

Statement of Lynn R. Goldman, MD, MS, MPH

May 31, 2018

Submitted to: the US Environmental Protection Agency Science Advisory Board

Comments on EPA Planned Action: NPRM “Strengthening Transparency in Regulatory Science”

Mr. Chairman and members of the EPA Science Advisory Board, it is my honor to testify to you about the EPA regulatory agenda and specifically the Notice of Proposed Rule Making (NPRM) called “Strengthening Transparency in Regulatory Science”. I am a pediatrician and an epidemiologist and have been Dean of the Milken Institute School of Public Health at the George Washington University since 2010. Prior to that time, I was a professor of environmental and occupational health at the Johns Hopkins Bloomberg School of Public Health. From 1993 through 1998, I served as Assistant Administrator for what now is called the Office of Chemical Safety and Pollution Prevention at the EPA. While serving in that position, I was responsible for the implementation of the nation’s pesticide and chemicals laws. Prior to joining the EPA, I worked for eight years in public health with the California Department of Health Services. I am a member of the National Academy of Medicine. My testimony represents my expertise as an environmental health scientist, and a former EPA official, and not the views of any one organization.

I support the SAB workgroup’s May 12 memo recommending that the SAB review the agency’s April proposed rulemaking, “Strengthening Transparency in Regulatory Science.” The workgroup points to a number of complex scientific issues for which the Agency should seek expert advice from the SAB. This NPRM suffers from lack of involvement of the scientific community, either within or outside of the EPA. No clear justification is given for why it is needed. The proposed rule is a dramatic departure from how the EPA and other US regulatory agencies, as well as similar agencies internationally, use regulatory science for the development of dose response assessments. It ignores a number of adverse downstream consequences including: rejecting high-quality academic research unless all raw data are made publicly available; generating risks of disclosure of personal information of people volunteering for human subjects’ research; exacting unknown but probably considerable costs to the research community and to the EPA for preparation and curation of data; and making best available science unavailable to the EPA. It creates an unfortunate precedent for EPA in the creation of science policy by rulemaking rather than guidance, thus freezing EPA’s risk assessment processes in the future. Finally, by restricting access to data and causing delays in EPA processes this proposal threatens EPA’s ability to protect public health and the environment.

Lack of Justification for the Proposed Rule:

First, why does EPA think that this proposed rule is necessary? No justification is given in the preamble. There are no examples of dose response curves that have been proven “wrong”

because of lack of reanalysis of raw data. There is no evidence given demonstrating that stakeholders are requesting increased transparency of these data. In 2013, Ellen Silbergeld and I published a paper in *Environmental Health Perspectives* documenting the use of the Information Quality Act (IQA) of 2001 for requests for raw data.¹ Between 2002–2012 only two IQA requests to the U.S. EPA were for raw data. Both of these were fulfilled under FOIA, not the IQA. This is if anything evidence of little demand for more transparency in terms of access to raw data. If, during that ten year period, EPA had accumulated datasets for all raw data for all dose response assessments that had been conducted, it would have been a tremendous waste in terms of 1) *delays* in EPA conducting assessments until data were obtained; 2) *costs* to the academic community in preparing datasets and extensive meta data files for EPA for all of their studies; 3) *expenditure* of agency staff resources in EPA compelling the submission of the data from academics; and 4) *EPA staffing and funds* for establishing and maintaining systems to house, protect and make available the raw data.

The proposal ignores the many mechanisms that the scientific community have developed to review and assess a body of evidence about an individual substance or chemical. Such methods, known as “systematic review” of evidence, have been developed, refined and improved over a number of years, especially in the US in the context of EPA programs like IRIS, pesticides, toxics, and priority air pollutants. The application of such methods has been reviewed by the National Academy of Sciences and they have offered recommendations for their improvement over time.² Likewise, the National Toxicology Program has been engaged in developing and refining these methodologies³. Of note is that none of these processes, nor any recommendations from the National Academies, has ever required the availability of “raw data” in order to perform dose response assessments. Nor have they ever concluded that scientific findings should be disregarded if “raw data” for dose response assessments were not available.

Costly to EPA and the Research Community

During the years I worked at EPA I learned that risk assessment activities at EPA are extensive; while many are performed in the flagship EPA IRIS program, far more are produced for chemical and pesticide as well as other regulatory decisions. The NPRM does not provide any estimates, but in 1996 we estimated that the agency performed more than 1,000 risk assessments per year. Such assessments have been required under a number of EPA’s statutes and range from premarket notification for chemicals, to periodic reviews of priority air standards, issuance of

¹ Goldman, L.R. and Silbergeld, E.K. Assuring access to data for chemical evaluations. *Environ Health Perspect*, 121(2):149-52, 2013.

² National Academies of Sciences, Engineering, and Medicine. 2018. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25086>.

³ Rooney AA, Boyles AL, Wolfe MS, Bucher JR, Thayer KA. 2014. Systematic review and evidence integration for literature-based environmental health science assessments. *Environ Health Perspect* 122:711–718; <http://dx.doi.org/10.1289/ehp.1307972>

pesticide tolerances, development of drinking water MCLs and assessment of risks of existing chemicals. We did not estimate how many of these included dose response assessments.

