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By Electronic Submission to www.regulations.gov

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 STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE, SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING 85 FED. REG. 15,396 (MAR. 18, 2020)

On its own behalf and on behalf of a distinguished group of science, medicine, and public health faculty at Harvard University and Harvard-affiliated teaching hospitals, the Emmett Environmental Law & Policy Clinic at Harvard Law School submits these comments on the supplemental notice of proposed rulemaking “Strengthening Transparency in Regulatory Science,” 85 Fed. Reg. 15,396 (Mar. 18, 2020) (the “Supplemental Notice” for the “Proposal”). The Proposal does not address any identified problem, is unauthorized by any statute, is inconsistent with scientific best practices and statutory authorities and mandates, will impose substantial costs, and has not been adequately explained in the Supplemental Notice. Most fundamentally, the Proposal, if finalized, will prevent the Environmental Protection Agency (“EPA”) from relying on the best available science, thereby undermining its ability to protect public health and the environment. We therefore urge EPA to withdraw the Proposal.

Our comments focus on the following issues:

- The Supplemental Notice still fails to identify any need for the dramatic change in EPA decision-making represented by the Proposal.
- The Proposal’s focus on reanalysis as the basis for determining the reliability of scientific studies is inconsistent with scientific best practices and EPA’s prior practice.
- The Supplemental Notice’s expansion of the scope of the Proposal to apply to “all data and models” and to “influential scientific information” exacerbates the problems with the Proposal and would hamper EPA’s regulatory functions.

- Both the tiered access and reduced weight alternatives proposed for 40 C.F.R. 30.5 are vague, not within EPA’s legal authority, and present the same problems as the Initial Proposal.¹
- The Supplemental Notice adopts only a partial approach to advancing transparency, treating academic and industry research differently.
- Multiple aspects of the Supplemental Notice are incomplete, ambiguous, or otherwise fail to provide adequate notice of the contents of the Proposal.
- Neither the Housekeeping Statute nor the other statutory provisions cited by EPA grant it the authority to promulgate the Proposal.
- Even as modified by the Supplemental Notice, the proposed waiver authority under 40 C.F.R. 30.9 leaves the EPA Administrator with impermissibly broad discretion to pick and choose which studies EPA may rely on in its decision-making.
- The Proposal violates multiple statutory and executive order requirements.
- The comment period that EPA has provided for the Supplemental Notice is inadequate in light of the global pandemic.

I. THE SUPPLEMENTAL NOTICE AGAIN FAILS TO ESTABLISH ANY NEED FOR THE PROPOSAL

Like the Initial Proposal, the Supplemental Notice fails to provide evidence that it is responsive to any real problem. Our previous comments on the Initial Proposal, as well as those of many other medical, academic and legal professionals and organizations, noted that EPA had not identified any problems that justified this dramatic change in the agency’s approach to science-based decision-making.² Almost two years have passed since the publication of the Initial Proposal, yet the Supplemental Notice still fails to provide any examples of past actions that were based on faulty models, untrustworthy data, or otherwise non-credible research. This failure alone calls for EPA to withdraw the Proposal.

¹ Proposed Rule, Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768 (Apr. 30, 2018) (the “Initial Proposal”).

² See, e.g., Emmett Environmental Law & Policy Clinic, Comments on Proposed Rule Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768 (Apr. 30, 2018), at 8-9 (submitted Aug. 15, 2018), <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6194> [hereinafter “ELPC Multi-Clinic Comments”]; Emmett Environmental Law & Policy Clinic, Comments on Proposed Rule Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768 (Apr. 30, 2018), at 15-16 (submitted Aug. 7, 2018), <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6111> [hereinafter “ELPC Science Comments”].

II. THE PROPOSAL IS GROUNDED IN A MISGUIDED CONCEPTION OF HOW TO DETERMINE THE VALIDITY OF SCIENTIFIC RESEARCH

We appreciate that the Supplemental Notice has eliminated some of the confusion caused by the unclear and inconsistent use of the terms “replicate” and “reproduce” in the Initial Proposal. By deleting the use of those terms, the Supplemental Notice has clarified its intent to focus on the availability of data for reanalysis. This clarification, however, has only made patent that the Proposal is based on a profoundly misguided view of how the scientific process works.

The Supplemental Notice replaces the terms used in the Initial Proposal with the term “reanalyze,” which it defines as meaning “to analyze exactly the same data to see if the same result emerges from the analysis by using the same or different programs and statistical methodologies that were originally used to analyze the data.” 85 Fed. Reg. at 15,400. This change shows that the Proposal treats the reanalysis of a study’s original data by separate researchers as the best measure of a study’s scientific validity. Indeed, the availability of data for such reanalysis is the only criterion that the Proposal applies to the question of whether, or to what degree, EPA will rely on a scientific study. This single-minded focus on reanalysis is not how the scientific process works and will result in EPA arbitrarily ignoring studies that constitute the best available science.

Contrary to the Supplemental Notice’s focus on reanalysis, other processes—including peer review and reproduction—play a far greater role in the scientific community. As EPA recognizes, “peer review” is “an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria and conclusions pertaining to the scientific or technical work product, and of the documentation that supports them,” which is carried out “by qualified individuals (or organizations) who are independent of those who performed the work and who are collectively equivalent in technical expertise to those who performed the original work (i.e., peers).”³ Replication, as defined in a National Academy of Sciences report (and quoted in the Supplemental Notice), is when a different group of scientists repeat a scientific experiment or trial using “exactly the same protocols . . . to see if the same results hold with data from a different population.”⁴ Reproduction, as defined in a National Academy of Sciences report (and again quoted in the Supplemental Notice), is when a different group of scientists “address[] the same research question but from a different angle than the original researcher did.”⁵

It is through the combined operation of peer review, replication, and reproduction that the scientific community typically determines whether the results of a particular study are reliable. Peer review has been a widely-accepted method for ensuring high-quality results for the past

³ EPA, *Peer Review Handbook* 20 (4th ed. 2015), https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.

