels of Lead, 63 Fed. Reg. 30,302, 30,316–30,317 (proposed June 3, 1998). The final rule was published at 66 Fed. Reg. 1,206 (Jan. 5, 2001).

[42] National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 66,964 (Nov. 12, 2008).

[43] *Coal. of Battery Recyclers Ass'n v. E.P.A.*, 604 F.3d 613, 622-624 (D.C. Cir. 2010) (rejecting need to make raw data publicly available from Bruce P. Lanphear, et al., *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, 113 ENVTL. HEALTH PERSP. 894 (2005)).

[44] National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6,976, 7,036 (Jan. 22, 2001).

[45] The FDA subsequently relied on EPA's drinking water standard, as well as the research underlying it, when it proposed an action level for arsenic for apple juice in 2013. *See* Draft Guidance for Industry on Arsenic in Apple Juice: Action Level; Supporting Document for Action Level for Arsenic in Apple Juice; A Quantitative Assessment of Inorganic Arsenic in Apple Juice; Availability, 78 Fed. Reg. 42,086 (July 15, 2013); *see also* Clark D. Carrington et al., FDA, *A Quantitative Assessment of Inorganic Arsenic in Apple Juice* (2013), https://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM360016.pdf.

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

[47] The original papers were W.P. Tseng et al., *Prevalence of Skin Cancer in an Endemic Area of Chronic Arsenicism in Taiwan*, 40 J. NAT'L CANCER INST. 453 (1968) and Wen-Ping Tseng, *Effects and Dose Response Relationships of Skin Cancer and Blackfoot Disease with Arsenic*, 19 ENVTL. HEALTH PERSP. 109 (1978). Subsequent articles discussed longer-term health effects among the study cohort.

examinations of the research subjects and therefore included confidential patient data that likely cannot be released to the public. In addition, given that the first data were collected more than 50 years ago, the studies are based on data that may no longer be available.

Even though the proposed rule "is intended to apply prospectively," it will also have a retroactive impact. Some of the Statutes require EPA to periodically review its prior regulatory decisions. For example, EPA must reconsider the lead NAAQS every five years.[48] EPA is also in the process of reconsidering the Lead and Copper Rule under the Safe Drinking Water Act.[49] The proposed rule would prohibit EPA from continuing to rely on Needleman's critically-important study in future reconsiderations of the lead NAAQS and revisions to the Lead and Copper Rule.

Other future rulemakings would also be undermined by the proposed rule. In 2011, EPA decided to regulate perchlorate as a contaminant under the Safe Drinking Water Act.[50] "Perchlorate is commonly used as an oxidizer in rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches, and signal flares" and is also present in some fertilizers.[51] It is known to disrupt thyroid function by competitively inhibiting the uptake of iodide by the thyroid, and EPA in 2011 concluded "that there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern."[52] Late in 2017, EPA issued a draft report identifying potential approaches to deriving a maximum contaminant level goal for perchlorate.[53] To develop these approaches, EPA focused on five epidemiological studies.[54] All five studies relied on confidential patient data. In addition, all five studies were carried out in Europe, where scientists may be subject to different data confidentiality requirements than in the United States. As a result, the proposed rule risks undermining the scientific basis for this EPA action as well.

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[48] 42 U.S.C. § 7409(d)(1).

[49] *See Lead and Copper Rule Long-Term Revisions*, EPA, https://perma.cc/U5GV-B93M.

[50] Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7,762 (Feb. 11, 2011).

[51] *Perchlorate in Drinking Water*, EPA, https://www.epa.gov/dwstandardsregulations/perchlorate-drinking-water (last visited August 3, 2018).

[52] 76 Fed. Reg. at 7,763.

[53] EPA, *Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water* (2017), https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0438-0019.