In terms of downstream consequences, the 2013 EHP paper considered these. Any consideration of a requirement on EPA scientists to gather raw data must consider, across dozens if not hundreds of assessments performed annually, the costs to the U.S. EPA and researchers, the significant time and paperwork burdens for researchers, and major regulatory delays that will occur when EPA is waiting for data to be submitted. How would the EPA compel the submission of such data? The U.S. EPA regulatory authority in this area is weak, especially for research conducted in the past, studies not funded by the U.S. government, and/or research conducted abroad. In some cases, it simply would not be feasible to obtain the raw data, either because it is not forthcoming from industry or international sources or because the data no longer exist or are stored on media that is no longer accessible. The U.S. EPA is also constrained by industry confidential business information (CBI) claims for regulatory testing data under U.S. chemical and pesticide laws. For whatever data it could obtain, EPA would have to establish a data repository for this information that would securely house not only the data (especially personal health information and/or CBI) but also a number of unique meta data elements required to understand the data.

Risk of Disclosure of Personal Information for Human Subjects

For human studies, to manage potential risks of disclosure of sensitive human data, the EPA would not be able to rely solely on data submitters to have deidentified the data but, to avoid liability, would have to perform checks to assure that EPA would not inadvertently disclose any personal health information. The NPRM considers none of these challenges. What constitutes a personal identifier? At the beginning of my career this was fairly straightforward, with variable combinations or variables, such as, name+date of birth, name+address, social security number and/or medical record number being the only means of identifying individual persons. With more recent expansion of availability of massive quantities of “big data” on the web, this is now a rapidly moving target. Most recently, the renowned geneticist Craig Ventner and colleagues reported the ability to identify persons using their genetic code alone (without needing to do a DNA match).⁴

⁴ “Here, we show that phenotypic prediction from WGS data can enable reidentification without any further information being shared. If conducted for unethical purposes, this approach could compromise the privacy of individuals who contributed their genomes into a database. In stratified analyses, we see that risk of reidentification correlates with variability of the cohort. Although sharing of genomic data is invaluable for research, our results suggest that genomes cannot be considered fully deidentifiable and should be shared by using appropriate levels of security and due diligence.” From: Christoph Lippert, Riccardo Sabatini, M. Cyrus Maher, Eun Yong Kang, Seunghak Lee, et al. Genomics of physical traits, PNAS Sep 2017, 201711125; DOI: 10.1073/pnas.1711125114

Sound Science Will be Excluded from EPA Regulatory Decisions

The predictable result of this proposal is that EPA will be forced to exclude studies that should be included in a systematic review, based solely on failure to meet the proposed disclosure requirement. For years, both Congress and successive administrations have required the EPA to use the best science for its decisions. It is a major departure for this NPRM to direct EPA scientists to exclude key studies merely because they cannot meet the proposed disclosure requirement. This is not consistent with good scientific practice and is contrary to years of effort to improve the research base underpinning EPA's decisions as well as EPA's mission to protect the public's health.

Paradoxically, the NPRM includes a provision for the EPA to waive this requirement. No clear decision criteria are provided to allow EPA scientists and stakeholders to understand how, and under what set of decision criteria, such waivers could be predicted to be granted. As proposed, this appears to be a process that would allow arbitrary and capricious application of the "raw data" requirement and not as a process invoking science judgment.

Reversal of EPA Science Policy and Precedents

Finally, the proposal seems to attempt, via a single rule making, to overturn years of EPA science policy guidelines and precedents around the selection and application of dose-response models for toxicity assessment. In so doing it misrepresents the recommendations of prior expert reviews such as the NAS "Silver Book"⁵ and the Bipartisan Commission review.⁶ (I peer reviewed the first and was a member of the committee that produced the second report.) For example, the NPRM is oblivious to NAS conclusions that thresholds of chemical exposure for chemical effects are the exception rather than the rule when accounting for factors including background exposures, co-exposures, and differential biological susceptibilities across the population.

The NPRM also seems to naively assume that single studies are used to inform risk assessors of the possible shape of dose response curves. They are not. As described by the EPA, the first step of the dose-response modeling process is to evaluate all of the scientific information to gain a biological understanding of how each type of toxicity or response (adverse effect) occurs; the understanding of how the toxicity is caused is called the "mode of action". Via this evaluation (and not via modelling of raw data from a single study), EPA identifies a sequence of key events and processes, that result in the effect. Frequently the data do not conclusively prove mode of action. In those cases, EPA often applies default assumptions such as low dose linearity for carcinogens unless the carcinogens can be shown to have a mode of action for which a threshold would be expected. Such defaults have been developed to assure that, in the face of uncertainty, the EPA will protect the public's health. In recent years, it has been

⁵ National Research Council. 2009. Science and Decisions: Advancing Risk Assessment. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12209>.

⁶ Bipartisan Commission. Improving the Use of Science in Regulatory Policy, Washington, DC. 2009

determined that often noncancer effects (e.g. lead and neurotoxicity) also have no threshold. Thus, dose response assessments require the review and analysis of many studies and endpoints.

This specific NPRM raises a general concern about opening the door to EPA enshrining its scientific practices in regulations. Issuing regulations on risk assessment methodology is a slippery slope that not only potentially subjects the process to at best, control by risk managers and attorneys, and at worst, politicization. Such rulemaking about risk assessment would freeze the science in procedures that may or may not make sense today, but will certainly not be scientifically defensible in the future. It would invite more such rulemaking and even legislating risk assessment methodologies and requirements in the years to come.

Conclusion

In conclusion, the proposed rule would make major changes and cause significant delays in how EPA uses science to make hundreds of regulatory decisions every year. It would overturn years of not only internal guidance and precedent, but also advice from scientific experts outside of EPA. It would be burdensome, for the agency and researchers alike. It would be contrary to EPA's mission to protect public health. I strongly urge the SAB to recommend the Administrator:

- (1) Do not use the agency's regulatory authority to prescribe specific risk assessment processes;
- (2) Do not adopt of any major changes to EPA's foundational policies on the use of science in rule-making without thorough advice and consultation with the SAB, and other authoritative scientific bodies.