CENTER FOR
Science IN THE
Public Interest
The nonprofit publisher of Nutrition Action Healthletter

May 18, 2020

EPA Docket Center
Environmental Protection Agency
Mail code 28221T
1200 Pennsylvania Ave NW
Washington, DC 20460

Re: Docket No. EPA-HQ-OA-2018-0259; Strengthening Transparency in Regulatory Science; Supplemental notice of proposed rulemaking

The Center for Science in the Public Interest (CSPI) respectfully submits the following comments on the U.S. EPA's supplemental notice of proposed rulemaking (SNPRM), which modifies the Strengthening Transparency in Regulatory Science Proposed Rulemaking published on April 30, 2018.

CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health. The organization has a strong history advocating for scientific transparency. Our Integrity in Science Project investigated, exposed, and sought to reduce corporate influence on science and science-based public policy in the 2000s.[1] More recently, CSPI led a call for the National Library of Medicine to be more transparent in publishing conflict of interest disclosures.[2] CSPI President Peter Lurie has authored numerous academic articles on transparency,[3] and formerly served as Associate Commissioner for Public Health Strategy and Analysis at the Food and Drug Administration where he led the agency's Transparency Initiative. Lurie was also a plaintiff in a lawsuit won against the FDA, National Institutes of Health, and Department of Health and Human Services in February 2020, when a federal judge ordered the government to collect and post a decade's worth of previously undisclosed trial results to ClinicalTrials.gov.[4] As long-time observers of the fields of transparency and science-based policymaking, it is clear to us that EPA's proposed rule is not about strengthening transparency in science.

The proposed rule would permit the EPA to exclude from consideration relevant peer-reviewed studies in its work to protect human health and the environment on the sole basis that the data underlying these studies are not publicly available. CSPI president Peter Lurie testified at EPA's public hearing on July 17, 2018 calling on the agency to withdraw its disingenuous proposal which would actually restrict the use of rigorous science rather than promote transparency.[5] Instead, with this SNPRM, the agency seeks to expand the scope of its original proposal.

---

[1] Integrity in Science: A CSPI Project. n.d. https://integrityinscience.org/integrity/index.html. Accessed April 13, 2020.
[2] Center for Science in the Public Interest. PubMed to Include Conflict-of-Interest Statements with Study Abstracts. April 18, 2017. https://cspinet.org/news/pubmed-include-conflict-interest-statements-study-abstracts-20170418. Accessed April 13, 2020.
[3] See list of publications appended to testimony at https://cspinet.org/resource/testimony-cspi-president-peter-g-lurie-epa-proposed-rule
[4] Center for Science in the Public Interest. Transparency Advocates Win Victory for Public Access to Clinical Trial Data. February 25, 2020. https://cspinet.org/news/transparency-advocates-win-victory-public-access-clinical-trial-data-20200225. Accessed May 13, 2020.
[5] Center for Science in the Public Interest. Testimony from CSPI President Peter G. Lurie on EPA Proposed "Transparency" Rule. July 17, 2018. https://cspinet.org/resource/testimony-cspi-president-peter-g-lurie-epa-proposed-rule. Accessed April 13, 2020.

CSPI maintains that the proposed rule and its supplement lack scientific justification, were not themselves developed transparently, and should be withdrawn. Here we will highlight some additional concerns based on the modifications introduced to the proposed rule by the SNPRM.

1. The SNPRM provides no justification for broadening the reach of an already-unjustified rule

The SNPRM seeks to broaden the reach of the original proposed rule in two discrete ways: 1) by extending the provisions requiring availability of raw data to apply to *all* data and models, not just those assessing dose-response relationships, and 2) by adding broad definitions of "influential scientific information" and "pivotal science" at 40 C.F.R. § 30.2 which extend the raw data requirement beyond studies informing agency rulemaking to studies informing other scientific assessments conducted by the agency.

In our July 17, 2018 testimony, we asked EPA: "What is the problem this proposed rule seeks to fix? Where is the study for which the lack of access to raw data resulted in misinterpretation or in the promulgation of an inappropriate regulatory standard?" These questions remain unanswered with respect to dose-response data in regulatory science, and no new information has been provided that rationalizes extending the rule to other data and scientific assessments at EPA.

2. The proposed approaches to dealing with studies for which underlying data cannot be made available lack scientific basis and would exclude important studies from consideration

In the SNPRM, EPA proposes two options for modified text at 40 C.F.R. § 30.5. The first option states that the agency will *only* use studies for which the underlying data and models are available in a manner sufficient for independent validation. The alternative states that the agency will give *greater consideration* to studies where the underlying data and models are available for independent validation. Neither of these options is acceptable, although the latter is less objectionable.

