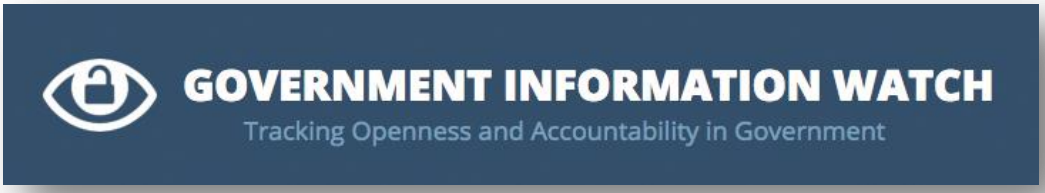

13 April 2020

Maria Doa, Director,
Science Policy Division
U.S. Environmental Protection Agency

Re: Strengthening Transparency in Regulatory Science Proposed Rulemaking

Dear Ms. Doa,

I am writing on behalf of Government Information Watch to urge EPA to withdraw the proposed rulemaking "Strengthening Transparency in Regulatory Science." While my comments do not necessarily reflect the views of all members of GIW's Advisory Committee, they do draw heavily on the work of Committee member Rena Steinzor.[1]

Professor Steinzor and Professor Wendy E. Wagner have written[2] cogently on how science is normally considered during the regulatory process, when agencies must evaluate the scientific evidence that informs a significant policy decision about health or environmental hazards. They outline four sequential steps[3] that are normally taken, and note that an elaborate version of such steps is mandated by the Clean Air Act for EPA to use when setting national ambient air quality standards (NAAQS).

The proposed rule, instead, advances a process that Steinzor and Wagner have called "deconstruction" of the evidence. Deconstruction is accomplished through a myriad of techniques, including undermining the validity of studies for nonscientific reasons, encouraging the reconsideration of raw data using unreliable models, and adding research engineered to confound a finding of harm.

Under the proposal, EPA would be required not only to prepare its own models with multiple assumptions, but also to "give explicit consideration" to a long list of models that could be prepared by outside stakeholders. The proposal presents a list of these models that EPA must *explicitly* consider, such as a "broad class of parametric dose-response or concentration-

[1] https://www.law.umaryland.edu/directory/profile.asp?id=118
[2] Wendy E. Wagner and Rena Steinzor, https://www.theregreview.org/2018/07/31/wagner-steinzor-real-not-faux-transparency-proposal/ and Deconstructing Regulatory Science
[3] Id.

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."

In addition to the requirement to give explicit consideration to such models, the rule allows the EPA to reserve the right to place less weight on the studies, "to the point of entirely disregarding them, if the data and models underlying pivotal regulatory science are not made available in full to EPA."

At the same time, the rule proposes an exclusionary test that eliminates individual studies based solely on whether the data is transparent. Specifically, the modified proposed rule states that EPA can only include research in its assessments if the data and models underlying *pivotal regulatory science* and pivotal science which support significant regulatory decisions *and influential scientific information*,[4] respectively, are "publicly available in a manner sufficient for independent verification."

There is, however, no clear mandate that the raw data underlying these models be publicly available in a manner sufficient for independent evaluation. [5]

Both the meaning of the exclusionary test itself and the decision to exempt a particular study from the requirement are explicitly left entirely to the discretion of the Administrator to apply on a "case-by-case" basis.[6]

Significantly, the revised proposal states EPA is deleting the 2018 proposed 40 CFR 30.2 definition of ''research data,'' *because this definition excludes* ''trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law'' and ''[p]ersonnel and 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.'' These types of data are intended to be subject to this rulemaking. [7]

It has long been an underlying principle of government transparency and accountability advocates that trust in government is dependent on both the openness of government policies, rules and practices *and* certainty that privacy protected information (PPI) will be held confidential when it is given to government agencies. We have become increasingly aware,

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[4] All terms inadequately described, where described at all.
[5] "Where data and models are controlled by third parties, EPA may work with those parties to endeavor to make the data and models available in a manner that complies with this section. Federal Register / Vol. 85, No. 53 / Wednesday, March 18, 2020 / Proposed Rules https://www.gpo.gov/fdsys/pkg/FR-2018-04-30/pdf/2018-09078.pdf
[6] Id. at 18772.
[7] Emphasis added.

also, of the near-impossibility of anonymizing personally-identifiable information – even with "tiered access" for "independent validation" when such "validation" includes the information "necessary to understand, assess, and reanalyze findings"[8] by entities outside the agency.

Perhaps it is the intent of this proposed rule to *preclude* scientific evidence based on data and models informed by raw data, including medical records, that is required to be held confidential. This is not transparency and nor is it science.

Finally, while the proposed policy would apply only to prospective, or new, regulation, not to existing rules and regulations, it is clear that when past rules and regulations come under review, all[9] science involved would be subject to the "transparency" rule.

As a final note, I point to the principles for transparent science, and for a proposal for transparent science, noted by Steinzor and Wagner.

Transparent science should make publicly available

- a conflict of interest disclosure statement if the study was privately sponsored, as well as the underlying contract governing that research, in order to ensure that researchers' independence to determine study design and report results was preserved;
- a clear statement of the methods for data collection and analysis used in the study to allow for scrutiny and even replication of the study; and
- all of the underlying data, presumably in digital form (e.g., not original specimens, etc.).

A proposal for transparent science should

- apply the same standards to all scientific research and analyses used by the agency, particularly research that is not published and that has escaped rigorous peer review;
- require that a list of all excluded research be shared with the public as the decisions are made. Such disclosure could be accomplished by listing excluded—or presumptively excluded—information on a dedicated website in the course of a rulemaking or agency decision.
- be applied to *all* technical analyses prepared by the agency.

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[8] Federal Register / Vol. 85, No. 53 / Wednesday, March 18, 2020 / Proposed Rules. 30.5 This may include, for example: (a) Data (where necessary, data would be made available subject to access and use restrictions); (b) Associated protocols necessary to understand, assess, and extend conclusions; (c) Computer codes and models involved in the creation and analysis of such information; (d) Recorded factual materials; and (e) Detailed descriptions of how to access and use such information.

[9] With some concessions made in the SNPRM.

As this proposed rule neither conforms with the principles above nor meets the requirements of a proposal for real transparent science, I urge that it be withdrawn in its entirety

Thank you for your consideration.

Sincerely,

Patrice McDermott, Director
Government Information Watch