[54] *Id.* at 6-1 to 6-19 (citing Tim I. M. Korevaar et al., *Association of Maternal Thyroid Function during Early Pregnancy with Offspring IQ and Brain Morphology in Childhood: A Population-based Prospective Cohort Study*, 4 THE LANCET DIABETES & ENDOCRINOLOGY 35 (2016); Martijn J. J. Finken et al. *Maternal Hypothyroxinemia in Early Pregnancy Predicts Reduced Performance in Reaction Time Tests in 5- to 6-Year-Old Offspring*, 98 J. CLINICAL ENDOCRINOLOGY & METABOLISM 1417 (2013); F. Vermiglio et al., *Attention Deficit and Hyperactivity Disorders in the Offspring of Mothers Exposed to Mild-Moderate Iodine Deficiency: A Possible Novel Iodine Deficiency Disorder in Developed Countries*, 89 J. CLINICAL ENDOCRINOLOGY & METABOLISM 6054 (2004); Victor J. Pop et al., *Maternal Hypothyroxinemia during Early Pregnancy and Subsequent Child Development: A 3-year Follow-up Study*, 59 CLINICAL ENDOCRINOLOGY 282 (2003); Victor J. Pop et al., *Low Maternal Free Thyroxine Concentrations during Early Pregnancy Are Associated with Impaired Psychomotor Development in Infancy*, 50 CLINICAL ENDOCRINOLOGY 149 (1999)).

Many other EPA rulemakings and decisions have relied on studies that cannot be replicated and whose data likely could not be made publicly available. For example:

- **PCBs**: EPA's regulations establishing water quality standards for polychlorinated biphenyls ("PCBs") under the Clean Water Act were based in part on long-term epidemiological studies of cancer rates in workers exposed to PCBs.[55]

- **Radionuclides**: EPA's Safe Drinking Water Act regulation for radionuclides relied on epidemiological studies of survivors from the Hiroshima and Nagasaki atomic bomb attacks.[56]

- **Particulate matter**: EPA's 1997, 2006, and 2012 NAAQS for fine particulate matter all relied on studies using confidential data, such as the Six Cities Study.[57]

- **Methylmercury**: EPA's reference dose for methylmercury in fish that will be consumed by humans relied on data from human exposures in the Faroe Islands.[58]

Precluding reliance on these and other studies for the sole reason that the underlying raw data has not been or cannot be released to the public is arbitrary, capricious, contrary to professional best practices, and antithetical to protection of public health and safety as required by the Statutes. The proposed rule will prevent EPA from relying on the "best available science."

III. "TRANSPARENCY" IN SCIENCE DOES NOT REQUIRE RELEASE OF PRIVATE INFORMATION; IT REQUIRES A CLEAR STATEMENT AND DETAILED DESCRIPTION OF THE METHODOLOGY USED BY THE RESEARCHER

Transparency is valuable and important. As used in the draft rule, however, transparency is a guise for excluding large bodies of valid—and best available—science. The concept of transparency promoted by the draft rule is harmful to good decision-making, to implementation of the Statutes, and, most of all, to protection of public health and safety.

In the professional scientific and medical research community, "transparency" means clear and detailed disclosure of all methods, data, assumptions, and uncertainties. Studies are considered "transparent" when the study design and methodology are clear enough to allow other scientists to challenge assumptions, test hypotheses, and either reproduce or replicate the study to

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[55] Thomas Sinks et al., *Mortality among Workers Exposed to Polychlorinated Biphenyls*, 136 AM. J. EPIDEMIOLOGY 389 (1992); Pier Alberto Bertazzi et al., *Cancer Mortality of Capacitor Manufacturing Workers*, 11 AM. J. INDUS. MED. 165 (1987).

[56] *See* Environmental Data and Governance Initiative ("EDGI"), *Public Protections Under Threat at the EPA: Examining Safeguards and Programs That Would Have Been Blocked by H.R. 1430* 9-10 (2017), https://perma.cc/3NUU-MDHM.

[57] Douglas W. Dockery, et al., *An Association between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENGLAND J. MED. 1753 (1993).

[58] P. Grandjean, et al., *Cognitive Deficit in 7-Year-Old Children with Prenatal Exposure to Methylmercury*, 19(6) NEUROTOXICOL TERATOL 417 (1997).

determine whether the results obtained are consistent with the original study. Having the raw data associated with the original study is not usually necessary to validate a study.[59]

Transparency does *not* mean violating the confidentiality of study participants or making all raw data publicly available. The proposed rule does not comport with the fundamental approach to conducting scientific and medical research that is the standard practice for experienced, advanced scholars and researchers.