As fervent advocates of transparency and rigor in science, CSPI acknowledges the benefits of data sharing practices that enable independent validation. We applaud efforts of agencies and institutions like the U.S. Centers for Disease Control and Prevention,[6] New York City Mayor's Office of Data and Analytics,[7] and Yale's Open Data Access (YODA) Project[8] to establish data repositories and work with scientists to make their data accessible when feasible. But not all data can be made fully transparent. In research involving human subjects, participants are often assured their data will not be shared with anyone outside the research team. Sometimes masked data can be made public, but even deidentified data is vulnerable to re-identification.[9]

Given that open data practices are not always ethical or feasible, no study should be downgraded or eliminated from consideration in policymaking solely on the basis of raw data availability. Various systems have been devised to rate the quality of scientific evidence, perhaps the most widely accepted of which is the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system. GRADE assesses the quality of a study based on study design (with randomized controlled trials starting as high quality and observation studies as low quality), and then considers various factors that may lower the quality of evidence (*e.g.*, risk of bias, inconsistency, indirectness, imprecision, publication bias) or increase the quality of evidence (*e.g.*, large effect size, dose-response relationship). EPA should rely on

[6] U.S. Centers for Disease Control and Prevention. Open CDC. n.d. https://open.cdc.gov/. Accessed May 13, 2020.
[7] City of New York. NYC Open Data. 2017. https://opendata.cityofnewyork.us/. Accessed May 13, 2020.
[8] Yale University. The YODA Project. n.d. https://yoda.yale.edu/. Accessed May 13, 2020.
[9] Li H, et al. Evaluating re-identification risks of data protected by additive data perturbation. *J Database Manage*. 2014; 25: 52–74.

these factors, rather than just one aspect—availability of raw data—to assess to what extent a study should inform policy decisions.

3. The SNPRM grants excessive authority to the EPA administrator to grant exemptions

The proposed text at 40 C.F.R. § 30.9 would grant the EPA administrator sole discretionary authority to exempt studies from the data availability requirements of this rule on a case-by-case basis. Granting this excessive authority to a single political appointee would introduce significant risk of bias and political influence on what is intended to be a science-based regulatory process.

EPA has requested comment on aspects (other than the year in which the data or model was collected, completed, or updated) that EPA should consider in determining whether to grant an exemption. Again, CSPI adamantly opposes the premise of this entire rule. However, should this rule be finalized, we strongly urge EPA to amend this text and require input from relevant scientific advisors in determining exemptions from any finalized data availability requirements. We also recommend that EPA develop and apply clear, transparent criteria to determine which studies warrant exemption from data sharing requirements.

Indeed, such criteria should include factors beyond the age of the data. These criteria must ensure that no high quality studies are excluded from consideration by EPA on the sole basis that raw data could not be made available. In developing these criteria, EPA should consider study design, sample size, rigor of analytical methods, and other factors, drawing from the principles of the GRADE system for evaluating quality of evidence.

4. If finalized, the rule should not apply to studies published prior to the effective date of the rulemaking

EPA has also requested comment on the consideration of the age of data and models in determining whether studies may be exempted from compliance with this proposed rule under 40 C.F.R. § 30.9. While we do not agree with the premise of this provision—which would grant the EPA administrator sole discretionary authority to exempt studies from the data availability requirements of this rule on a case-by-case basis—we do believe that the age of data, as well as the date of publication, should be considered in exempting studies from data availability requirements should this rule be finalized. More explicitly, we believe the rule should not apply to any studies published prior to the effective date of the rulemaking. In fact, EPA should allow a significant lead-in period during which the agency will need to coordinate with stakeholders in the scientific community to build data sharing infrastructure and eliminate barriers to data sharing. If the intent of this rule is to incentivize data-sharing, applying the new standard retroactively would be immaterial to its purpose.

High quality studies published to date must not be excluded on the grounds that authors did not follow data sharing practices which were not required nor expected at the time of publication. EPA may work with and encourage scientists to make publicly available the data underlying previously published studies in the name of transparency, but such retrospective data publication will be impossible in many cases. Factors such as changes in data storage practices, legally binding confidentiality agreements, and inadvertent data loss which may have nothing to do with the quality of science should not prevent studies from informing public policy. Such a standard should apply across the board, not only when the EPA administrator decides to grant an exemption.

In sum, open data is a positive trend in science and EPA is right in seeking to support and encourage this trend, but this proposed rule serves to undermine science-based policymaking processes rather than to elevate the worthy cause of increased transparency. In this SNPRM, EPA solicited input on how to ensure that, over time, more of the data and models underlying the science that informs significant regulatory decisions and influential scientific information are available to the public for independent validation. The answer: by working together with stakeholders in the scientific community to build infrastructure for data sharing, not by ignoring all science—archival and forthcoming— that has not achieved these new and ambitious (and in many cases, unreachable) transparency aspirations.

We urge EPA to withdraw its proposed rule in favor of a more participatory, transparent approach to an initiative allegedly aimed at increasing transparency in science.

Sincerely,

Eva Greenthal
Policy Associate
Center for Science in the Public Interest

Peter Lurie, MD, MPH
President
Center for Science in the Public Interest