⁴ 85 Fed. Reg. at 15,400 (quoting National Academy of Sciences, *Principles and Obstacles for Sharing Data from Environmental Health Research: Workshop Summary* (2016)).

⁵ *Id.*

three and a half centuries.⁶ EPA has integrated the scientific community's peer-review standards into its policies since at least 1993.⁷ Reproduction, especially when it involves the integration of results from multiple lines of inquiry, is particularly important. As the National Academy of Sciences recently explained, "[t]he robustness of science is less well represented by the replications between two individual studies than by a more holistic web of knowledge reinforced through multiple lines of examination and inquiry."⁸

All of the information necessary for peer review, replication, and reproduction are typically made available by researchers.⁹ This information includes the research protocols, methods for recruiting study participants, measurement techniques, and statistical methods that the researchers have used. The disclosure of such information does not implicate the data privacy and confidentiality issues raised by the Proposal.

EPA itself has traditionally relied on these scientific best practices when determining the weight to be accorded studies, including epidemiological studies for which the raw data are frequently not available because of confidentiality and privacy concerns. For example, under EPA's *Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides*,¹⁰ the agency "incorporates" epidemiological studies into a broader review of available data.¹¹ This step requires EPA to analyze the "weight of the evidence" across all peer-reviewed studies.¹² Thus, in its 2016 Revised Human Health Risk Assessment for chlorpyrifos, EPA based its finding that the pesticide caused harmful neurodevelopmental effects at low doses on the fact that studies from "different investigators, locations, points in time, exposure assessment procedures, and outcome measurements" all reached similar results.¹³ More

⁶ *What is peer review?*, ELSEVIER, <https://www.elsevier.com/reviewers/what-is-peer-review> (last visited May 14, 2020).

⁷ EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* 11 (2002).

⁸ National Academy of Sciences, *Reproducibility and Replicability in Science* 143 (2019); see Joel Schwartz, "Transparency" as Mask? *The EPA's Proposed Rule on Scientific Data* 379 *NEW ENGLAND J. MED.* 1496, 1497 (2018) ("[T]he 'gold standard' of science is not reanalysis, but replication. In the case of PM_{2.5} mortality studies, a recent meta-analysis found 53 cohorts, indicating that the results have been replicated many times by many groups in many countries.") (using "replication" in the sense that the Supplemental Notice uses "reproduction").

⁹ See, e.g., Letter from Marcia McNutt, President of the National Academy of Sciences, C.D. Mote, Jr., President of the National Academy of Engineering, and Victor J. Dzau, President of the National Academy of Medicine, to Acting Administrator Andrew Wheeler 2 (July 16, 2018) ("Individual study quality should be evaluated on the basis of information that is available in standard journal articles, such as the study design elements, analytical techniques, and statistical methods."), <https://www.nationalacademies.org/includes/EPA%20Proposed%20Rule%20Docket%20EPA-HQ-OA-2018-0259%20NASEM%20Comment.pdf>.

¹⁰ EPA, *Office of Pesticide Programs' Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides* (2016).

¹¹ *Id.* at 12.

¹² *Id.*

¹³ EPA, *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review* 12 (2016).

generally, as explained in our previous comments, EPA has never previously treated the lack of availability of a study's raw data as a basis for refusing to consider that study.¹⁴

The Supplemental Notice is inconsistent with these best practices. While reanalysis has a limited role to play in assessing the reliability of scientific studies, it is not the cure-all that the Supplemental Notice treats it as being. Requiring that the data from any and all studies upon which EPA relies be available for reanalysis is unnecessary, impractical, and will undermine EPA's ability to fulfill its mandate to protect public health and the environment. As the editors of several of the world's leading scientific journals explained last year, using the best available science "will at times require consideration of peer-reviewed scientific data, not all of which may be open to all members of the public. The most relevant science, vetted through peer review, should inform public policy. Anything less will harm decision-making that claims to protect our health."¹⁵

III. THE PROPOSAL'S EXPANSION IN SCOPE TO INCLUDE "ALL DATA AND MODELS" AND ALL "PIVOTAL SCIENCE" UNDERLYING "INFLUENTIAL SCIENTIFIC INFORMATION" FURTHER IMPEDES EPA'S ABILITY TO BASE ITS SCIENTIFIC ASSESSMENTS AND REGULATORY ACTIONS ON THE BEST AVAILABLE SCIENCE

The Supplemental Notice's expansion in scope to cover "all data and models" and "pivotal science" underlying "influential scientific information" unnecessarily impedes EPA's ability to base its internal analyses and regulatory decisions on the best available science, not only leading the agency to ill-informed environmental and public health policies, but also depriving regulators, researchers, and academics of EPA's objective insight and evaluation of harmful pollutants and chemicals.

Pursuant to the Supplemental Notice, the Proposal now applies to all scientific data and models, not only dose-response data and models (*i.e.*, those that describe the effect of increased levels of exposure of an agent on an organism or the environment). The Supplemental Notice provides some examples of the types of data and models that are now covered, including: "environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, data on environmental releases, exposure estimates, quantitative structure activity relationship data, and environmental studies." 85 Fed. Reg. at 15,400. This list, while not exhaustive, makes it clear that the Supplemental Notice represents an immense expansion in the scope of the Proposal.

Although not all of these studies are likely to raise privacy and confidentiality concerns to the same extent as epidemiological studies, there are still multiple legitimate reasons why it may not be possible to make their data publicly available. For example, due to the passage of time, records may have been lost, researchers may have retired or passed away, or the data may have

¹⁴ ELPC Multi-Clinic Comments, *supra* note 2, at 11.

