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Submitted to: the US Environmental Protection Agency
Comments on EPA Proposed Rule: "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. From 1993 through 1998, I served as Assistant Administrator for Toxic Substances at the US Environmental Protection Agency leading what is now known as the Office of Chemical Safety and Pollution Prevention. While serving in that position, I was responsible for the implementation of the nation's pesticide and chemicals laws. I am a member of the National Academy of Medicine. My comments represent my expertise as an environmental health scientist, and a former EPA official, and not the views of any one organization.

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 the scientific community, use science for the development of dose response assessments. It ignores a number of adverse downstream consequences including: risking disclosure of personal information of people volunteering for human subjects' research; delaying EPA decision-making; exacting unknown but probably considerable costs to the research community and to the EPA; and making best available science unavailable to the EPA. It creates no regulatory authority or any other mechanism for the EPA to compel submission of data from academic scientists and industry, other than those that already are accessible under the Information Quality Act of 2001, nor a mechanism for access to industry data claimed as Confidential Business Information. It creates an unfortunate precedent for EPA in the creation of science policy by rulemaking, thus freezing EPA's risk assessment processes in the future and breaking the important separation between risk assessment and risk management that has been fundamental to science based decision-making.

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. In 2013, our paper in *Environmental Health Perspectives* documented the use of the Information Quality Act for requests for raw data.[1] We found little evidence for unfulfilled demand for more 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

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

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 "systematic review" methods for review of evidence that have been developed, refined and improved over a number of years in the context of IRIS, pesticides, toxics, and priority air pollutants. The application of such methods has been reviewed and improved upon by the National Academy of Sciences[2] and the National Toxicology Program[3]. Of note is no authoritative body of experts has ever recommended requiring "raw data" in order to perform or review dose response assessments. As a corollary, they have never concluded that scientific findings should be disregarded if "raw data" for dose response assessments are not available.

Costly to EPA and the Research Community

While at EPA I learned that risk assessment activities at EPA are extensive; not only the flagship IRIS program, but several regulatory programs are actively engaged in performing more than 1,000 risk assessments per year (a 1996 estimate). Such assessments are required under a number of EPA's statutes, for example: premarket notification for chemicals; assessments of priority air standards; pesticide tolerances; drinking water MCLs; and assessment of existing chemicals risks. The burdens for these assessments under the proposed rule are likely to be considerable. The proposal does not consider, across 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 made publicly available, which may not ever happen. It does not address how EPA could compel the submission of such data in the context of weak regulatory authority for research conducted in the past; studies not funded by the U.S. government; and/or research conducted abroad. It seems unaware of the Paperwork Reduction Act that tilts against information gathering from private parties. The U.S. EPA is further constrained by industry confidential business information (CBI) claims for regulatory testing data under U.S. chemical and pesticide laws; even when the EPA receives raw data from industry, it provides only data summaries to the public. For whatever data it could obtain, EPA would have to establish a public 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.

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[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

Risk of Disclosure of Personal Information for Human Subjects

To manage risks of disclosure of sensitive human data, the EPA would have to perform checks to assure that no personal health information would be in public data sets. We live in a day when not only name&date of birth, name&address, social security number and/or medical record number can be used to identify person but when massive quantities of "big data" are on the web. Most recently, the renowned geneticist Craig Venter and colleagues reported identified persons using their genetic code alone.[4]

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. For years, both Congress and successive administrations have required the EPA to use the best science for its decisions. Directing EPA scientists to exclude key studies is not consistent with good scientific practice and is contrary to years of effort to improve the base of knowledge underpinning EPA's decisions. While the NPRM includes a provision for the EPA to waive this requirement, it provides no clear criteria for such waivers and appears to be a process that would allow arbitrary and capricious application of the proposed rule.

Reversal of EPA Science Policy and Precedents

The proposal seems to attempt, via a single rulemaking, to overturn years of well-thought EPA science policy guidelines and precedents in the selection and application of dose-response models for toxicity assessment. It misrepresents the recommendations of prior expert reviews such as the so-called NAS "Silver Book"[5] and the Bi-Partisan Commission review[6]. It is oblivious to NAS conclusions that thresholds of chemical exposure for chemical effects are the exception rather than the rule. The NPRM seems to naively assume that single studies are used to inform risk assessors of the possible shape of dose response curves. That was true at one time, but today, 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 "mode of action". This is not done via modelling of raw data from a single study. When data do not prove mode of action, EPA often applies default assumptions such as low dose linearity for carcinogens. According to the NAS "Silver Book", often noncancer

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[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

[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

effects (such as, lead and other neurotoxic substances) also have no practically identifiable thresholds. More fundamentally, this NPRM for the first time opens the door to EPA's scientific practices being determined by regulators, and not scientists. This is a rush down a slippery slope that would replace a scientific process with a political one and would freeze the science in procedures that may be dubious today but certainly will not be scientifically defensible in the future. This is a breach of the fundamental notion of separating risk assessment from risk management.

Conclusion

In conclusion, the proposed rule would cause significant delays in how EPA uses science to make hundreds of regulatory decisions every year. It would overturn years of precedent, as well as advice from scientific experts outside of EPA. It would be burdensome, for the agency and researchers alike.

I strongly urge the EPA Administrator (1) not to use the agency's regulatory authority to prescribe specific risk assessment processes; and (2) not undertake changes in EPA's science policies without leadership from EPA scientists and full engagement of the science community.

What is at stake is no less than the public's confidence in the integrity of EPA's science and decisions.