Nor is it necessary to reproduce[60] a study to validate it. The proposal provides that "[i]nformation is considered 'publicly available in a manner sufficient for independent validation' when it includes the information necessary for the public to understand, assess, and *replicate* [sic] findings."[61] Neither reproducing nor replicating studies is always possible. Indeed in some circumstances it would be inhumane, immoral, or physically impossible to do so. Some studies involve natural disasters, other one-time events, or exposures and conditions that no longer exist and cannot be reproduced or replicated. Those studies are valid but would be excluded by the proposed rule. Examples include:

- Studies of Hiroshima and Nagasaki survivors that underlie Safe Drinking Water Act radionuclides regulation;
- Studies of the effects of lead from 1970s, when blood lead levels were higher than they are now;
- Studies of worker exposure to polychlorinated biphenyls before PCBs were banned; these studies formed the basis of water quality standards for PCBs under the Clean Water Act;
- Long-term cohort studies of benzene exposure in workers which formed the basis of EPA's 2007 Clean Air Act regulation for emissions of hazardous air pollutants from mobile sources; and
- Studies based on the massive oil leak at Deepwater Horizon.

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[59] *See supra* notes 3, 7, 8. In the rare instance when the raw data is needed to validate a study, EPA already has the ability to request it. This should be the exception, not the default as it has become in the proposed rule. If, ultimately, EPA is unable to obtain the raw data to verify the study results, it is within the agency's discretion to categorize such data as "qualitative," and taking into consideration inherent uncertainties, weigh the study relative to other evidence. *See* EPA, *Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessments* 9 (Aug. 28, 2012), https://www.epa.gov/sites/production/files/2015-07/documents/lit-studies.pdf.

[60] In the proposed rule, EPA incorrectly uses the term "replicate." *See* note 3, above.

[61] 83 Fed. Reg. at 18,773–18,774.

IV. THE PROPOSED RULE IGNORES MECHANISMS THAT ALREADY EXIST TO DEAL WITH CONCERNS ABOUT ACCESS TO RAW DATA

The proposed rule fails to acknowledge numerous federal laws, regulations, and guidance that regulate the quality of and access to raw data. These include: the Information Quality Act, Office of Management and Budget ("OMB") Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards ("OMB Uniform Guidance"),[62] and EPA's own Information Quality Guidelines. These already address the data access concerns that EPA raises in the proposed rule. Moreover, the proposed rule is inconsistent with some aspects of these other requirements. For example, OMB Uniform Guidance exempts from its definition of "research data" subject to disclosure any "medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study."[63] In contrast, the proposed rule would generally prohibit EPA from relying on studies based on data not disclosed to the public, even when disclosure would be a clearly unwarranted invasion of personal privacy. Any decision to consider the study while allowing the data to remain confidential is left to the whim of the EPA Administrator. This standardless, case-by-case approach is inconsistent with OMB's uniform privacy protections.

In the proposed rule, EPA ignores a variety of commonly-used mechanisms for assessing and ensuring the validity of studies without requiring public disclosure of the raw data. These mechanisms include peer reviews, pre-registration of study methodology, corroboration of results by subsequent studies, and in some instances special agreements that enable an independent third party, such as the Health Effects Institute ("HEI"), to re-analyze the raw data. As explained by the Science Advisory Board, the HEI's reanalysis of the Six Cities Study, through "an unusually rigorous form of peer review and independent reanalysis, coupled with many follow-up studies, has accomplished a measure of confidence in findings without public access to data and analytic methods."[64]

For these reasons, the public health, medical, and scientific research community does not regard the public disclosure of all raw data as necessary. For example, the Committee on Publication Ethics ("COPE"), which has over 12,100 member journals and editors covering all areas of scholarly inquiry, has established 10 core practices. COPE's core practice #5 on data and reproducibility provides that "[j]ournals should include policies on data availability and encourage the use of reporting guidelines and registration of clinical trials and other study designs according to standard practice in their discipline."[65] The simplicity and generality of this core practice statement signals that the question of standards for data transparency, data access,

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[62] *See* OMB, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*, 78 Fed. Reg. 78,590, at 78,631, 2 C.F.R. § 200.315(e)(3) (Dec. 26, 2013) (guidance incorporated from OMB, *OMB Circular A–110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations* § 36(d) (as amended Sept. 30,1999)) [hereinafter "OMB, *Uniform Guidance*"].