¹⁵ H. Holden Thorp, et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data* (2019), 576 NATURE 39 (2019).

been stored in electronic media such as tapes (and to some extent disks) that are no longer compatible with existing systems.¹⁶

Even if researchers are able to make raw data and models publicly available, such a process could be prohibitively expensive and time-consuming in light of the Supplemental Notice's expansion of the Proposal's scope. Indeed, not only would such a scheme hamper EPA's regulatory functions, but, as mentioned below,¹⁷ it would also favor industry interests. While academic researchers have no incentive to revisit their old research and make the raw data and models publicly available, industry scientists have a strong monetary incentive to do so if their research supports the industry's goals.

The Supplemental Notice also expands the Proposal to apply to all "pivotal science" underlying "influential scientific information." 85 Fed. Reg. at 15,001.

The term "influential scientific information" means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions (OMB M-05-03). A "highly influential scientific assessment" is a subset of influential scientific information and refers to 'an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information' and that the dissemination of such assessment could have "a potential impact of more than \$500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest."

Id. at 15,398 n. 5. EPA maintains an online archive of "influential scientific information," which includes materials such as:

- Integrated Scientific Assessments ("ISAs") for the periodic revision of the National Ambient Air Quality Standards ("NAAQS");
- Integrated Risk Information System ("IRIS") toxicological reviews;
- The report "Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence" that provided the scientific basis for the 2015 Clean Water Rule;
- The 2016 report "Impacts of Climate Change on Human Health in the United States: A Scientific Assessment;" and

¹⁶ See ELPC Science Comments, *supra* note 2, at 9.

¹⁷ See Section V, *infra*.

- The 2015 report “Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources.”¹⁸

Many of these assessments, reviews, and reports cite thousands of scientific papers. It is unclear how many of those papers would be subject to the Proposal; the definition of “pivotal science” does not provide any clarity on the subject as the term is defined circularly as “the specific scientific studies or analyses that underly influential scientific information.” 85 Fed. Reg. at 15,405. EPA’s Science Advisory Board (“SAB”), in its recent report on the Proposal, agrees that the Proposal’s definitions of “data and models” and “pivotal regulatory science” are inadequate and require further clarity.¹⁹

Because the Proposal would systematically exclude studies that do not meet EPA’s criteria for reanalysis and independent validation, critical studies that would otherwise inform influential scientific information would not be incorporated into key documents, such as the Integrated Scientific Assessment for Particulate Matter.²⁰ Many of the studies cited in the assessment are epidemiological papers analyzing the numbers of patient hospital visits or other sensitive medical information. As such, these studies cannot be made publicly available due to laws and contracts designed to protect patient and human subject privacy.²¹ Thus, the Proposal’s expansion in scope would in many instances *prohibit* EPA from relying on the best available science when assessing and determining highly influential scientific information, depriving regulators, researchers, and academics of a valuable and objective source of information.

IV. BOTH THE PROPOSED AND ALTERNATE 40 C.F.R. 30.5 ARE VAGUE, NOT WITHIN EPA’S LEGAL AUTHORITY, AND PRESENT THE SAME PROBLEMS AS THE INITIAL PROPOSAL

While the Supplemental Notice presents the proposed and alternate versions of 40 C.F.R. 30.5 as solutions to concerns that we and many others raised regarding the Initial Proposal, the new provisions are in fact no improvement. In our comments on the Initial Proposal, we explained that the proposed rule would prevent EPA from relying on studies involving confidential human health data, thus violating the agency’s duty to rely on the best available science.²² The Supplemental Notice offers two alternatives that purportedly address this concern, one allowing EPA to consider studies without publicly-available data “if there is tiered access to these data

¹⁸ All of the cited documents are available at *Science Inventory*, EPA, https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm (last visited May 14, 2020).

¹⁹ EPA SAB, EPA-SAB-20-005, *Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA’s Proposed Rule Titled Strengthening Transparency in Regulatory Science 3* (Apr. 4, 2020), [https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentBOARD/2DB3986BB8390B308525855800630FCB/\\$File/EPA-SAB-20-005.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf) [hereinafter, “SAB Report”].

²⁰ EPA, EPA/600/R-19/188, *Integrated Science Assessment (ISA) for Particulate Matter* at 2-97 to 2-122 (Final Report, 2019), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=539935 [hereinafter, “Integrated Scientific Assessment for Particulate Matter”].

²¹ For more discussion on the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) Privacy Rule, please reference the Clinic’s comment letter on behalf of public health experts. See ELPC Science Comments, *supra* note 2, at 6-9.

²² See ELPC Science Comments, *supra* note 2, at 3-9.

and models in a manner sufficient for independent validation,” 85 Fed. Reg. at 15,399, and the other giving lesser weight to studies whose data are not publicly available, *id.*

A. Both Alternatives Would Prevent EPA from Considering Important Studies Based on Data that Cannot Be Released Publicly, Mistakenly Rely on Reanalysis, and Conflict with Multiple Statutes

There are several problems that are common to both alternatives. First, both will result in EPA arbitrarily ignoring, or giving insufficient weight to, important scientific research. Second, both rely on the same flawed assumption that the scientific reliability of a study can be best determined by a reanalysis of the original data. Third, both are inconsistent with EPA’s statutory authorities in that they introduce arbitrary criteria for weighing the significance of scientific studies.

While the Supplemental Notice modifies 40 C.F.R. 30.5 from the language used in the Initial Proposal, a fundamental concern we raised almost two years ago remains;²³ the Proposal reduces EPA’s consideration of scientific studies based on the availability of raw data, even though, as the SAB recently put it, “there are legitimate legal, ethical, professional and financial reasons why researchers may be unable or unwilling to fully share ‘data’—including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data.”²⁴

These arguments apply with equal force to the Supplemental Notice. A tiered access system would still lead to the exclusion of many studies from EPA’s consideration if researchers either cannot or choose not to go to the time and expense of making data available through such a system. The reduced weight alternative would give less weight to some studies based on whether the study’s raw data are publicly available. While providing those studies with less consideration is perhaps preferable to ignoring them altogether, it is still an arbitrary and non-scientific criterion that violates EPA’s duty to engage in reasoned, scientific decision-making.