[63] OMB, *Uniform Guidance*, 2 C.F.R. § 200.315(e)(3)(ii).

[64] SAB Memo, *supra* note 8, at 4.

[65] *Core Practices*, COPE, https://publicationethics.org/core-practices (last visited August 3, 2018).

data sharing, data peer review, and replication and reproducibility practices are far from settled. There is no one-size-fits-all approach to the critical questions of data transparency, data sharing, and reproducibility.

The proposed rule was announced by EPA without any meaningful consultation with the broad research community despite the fact that it addresses a complex and contentious issue that is not yet ripe for regulatory action. There are ample and adequate safeguards in place at the leading journals to ensure "transparency" – the ability of other researchers to question, challenge, and validate the results of published studies. This would include the journals' policies on treatment of data from research published years and even decades ago. It is contrary to good scientific study and practice and the advancement of knowledge for EPA to arrogate to itself the determination of what constitutes useable research and data, and to grant sweeping discretion to the Administrator—who may not even be a scientist—to make those determinations.

In a rare joint statement, the editors of the journals *Science*, *Nature*, *PLOS One*, *Proceedings of the National Academy of Sciences*, and *Cell* explained:

> 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.[66]

As has long been recognized by the professional public health, medical, and scientific research community—and by EPA itself until now[67] —whether or not the raw data underlying a study is released does not determine the quality of the study. Rather, it is the scientific method that is determinative. The proposed rule fails to take into account the fact that studies are reliable and constitute the best available science when they comply with professionally-established best practices for describing the methodology, sampling size, sampling procedure and assumptions utilized and the results are consistent with those of other studies.

V. THE PROPOSAL WOULD IMPOSE AN IMMENSE AND UNNECESSARY COST AND PAPERWORK BURDEN ON EPA, OTHER FEDERAL AGENCIES, AND THE RESEARCH COMMUNITY

EPA has not established a legitimate need for the proposed rule. EPA has made thousands of regulatory decisions over the last 50 years. The Congressional Budget Office estimates that EPA "relies on about 50,000 scientific studies annually to perform its mission."[68] The proposed rule

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[66] 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.

[67] *See supra* note 7.

[68] Congressional Budget Office ("CBO"), *Cost Estimate: H.R. 1030, Secret Science Reform Act of 2015* 2 (Mar. 11, 2015), https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf.

fails to identify a single regulatory action based on faulty science.[69] The rule is not needed or warranted. It will do far more harm than good.

Although OMB did not have a meaningful opportunity to review the proposed rule before former Administrator Pruitt signed and released it (OMB had a mere five days) and presumably did not intend to allow EPA's new definitions to modify OMB's Uniform Guidance, one might argue that that is an effect of the proposed rule. If so, its radical and erroneous "transparency" requirements would extend to all federal agencies, wreaking chaos.

The CBO estimates that it will cost between $10,000 and $30,000 per study to make the raw data available.[70] If EPA continues to rely on roughly the same number of studies, it could cost hundreds of millions of dollars a year to implement the proposal. Imposing these costs on all federal agencies would be a staggering burden. Given the cost and the impracticality of releasing all raw data to the public, EPA will have effectively but wrongly undermined public health and safety.[71]

Even if EPA or the researchers do spend this money and considerable time to de-identify data to comply with the proposed rule, that effort will not necessarily protect patient or research subject confidentiality. As mentioned above, it is frequently possible to re-identify individuals from supposedly de-identified datasets. For example, one study found that the researchers could re-identify approximately one-quarter of the records in a subset of a HIPAA-compliant environmental health dataset.[72]

Relatedly, for some studies (e.g. prospective cohort studies that include extensive personal data; environmental health effects studies), it is impossible to de-identify the data without negating its scientific value. To protect against re-identification, it would be necessary to remove so much demographic information from the dataset that other scientists would not be able to perform meaningful re-analyses of the data.