Second, both alternatives reflect the mistaken assumption that reanalysis of a study’s raw data is the best way to determine whether a study is reliable. As discussed above, this vision of reanalysis is flawed and does not reflect best practices in the scientific community.²⁵

Third, both alternatives are inconsistent with the statutes directing which data EPA *must* consider in certain contexts. As we explained in a previous comment letter, many statutes require EPA to consider science in its decision-making, without any reference to whether such science is based on studies with raw data that is publicly available.²⁶ For example, under the Clean Air Act, EPA must set and review the NAAQS for six common pollutants.²⁷ In setting these standards, the Clean Air Act instructs EPA to use “the latest scientific knowledge useful in indicating the kind

²³ ELPC Science Comments, *supra* note 2, at 3-9.

²⁴ SAB Report, *supra* note 19, at 17.

²⁵ See Section II, *supra*.

²⁶ ELPC Multi-Clinic Comments, *supra* note 2, at 13-17.

²⁷ 42 U.S.C. § 7409.

and extent of all identifiable effects [of air pollution] on public health or welfare.”²⁸ Thus, a conflict would arise between the statutory language and the reduced-weight alternative if EPA gave less weight to a study that was “the latest scientific knowledge” on a relevant question merely because the raw data from that study is not publicly available. The same conflict would exist with the proposed tiered-access system, if the “latest scientific knowledge” came from a study with raw data to which researchers have not or could not grant restricted access.

B. The Tiered-Access Alternative Is Ambiguous, Raises Questions about EPA’s Legal Authority to Implement it, and Involves Significant Costs for which EPA Has Failed to Account

In addition, each alternative has its own unique flaws. The tiered-access alternative provides that EPA will take into consideration studies that include “restricted data and models (i.e., those that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects)” only “if there is tiered access to these data and models.” 85 Fed. Reg. at 15,405 (emphasis added). Under this alternative, data and models from studies that do not involve “restricted data and models” must be made publicly available for EPA to consider those studies. *Id.*

The Supplemental Notice does not explain how “tiered access” will be achieved, who will determine which data and models count as “restricted,” where data will be stored, who will determine who has access to the stored data, and who will pay for the operation of such a system. We urge EPA to withdraw the Proposal to address these important gaps and ambiguities.

For example, it is not clear from the Supplemental Notice whether EPA intends to operate its own data enclave to administer the tiered access alternative. If EPA does intend to do so, it should state that intention unambiguously, identify the source of its legal authority to do so, and address how it will pay for it. The Supplemental Notice suggests that EPA intends to address such issues in “implementation guidance,” 85 Fed. Reg. at 15,403, but they are far too fundamental to be left to guidance documents.

The Supplemental Notice is also unclear with regard to who will decide, and on the basis of what standards, what counts as “restricted data and models” subject to tiered access. At a minimum, EPA must clarify how such a determination would be made. These decisions are not straightforward. To take one example, the Supplemental Notice says virtually nothing about the risk of re-identification from supposedly anonymized data sets. In general, the Supplemental Notice expresses too much confidence that de-identification can adequately address privacy and confidentiality concerns. As the SAB recently put, “[a]lthough the Proposed Rule suggests that privacy and confidentiality issues can be addressed through anonymization or de-identification,

²⁸ *Id.* § 7408(a)(2). Other examples of statutes that require EPA to use scientific information include the Safe Drinking Water Act, which requires EPA to use “the best available, peer-reviewed science,” *id.* § 300g-1(b)(3)(A)(i), and the Toxic Substances Control Act, which requires EPA to make decisions “based on the weight of the scientific evidence,” 15 U.S.C. § 2625(h), (i); *see also* Clean Water Act, 33 U.S.C. § 1314(a)(1) (requiring EPA to set water quality criteria that “accurately reflect[] the latest scientific knowledge” on a variety of factors).

this is not always the case.”²⁹ Anonymization is not always effective because “even de-identified datasets present significant risks of reidentification given modern techniques for combining these datasets with other sources of individual information (also known as a ‘mosaic effect’).”³⁰

In particular, recent research suggests that the risk of re-identification for environmental health data is greater than traditionally thought. A recent paper by Boronow et al. demonstrates that it is possible to successfully re-identify environmental health study participants using information that is publicly or commercially available.³¹ If data with geographic information about the study participants becomes public, that data can be combined with information that is readily available online such as voter lists, tax and real estate information, or information that is available from data brokers.³² In light of the risk of re-identification with environmental health data, researchers would have a strong interest in ensuring the data is restricted and not publicly available. Will researchers be able to make this determination or will EPA demand that certain studies be made public? If EPA will decide, what process will be available if the researchers and EPA disagree about the risk of re-identification?

The tiered access alternative will also introduce additional costs for both the government and individual researchers. As explained in our previous comment letter,³³ the Congressional Budget Office (“CBO”) estimated that a bill similar to the Proposal would cost EPA as much as \$250 million per year.³⁴ A tiered access approach will be even more costly to implement than a requirement that all data and models be made available to the public. For example, some researchers will have to submit data to a secure data repository, the operator of the repository will have to maintain and operate the facility, and researchers who want to reanalyze the data will typically need to pay fees to access the data as well as pay to travel to the repository. Nevertheless, the Supplemental Notice says nothing about the costs of the tiered access alternative or who will bear those costs. Without any details, or cost analysis, it is not unreasonable to assume that the cost of the tiered access approach would fall on researchers, other federal agencies such as the Centers for Disease Control (“CDC”), and other third parties.

Taken together, these gaps and ambiguities indicate that EPA has either not fully thought through the implications and legal challenges to a tiered access system or is keeping the public in the dark by withholding key details regarding how this system would operate. Either way, the public does not have enough information on such a program and therefore EPA has not given the public a meaningful opportunity to comment on the Proposal.

²⁹ SAB Report, *supra* note 19, at 11.

³⁰ *Id.* at 12.

³¹ Katherine E. Boronow et al, *Privacy Risks of Sharing Data from Environmental Health Studies*, 128 ENVTL. HEALTH PERSPS. 017008-1, 017008-5 (2020).

³² *Id.* at 017008-5.

³³ ELPC Multi-Clinic Comments, *supra* note 2, at 5.

³⁴ Congressional Budget Office, *Cost Estimate: H.R. 1030, Secret Science Reform Act of 2015*, at 2 (Mar. 11, 2015), <https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf> [hereinafter, “CBO Analysis”].

C. The Reduced-Weight Alternative Creates a New Source of Arbitrary Discretion

As a second alternative, EPA is proposing another system whereby:

when promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will, other things equal, give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because the information is publicly available or available through tiered access when the data include CBI, proprietary data, or PII and appropriate techniques have been used to reduce the risk of re-identification.

85 Fed. Reg. at 15,402. This approach introduces a new source of arbitrary discretion, as it places no constraints on *how much* EPA will reduce the weight attached to each study. As written, the alternative version of 40 C.F.R. 30.5 leaves EPA with complete discretion to consider or disregard studies, so long as it writes a “short description” when greater consideration is given, from which it is safe to conclude that EPA has not determined key implementation details, including how the scale of a weighted system would be structured.

V. THE SUPPLEMENTAL NOTICE IS INCONSISTENT IN ITS TREATMENT OF ACADEMIC AND INDUSTRY RESEARCH

Not only is the Supplemental Notice’s focus on reanalysis inconsistent with scientific and regulatory best practices, but it adopts a partial and biased approach to transparency that systematically favors industry science over academic science. Three related points demonstrate this fact.

First, nothing in the Supplemental Notice requires that EPA itself gain access to the raw data from studies. Instead, the primary alternative for 40 C.F.R. 30.5 requires only that “there is tiered access to these data and models in a manner sufficient for independent validation.” 85 Fed. Reg. at 15,405. The proposed definition of “independent validation” refers to “reanalysis of study data by subject matter experts,” *id.*, not by EPA itself. This distinction is made clear by the preamble, which refers to how “increasing access to data and models can often allow *stakeholders* to reanalyze the data and models.” *Id.* at 15,399. As Bernard Goldstein, the EPA Assistant Administrator for Research and Development during the Reagan administration, recently testified before the SAB, the goal of providing such access:

is to obtain raw data that can be used by paid consultants who nitpick to find blemishes in each study. These blemishes are then falsely magnified into scars The overall goal is to change the consensus processes of science into the confrontational processes appropriate for law.³⁵

³⁵ Testimony for the Public Meeting of the Science Advisory Board (SAB) Written Comments of Dr. Bernard Goldstein on behalf of the Environmental Protection Network, June 5, 2019, [https://yosemite.epa.gov/sab/sabproduct.nsf/A51E8AFCF21F6371852584110052AD3D/\\$File/Written+statement+from+Bernard+Goldstein+\(revised+June+5,+2019\).pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/A51E8AFCF21F6371852584110052AD3D/$File/Written+statement+from+Bernard+Goldstein+(revised+June+5,+2019).pdf).

Second, the definition of “publicly available” in the Supplemental Notice will systematically favor EPA’s use of industry-submitted data even when public access to those data is cumbersome and inconvenient. The definition provides that “publicly available” means, among other things, “lawfully available to the general public from federal, state, or local government records.” 85 Fed. Reg. at 15,405. This means that data submitted by industry when applying to state or federal agencies for a permit or approval—such as pesticide registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”)—will be treated as “publicly available” for purposes of the Proposal, even if members of the public could obtain access to those data only by filing a federal Freedom of Information Act (“FOIA”) or state public records law request. In many instances, these industry studies will not have been peer reviewed or even published.

However, the fact that these studies and data are subject to FOIA does not mean they are immediately or easily available to the public. The burden and expense of requesting access to those materials falls on the requestor. Once someone files a FOIA request, it may take months or years for an agency to provide all requested documents.³⁶ Frequently, an agency will deny a request or miss statutory deadlines to respond, meaning that the requestor must resort to the courts to obtain the desired documents.

By contrast, academic research that is peer-reviewed and published in open-access journals is not treated as publicly-available under the Proposal unless the researchers make the raw data available to the general public or, in the case of studies with confidential data, make the data available through a tiered-access mechanism. Here, the burdens are flipped: an industry representative who wants access to such data faces no costs or burdens. Instead, academic researchers and universities would assume the responsibility and the financial burden of managing the logistics of making the data and models publicly available. Even then, EPA is under no obligation to consider or use the study to inform its regulatory or informational processes. In fact, even research, such as the Six Cities Study,³⁷ that has been subject to a comprehensive reanalysis by the Health Effects Institute,³⁸ would apparently not be eligible for consideration under the Supplemental Notice, because its data are not available for further reanalysis by other researchers.

Third, even as to industry studies that have not been submitted to government agencies and therefore are not “publicly available” through FOIA or state public records laws, the fact that the Proposal places the burden of making data publicly available on researchers systemically favors industry data over academic data. Academic scientists have no incentives to go back to old studies and—at a considerable cost of time and money—identify the relevant data and make it

³⁶ See, e.g., EPA, *Freedom of Information Act Annual Report Fiscal Year 2019*, at 21 (2020) (listing median response time for “expedited processing” of FOIA requests by EPA as 493 days).

³⁷ Douglas W. Dockery et al., *An Association between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENGLAND J. MED. 1753 (1993).