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[69] Importantly, this proposed rule shifts the presumption of validity away from non-biased, peer-reviewed studies conducted by professional and academic researchers to non-peer reviewed studies conducted by the interested, regulated enterprises. In fact, if there is a problem anywhere in the science on which EPA relies, it is in the industry studies submitted for licensing and permitting—yet these actions are excluded from the coverage of the rule by the definition of "regulatory decisions." *See* Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 WASHBURN L.J. 549, 559-63 (2002) (detailing incidents in which data required to be submitted by manufacturers or their contractors under the Federal Fungicide, Insecticide, and Rodenticide Act ("FIFRA") and the Food, Drug, and Cosmetic Act ("FDCA") were either withheld or were misleading or fraudulent); *cf.* SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED THE VIRTURE OF BIOMEDICAL RESEARCH? (2003) (discussing this problem throughout the book and providing considerable support).

[70] CBO, *supra* note 68, at 2.

[71] In the proposal, EPA cites a paper prepared by Randall Lutter and David Zorn for the Mercatus Center, which arrives at a lower cost estimate than the CBO, to support its conclusion that "the benefits of this proposed rule justify the costs." 83 Fed. Reg. at 18,772 & n.24. EPA cannot abdicate its responsibility to conduct its own analysis of the costs and benefits of this regulation by relying on this paper.

[72] Sweeney, et al., *supra* note 28.

VI. THE PROPOSED RULE WOULD CREATE CONFUSION AND CHAOS DETRIMENTAL TO THE PROTECTION OF PUBLIC HEALTH

The proposal, as drafted, contains significant ambiguities. As a result, it is entirely unclear what the effect of the proposed rule will be on studies that have already formed the basis of existing rules but as to which the underlying raw data has not been and cannot be made available for various reasons. These studies are considered by professionals to be the "best" available science.

The following crucial questions are not addressed by the proposed rule:

1. Will EPA continue to rely on those studies or will they now arbitrarily be excluded from consideration?

2. Will EPA implement the new rule by ensuring that raw data are made available (very costly) or simply by ignoring existing, valid studies as to which the data cannot be made available or would be extremely expensive to de-identify?

3. How will EPA implement its exemption authority? What are the governing standards for when the Administrator will exercise this authority?

4. Will the proposed rule apply to old studies or only new ones and to past regulatory decisions or only new ones? The latter point is especially a concern under statutes that require EPA to revise standards periodically. Will previously-established standards be abandoned because the data from the studies underlying those decisions (in many cases decades old) is no longer available?

5. How will the proposal affect the actions of other agencies that rely on EPA's findings or decisions or that provide information to EPA? For example, what will the effect be on Agency for Toxic Substances and Disease Registry ("ATSDR") analyses that EPA is required to consider pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act?

6. How will EPA's re-interpretation of OMB's Uniform Guidance and other rules that apply uniformly to the entire federal government be administered? For example, how will the Food and Drug Administration's review of applications for new drugs be affected?

In addition, EPA has not included any analysis of the impact of the proposed rule on its existing or future regulations.

Many of the signatories conduct studies, reports, analyses, and models that are used to support the work of numerous state and federal agencies. The proposed rule will interfere with the ability of these agencies to work together as required by some statutes to develop joint approaches to protection of public health and safety due to the restrictions in the proposed rule. Specifically, the rule will impede EPA's ability to work effectively with the Food and Drug Administration, ATSDR, the Department of Agriculture, and other agencies whose mission is to protect public health.