³⁸ 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>.

available to the general public or through a tiered access system.³⁹ Industry scientists, however, have a financial incentive to make available data from studies that support those industries' goals. Even on its own terms, such an approach does not evenhandedly promote transparency in science.

VI. MULTIPLE ASPECTS OF THE SUPPLEMENTAL NOTICE ARE INCOMPLETE, AMBIGUOUS, OR OTHERWISE FAIL TO PROVIDE ADEQUATE NOTICE OF THE CONTENTS OF THE PROPOSAL

Under the Administrative Procedure Act (“APA”), a notice of proposed rulemaking must include “the terms or substance of the proposed rule or a description of the subjects and issues involved.” 5 U.S.C. § 553(b)(3). The purpose of this requirement is to “provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.”⁴⁰ The Supplemental Notice fails to meet this requirement. Several aspects of the Proposal remain too incomplete or vague to allow for meaningful and targeted comments.

While we identify multiple topics on which the Supplemental Notice has not provided sufficient detail throughout this comment letter, some of the most important issues are highlighted below.

- **It is not clear which studies will be subject to the data availability requirements of the Proposal.** The Supplemental Notice indicates that the Proposal will apply to “pivotal science,” which it defines as “the specific scientific studies or analyses that underly influential scientific information.” 85 Fed. Reg. at 15,405. The Supplemental Notice also retains the requirement from the initial notice that the Proposal will apply to “pivotal regulatory science,” defined as “the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions.” *Id.* at 15,398; 83 Fed. Reg. at 18,773. It does not explain, however, what it means for a study to “underly” influential scientific information or to “drive” a regulatory decision. These ambiguities create substantial uncertainty about the number of studies covered by the Proposal. For example, the December 2019 Integrated Science Assessment for Particulate Matter is 1,879 pages long and cites hundreds (perhaps thousands) of studies.⁴¹ Will the Proposal apply to all of these studies? What about studies that are not cited in the assessment, but constitute the foundational research on which the cited studies build? If the Proposal applies only to some subset of these studies, what standards will EPA apply in identifying those studies, and who will be responsible for making those decisions? The Supplemental Notice answers none of these questions.
- **It is not clear how the tiered access alternative would be implemented or who would be responsible for implementing it.** The tiered-access alternative in the Supplemental

³⁹ The Supplemental Notice implicitly acknowledges this problem by requesting comments on “how to provide sufficient incentives and support to researchers to increase access to the data that may be used as pivotal regulatory science or pivotal science.” 85 Fed. Reg. 15,403.

⁴⁰ *Honeywell International, Inc. v. EPA*, 372 F.3d 441, 445 (D.C. Cir. 2004).

⁴¹ It is difficult to determine the exact number because the citations are not numbered and each chapter of the report has a separate list of citations, with some papers being cited in multiple chapters. Chapter two alone, however, cites more than 350 papers. Integrated Scientific Assessment for Particulate Matter, *supra* note 20, at 2-97 to 2-122.

Notice contains multiple gaps and ambiguities, as we discuss below, including aspects of the implementation of this process that are absent from the Supplemental Notice.⁴²

- **The reduced-weight alternative includes virtually no details about how it would be implemented.** The Supplemental Notice does not include any implementation details for the weighting approach, such as any concrete ideas about how the scale of a weighted system would be structured.⁴³
- **EPA has not completed the cost-benefit analysis required by Executive Order 12,866 or even decided yet whether it intends to complete one.**⁴⁴ Absent this analysis, there is no estimate of the cost of the rule, either for the EPA, the external research community or both.

The SAB highlighted the multiple ambiguities in the Proposal in its recent report. As the SAB put it, “key considerations that could inform the Proposed Rule are not present in the proposal, or presented without analysis, and certain key terms and implementation issues have not been adequately defined or described.”⁴⁵ Moreover, the SAB concluded that, “[g]iven the relatively skeletal nature of the Proposed Rule, *it is not possible to define the implications of the rule with confidence.*”⁴⁶ If even EPA’s expert science advisors cannot determine the implications of the Proposal, it is impossible for the public to understand and provide meaningful comment on the Supplemental Notice.

VII. THE HOUSEKEEPING STATUTE DOES NOT GRANT EPA AUTHORITY TO PROMULGATE THE PROPOSAL

The Proposal is not authorized by the Housekeeping Statute, 5 U.S.C. § 301, because (i) Congress did not intend for the Housekeeping Statute to delegate rulemaking authority to independent agencies such as EPA; (ii) Reorganization Plan No. 3 does not grant EPA housekeeping or equivalent authority; and (iii) even if EPA has such housekeeping authority, the Proposal is a substantive rule that may not be promulgated under the Housekeeping Statute or equivalent authority.

A. Congress did not Grant Independent Agencies, such as EPA, Rulemaking Authority under the Housekeeping Statute

The plain text of the Housekeeping Statute demonstrates that it applies only to Executive departments and military departments, and not to independent agencies such as EPA. The statute provides, in relevant part, that “[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its

⁴² See Section IV.B, *supra*.

⁴³ See Section IV.C, *supra*.

⁴⁴ See Section X.C, *infra*.

⁴⁵ SAB Report, *supra* note 19, at 1.

⁴⁶ *Id.* at 2 (emphasis added).

records, papers, and property.” 5 U.S.C. § 301. While the EPA is clearly not a military department, the agency also does not qualify as an “Executive department” within the meaning of the statute. An earlier provision in the same chapter of the United States Code provides an exclusive list of “the Executive departments.” 5 U.S.C. § 101. EPA is not on that list.⁴⁷

It is a firmly established rule of statutory construction that definitions of terms included within the framework of a law usually dictate the meaning of those terms as used in the statute.⁴⁸ Importantly, the definition of “Executive departments” does not start with the words “include” or “such as,” which would indicate that the list of departments is non-exhaustive.⁴⁹ Rather, the definition provides that “the Executive departments *are*” and proceeds to list those departments. Under the ordinary use of the verb “are,” *i.e.*, to be equal in meaning, the definitional list of Executive departments is exclusive.⁵⁰ Moreover, according to the canon of negative implication,⁵¹ EPA’s omission from this *long* list of departments (which has been intermittently amended) indicates that EPA is not an “Executive department” for purposes of the Housekeeping Statute.⁵²

Instead, EPA is an “independent establishment,” defined as “an establishment in the executive branch (other than the United States Postal Service or the Postal Regulatory Commission) which is not an Executive department, military department, Government corporation, or part thereof.”