VII. THE PROPOSED NEW APPROACH TO DOSE-RESPONSE MODELING IS ANTITHETICAL TO PROPER SCIENTIFIC METHODOLOGY AND CONTRAVENES THE ADVICE OF EXPERTS IN THE FIELD, INCLUDING THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE

EPA proposes to use "default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. . . . When available, EPA shall give explicit consideration to high quality studies that explore: a broad class of parametric dose-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity."[73] This proposed new approach allows for assuming a safe threshold below which humans can be exposed to chemicals in circumstances where data may be sparse. This approach runs counter to EPA's own historic practice and to the best practice employed by the scientific community when conducting risk assessments. Specifically, the National Research Council has recommended that linear and conceptual models be used "unless data is sufficient to reject low-dose linearity."[74] The scientific research and risk assessment community have also reached a consensus that cancer and non-cancer risk assessment should be unified so that all compounds, not just carcinogens, should be subjected to benchmark dose modeling.[75] This means that researchers should <u>not</u> assume a safe threshold of exposure even for non-carcinogens such as lead and mercury.[76]

The approach EPA proposes also conflicts with the advice of EPA's own Science Advisory Board as well as the advice of the National Academies of Sciences, Engineering, and Medicine.[77] And, EPA's proposed new approach directly conflicts with the statutory mandates that it must protect develop rules that protect human health "with an adequate margin of safety."[78]

EPA's assertion in the proposed rule that there is "growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects" is dangerous and unsupported by scientific evidence.[79] In recent years, several toxicants such as lead and

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[73] 83 Fed. Reg. at 18,774.

[74] This has also been the position of the federal government since 1983. Eileen Abt, et al. *Science and Decisions: Advancing Risk Assessment*, 30 RISK ANALYSIS 1028 (2010); Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences and National Research Center, *Risk Assessment in the Federal Government: Managing the Process* (1983), http://www.nap.edu/catalog/366/risk-assessment-in-the-federal-government-managing-the-process.

[75] EPA, Risk Assessment Forum, *Benchmark Dose Technical Guidance* (June 2012), https://www.epa.gov/sites/production/files/2015-01/documents/benchmark_dose_guidance.pdf; Eileen Abt, et al. *Science and Decisions: Advancing Risk Assessment*, 30 RISK ANALYSIS 1028 (2010).

[76] EPA, *supra* note 75; Eileen Abt, et al., *supra* note 75.

[77] EPA, *supra* note 75; Eileen Abt, et al., *supra* note 75.

[78] For example, the Clean Air Act, 42 U.S.C. § 7409(b)(1) (setting NAAQS); the Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(4)(A) (setting Maximum Contaminant Level Goals ("MCLG's")).

[79] 83 Fed. Reg. at 18,770.

particulate matter air pollution have been shown to have either superlinear responses at low dose or no threshold.[80] The consensus of the academic scientific community has been for over a decade that threshold effects should not be presumed in the absence of robust concentration-response data.[81] Accordingly, this comment letter endorses and incorporates by reference the comments on this point that have been submitted by: The National Academies of Sciences, Engineering, and Medicine dated July 16, 2018, and the Center for Science in the Public Interest dated July 17, 2018.

VIII. THE RULE SHOULD BE WITHDRAWN

The proposed rule will undermine EPA's ability to fulfill its mission to protect human health, safety, and the environment by using the best available information and science. First, the proposed rule would exclude from EPA's consideration any reports, studies, analyses, and models that rely on confidential, inaccessible, or unavailable data but that historically have been considered the best available science and therefore used to support regulations and standards designed to protect public health and safety. Second, in so doing, the rule also eliminates EPA's access to fundamental information necessary for identifying and calculating the "health benefits" of rules and standards needed to protect public health. Finally, it threatens to impose significant costs on both the federal government and independent scientists. Worst of all, the proposed rule creates these multiple problems without providing any significant countervailing benefits.

For these and all of the reasons explicated above, the proposed rule should be withdrawn.

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[80] Bruce P. Lanphear, et al., *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, 113 ENVTL. HEALTH PERSP. 894 (July 2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1257652/; Joel Schwartz, *Assessing Confounding, Effect Modification, and Thresholds in the Association between Ambient Particles and Daily Deaths*, 108 ENVTL. HEALTH PERSP. 563 (June 2000), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1638159/pdf/envhper00307-0129.pdf; Qian Di, et al., *Association of Short-term Exposure to Air Pollution With Mortality in Older Adults*, JAMA NETWORK (Dec. 26, 2017), https://jamanetwork.com/journals/jama/fullarticle/2667069.

[81] Eileen Abt, et al., *supra* note 75.

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Comments re: Docket ID No. EPA-HQ-OA-2018-0259

August 7, 2018

ATTACHMENT 1

Partial List of Studies That May Contain Protected Health Information and That Have Been Relied on by the Environmental Protection Agency (EPA) and Cited in EPA Documents

The following studies were cited in supporting or decision making EPA documents.

Safe Drinking Water Act (SDWA)

Six Year Review #1 Health Effects Technical Support Document

- Barrett JH, Parslow RC, McKinney PA, et al. 1998. Nitrate in drinking water and the incidence of gastric, esophageal, and brain cancer in Yorkshire, England. *Cancer Causes Control.* 9:153-159.
- Croen LA, Todoroff K, Shaw GM. 1997. Maternal dietary nitrate exposure and risk for neural tube defects. *Am J Epidemiol.* 145:S30.
- Van Loon AJ, Botterweck AA, Goldbohm RA, et al. 1998. Intake of nitrate and nitrite and the risk of gastric cancer: A prospective cohort study. *Br J Cancer.* 78:129-135.
- Ward MH, Mark SD, Cantor KP, et al. 1996. Drinking water nitrate and the risk of non-Hodgkin's lymphoma. *Epidemiology.* 7:465-471.
- Weyer PJ, Cerhan JR, Cross BC, et al. 2001. Municipal drinking water nitrate level and cancer risk in older women: the Iowa Women's Health Study. *Epidemiology.* 12(3):327-338.

Six Year Review #2 Health Effects Technical Support Document

- Moertel, CG et al. 1982. A clinical trial of amygdalin (laetrile) in the treatment of human cancer. *New England J. Med*. 306: 201-206.
- Rothman, N; GL Li; M Dosemeci; et al. 1996. Hematotoxicity among Chinese workers heavily exposed to benzene. *Am. J. Ind. Med.* 29: 236-246.
- Tajtakova, M; Z Semanova; et al. 2006. Increased thyroid volume and frequency of thyroid disorders signs in schoolchildren from nitrate polluted area. *Chemosphere*. 62(4): 559-564.
- Tseng, WP. 1977. Effects and dose-response relationships of skin cancer and blackfoot disease with arsenic. *Environ. Health Perspect*. 19: 109-119.
- Tseng, WP; HM Chu; SW How; et al. 1968. Prevalence of skin cancer in an endemic area of chronic arsenicism in Taiwan. *J. Natl. Cancer Inst*. 40: 453-463.
- Wones, RG; BL Stadler; and LA Frohman. 1990. Lack of effect of drinking water barium on cardiovascular risk factor. *Environ. Health. Perspect*. 85: 355-9.

- Yang, G; S Wang; R Zhou; and S Sun. 1983. Endemic selenium intoxication of humans in china. *American J. Clin. Nutr.* 37:351-357.