⁴⁷ The full list is: the Department of State; the Department of the Treasury; the Department of Defense; the Department of Justice; the Department of the Interior; the Department of Agriculture; the Department of Commerce; the Department of Labor; the Department of Health and Human Services; the Department of Housing and Urban Development; the Department of Transportation; the Department of Energy; the Department of Education; the Department of Veterans Affairs; and the Department of Homeland Security. 5 U.S.C. § 101.

⁴⁸ See, e.g., *Stenberg v. Carhart*, 530 U.S. 914, 942 (2000) (“When a statute includes an explicit definition, we must follow that definition, even if it varies from that term’s ordinary meaning.”); *Colautti v. Franklin*, 439 U.S. 379, 392 n. 10 (1979) (“As a rule, ‘[a] definition which declares what a term ‘means’ . . . excludes any meaning that is not stated.”).

⁴⁹ See, e.g., *United States v. Howard*, 742 F.3d 1334, 1348 (11th Cir. 2014) (“The items that follow each use of the word ‘includes’ in the statute are non-exhaustive examples of items that qualify.”); *United States v. Chapman*, 21 F. Supp. 3d 839, 847 (S.D. Tex. 2014) (“[T]he use of the word ‘includes’ indicates a nonexhaustive, incomplete list.”).

⁵⁰ *Colautti*, 439 U.S. at 392 n.10 (noting that the definition at issue uses the word “means,” not “includes,” indicating that Congress intended the provision to be the exclusive definition throughout the statute); see also *Be (verb)*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/be> (last visited May 14, 2020).

⁵¹ The canon of negative implication, otherwise known as “*expressio unius est exclusio alternius*,” means “expressing one item of [an] associated group or series excludes another left unmentioned.” *N.L.R.B. v. SW Gen., Inc.*, 137 S. Ct. 929, 940 (2017). The canon applies when the circumstances support a sensible inference that Congress intended the omitted term to be excluded. See *id.*

⁵² See, e.g., *Greenblatt v. Nat’l Pork Bd.*, No. CV ELH-15-00054, 2015 WL 6549578, at *8 (D. Md. Oct. 27, 2015) (“Title 5 U.S.C. § 101 provides an exhaustive list of ‘executive departments,’ which includes the [U.S. Department of Agriculture], but not the [National Pork Board].”).

5 U.S.C. § 104.⁵³ For decades, the United States Government Manual included EPA in the list of “independent establishments and government corporations” rather than in the list of “departments.”⁵⁴ Since 2010, the manual has changed the terminology to “independent agencies and government corporations,” but EPA remains part of the same list.⁵⁵ Independent establishments do not have rulemaking authority under the Housekeeping Statute.

The legislative history of the Housekeeping Statute confirms that Congress intended to grant rulemaking authority *only* to those executive departments listed under 5 U.S.C. § 101. When Congress enacted the current version of the Housekeeping Statute in 1958,⁵⁶ a staff memorandum submitted to the Special Subcommittee on Government Information of the House Committee on Government Operations noted:

The statute does not apply to independent agencies, although some of the regulatory agencies cited it as authority to withhold information in answers to subcommittee questions. After the subcommittee discussed the matter with regulatory agency officials, they admitted that title 5, United States Code, section 22, [now 5 U.S.C. § 301] applies *only* to the executive departments of the Federal Government.⁵⁷

⁵³ See William Funk, *Is the Environmental Appeals Board Unconstitutional or Unlawful?*, 49 ENVTL. L. 737, 742–43 (2019) (“EPA would fall under the term “independent establishment,” defined in Section 104, which explicitly distinguishes such establishments from Executive departments.”); Christopher D. Ahlers, *Presidential Authority over EPA Rulemaking Under the Clean Air Act*, 44 ENVTL. L. 31, 53 (2014) (reviewing the history of the 1966 Reorganization Act, the Postal Reorganization Act, and the Reorganization Plan No. 3 and concluding that “it was the intention of Congress that EPA be an independent establishment that would not be managed as an executive department”).

⁵⁴ See, e.g., Office of the Federal Register, National Archives and Records Administration, *The United States Government Manual 2009/2010*, at 6 (2009), <https://www.govinfo.gov/content/pkg/GOVMAN-2009-09-15/pdf/GOVMAN-2009-09-15.pdf>; Office of the Federal Register, National Archives and Records Service, *The United States Government Manual 1983/84*, at vi (1983), https://www.govinfo.gov/app/collection/govman/2010_United%20States%20Government%20Manual/1983-84%20Edition; see also 2 Fed. Proc., L. Ed. § 2:22 (including EPA in a list of “independent establishments”).

⁵⁵ See, e.g., Office of the Federal Register, National Archives and Records Administration, *The United States Government Manual 2019 Edition*, at 171 (2019), <https://www.govinfo.gov/content/pkg/GOVMAN-2019-11-21/pdf/GOVMAN-2019-11-21.pdf>.

⁵⁶ The Housekeeping Statute was originally enacted in 1789 to help “General Washington get his administration underway by spelling out the authority for executive officials to set up offices and file Government documents.” H.R. Rep. No. 85-1461, 1958 U.S.C.C.A.N. 3352, 3352 (Mar. 6, 1958). In 1958, Congress amended the Housekeeping Statute to clarify the scope of the law and to prevent executive departments from improperly invoking the statute to withhold information from the public. See *id.* at 3353. The Housekeeping Statute was subsequently codified at 5 U.S.C. § 301 on September 6, 1966. See Pub. L. 89 554, Sept. 6, 1966, 80 Stat. 379.