Six Year Review #3 Health Effects Technical Support Document

- Baccarelli, A; SM Giacomini; C Corbetta; et al. 2008. Neonatal thyroid function in Seveso 25 years after maternal exposure to dioxin. *PLoS Med.* 5(7): e161.
- Ciesielski, T; J Weuve; DC Bellinger; J Schwartz; B Lanphear; and RO Wright. Cadmium exposure and neurodevelopmental outcomes in U.S. children. *Environ Health Perspect*. 2012 May;120(5):758-63.
- Mocarelli, P; PM Gerthoux; DG Patterson, Jr; et al. 2008. Dioxin exposure, from infancy through puberty, produces endocrine disruption and affects human semen quality. *Environ Health Perspect.* 116(1): 70-77.
- Nawrot, TS; DS Martens; A Hara; M Plusquin; J Vangronsveld; HA Roels; and JA Staessen. 2015. Association of total cancer and lung cancer with environmental exposure to cadmium: the meta-analytical evidence. *Cancer Causes Control.* 26(9):1281-8.
- Walton, G. 1951. Survey of literature relating to infant methemoglobinemia due to nitratecontaminated water. *Am. J. Public Health*. 41(8 Pt 1): 986-996.
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- Bassin, E.B., Wypij D., Davis R.B., Mittleman M.A. 2006. “Age-specific Fluoride Exposure in Drinking Water and Osteosarcoma.” *Cancer Causes and Control.* 17: 421-8.
- Broadbent, Jonathan M., W. Murray Thomson, Sandhya Ramrakha, Terrie E. Moffitt, Jiaxu Zeng, Lyndie A. Foster Page, and Richie Poulton. 2015. Community Water Fluoridation and Intelligence: Prospective Study in New Zealand. *American Journal of Public Health.* 105.1 (2015): 72-76.
- Grimes, D.R. 2015. Commentary on are fluoride levels in drinking water associated with hypothyroidism prevalence in England? A large observational study of GP practice data and fluoride levels in drinking water. *J Epidemiol Community Health*. 69(7): 616.
- Malin, Ashley J., and Christine Till. 2015. Exposure to Fluoridated Water and Attention Deficit Hyperactivity Disorder Prevalence among Children and Adolescents in the United States: An Ecological Association. *Environmental Health*. 14:17.
- Larsson, SC; N Orsini; and A Wolk. 2015b. Urinary cadmium concentration and risk of breast cancer: a systematic review and dose-response meta-analysis. *Am J Epidemiol*. 182(5):375-80.

Contaminant Candidate List Examples

Boron Health Effects Support Document

- Baker, M.D. and S.C. Bogema. 1986. Ingestion of boric acid by infants. *Am. J. Emerg. Med*. 4(4):358-361 (as cited in U.S. EPA, 2004a).

- Culver, B.D., P.T. Shen, T.H. Taylor, et al. 1994. The relationship of blood- and urine-boron to boron exposure in borax-workers and the usefulness of urine-boron as an exposure marker. *Environ. Health Perspect*. 102(Suppl. 7):133-137 (as cited in U.S. EPA, 2004a).
- Friis-Hansen, B., B. Aggerbeck, and J.A. Jansen. 1982. Unaffected blood boron levels in newborn infants treated with a boric acid ointment. Food Chem. *Toxicol.* 20:451-454 (as cited in U.S. EPA, 2004a).
- Naghii, M.R. and S. Samman. 1997. The effect of boron supplementation on its urinary excretion and selected cardiovascular risk factors in healthy male subjects. *Biol. Trace Element Res*. 56:273-286 (as cited in U.S. EPA, 2004a).
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- Rainey C.J., L.A. Nyquist, R.E. Christensen, et al. 1999. Daily boron intake from the American diet. *J. Am. Diet Assoc*. 99(3):335-40.
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Perfluorooctanoic Acid Health Effects Support Document

- Andersen, C.S., C. Fei, M. Gamborg, E.A. Nohr, T.I.A. Sørensen, and J. Olsen. 2010. Prenatal exposures to perfluorinated chemicals and anthropometric measures in infancy. *American Journal of Epidemiology.* 172:1230–1237.
- Apelberg, B.J., F.R. Witter, J.B. Herbstman, A.M. Calafat, R.U. Halden, L.L. Needham, and L.R. Goldman. 2007. Cord serum concentrations of perfluorooctane sulfonate (PFOS) and perfluorooctanoate (PFOA) in relation to weight and size at birth. *Environmental Health Perspectives.* 115:1670–1676.
- Barry, V., A. Winquist, and K. Steenland. 2013. Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. *Environmental Health Perspectives*. 121:1313–1318.
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- Bloom, M.S., K. Kannan, H.M. Spiethoff, L. Tao, K.M. Aldous, and J.E. Vena. 2010. Exploratory assessment of perfluorinated compounds and human thyroid function. *Physiology & Behavior*. 99:240–245.
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women: a case-control study nested in the Danish National Birth Cohort. *Cancer Causes & Control*. 25(11):1439–1448.

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