⁵⁷ *Availability of Information from Federal Departments and Agencies: Part 11—Amendment of “Housekeeping Statute” [Revised Statutes 161 (5 U.S.C. 22)] Proposed by H. R. 2767, H. R. 2768, H.R. 2769, H. R. 3497, and H.R. 2810 Before the Special Subcomm. On Government Information of the H. Comm. On Government Operations 85th Cong. 2618 (1957) (Exhibit IV, Staff Memorandum of Subcommittee) (emphasis added) [hereinafter, “Part 11”].*

In coming to this conclusion, the staff memorandum recognized that such independent agencies were not listed in the definition of an executive department under what is now 5 U.S.C. § 101.⁵⁸ Indeed, not only did the Department of Justice support this interpretation of the statute,⁵⁹ but the Subcommittee also decried independent agencies’ disregard of the definition when claiming such authority in the past; such claims were an “unhappy history” that pointed to the fact that “the ‘housekeeping’ statute [had] been twisted from the original authority of the department head.”⁶⁰ Moreover, during the Subcommittee hearing, independent executive agencies, some of which have been superseded by new agencies or departments, clearly acknowledged the inapplicability of the Housekeeping Statute to their operations.⁶¹

The fact that Congress intended to exclude independent agencies, such as EPA, from the Housekeeping Statute is further evidenced by the fact that one proposed version of the bill used the word “agency” rather than “Executive department” in 5 U.S.C. § 301, but that version was explicitly rejected because the “term is often used in referring to the independent regulatory agencies, to which the section does not apply, [and] it could lead to confusion and uncertainty in the future application of the section.”⁶²

This conclusion is also supported by the fact that Congress has since amended the definition of an “Executive department” under 5 U.S.C. § 101 to add two of the former independent agencies that had recognized the inapplicability of the statute to their operations in 1958—the Housing and Home Finance Agency (now the Department of Housing and Urban Development) and

⁵⁸ *Availability of Information from Federal Departments and Agencies: Part 14—Second Hearing on Amendment of “Housekeeping Statute” [Revised Statutes 161 (5 U.S.C. 22)] Proposed by H. R. 2767, H. R. 2768, H. R. 2769, H. R. 3497, and H. R. 2810 Before the Special Subcomm. On Government Information of the H. Comm. On Government Operations 85th Cong. 3414 (1957) (Exhibit VII, Staff Memorandum of Subcommittee) [hereinafter, “Part 14”].*

⁵⁹ Part 11, *supra* note 57, at 2928-29 (“Title 5 of the United States Code deals with the executive departments. Sections 1 through 117 of chapter 1, dealing with salaries of heads of departments, vacancies in office etc., are specifically made as applicable to the three departments just discussed, as they are to the other seven departments created between 1789 and 1849. By definition, the word “department” means one of the 10 executive departments enumerated in section 1 of title 5.”) (Exhibit XVII, Department of Justice Memorandum).

⁶⁰ Part 14, *supra* note 58, at 3414.

⁶¹ Part 11, *supra* note 57, at 2608 (“Section 161 authorizes the ‘head of each department’ to prescribe regulations for the Government of his department, the conduct of its officers, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. It is clear from the provisions of the statute that would be amended by this bill (R. S. secs. 158 and 159; 5 U.S.C. 1 and 2) that the proposed amendment would apply only to the executive departments and not to other agencies of the Government, including the independent regulatory Commissions and agencies such as the Federal Power Commission.”) (Response of Jerome K. Kuykendall, Chairman, Federal Power Commission); *id.* at 2612 (“By the terms of the statute itself, title 5, United States Code, section 22, applies only to executive departments enumerated in title 5 United States Code, Section 1. This Commission is not included in that list; it is not an executive department but an independent, bipartisan, quasi-judicial agency.”) (Memorandum of the Securities Exchange Commission to the Committee of Government Operations, House of Representatives, on H.R. 2810, 2767, 2768, 2769, and 3497, 85th Congress, 1st Session); *id.* at 2613 (The proposed legislation will not directly affect the Small Business Administration, because section 161 of the Revised Statutes applies only to the heads of the executive departments as defined in section 1 of title 5 of the United States Code.”) (Response of Wendell B. Barnes, Administrator, Small Business Administration).

⁶² Part 11, *supra* note 57, at 2610 (Statement of Owen Clarke, Chairman, Committee on Legislation).

Veterans Administration (now the Department of Veterans Affairs).⁶³ Congress, by contrast, has not added EPA to the list. As these examples demonstrate, when Congress wanted to grant housekeeping authority to a former independent agency, it knew how to do so *explicitly* by amending Section 101. If an agency could assert housekeeping authority absent explicit congressional authorization, it would render Section 101 effectively meaningless. In sum, given that EPA is an independent establishment and acknowledges that it is “not one of the 15 ‘Executive Departments’ listed at 5 U.S.C. 101,” it cannot avail itself of the Housekeeping Statute.

B. Reorganization Plan No. 3 Does Not Grant EPA Housekeeping Authority or Equivalent Authority

Reorganization Plan No. 3, which established EPA in 1970, does not grant the agency housekeeping or equivalent authority.⁶⁴ The Supplemental Notice asserts that although the agency “is not one of the ‘Executive Departments’ listed at 5 U.S.C. 101,” EPA gained full housekeeping or equivalent authority because Section 2(a)(9) of the Reorganization Plan transferred so much of the functions of the transferor offices and agencies, including those of the Department of the Interior and Department of Agriculture, “as is incidental to or necessary for the performance by or under the [EPA] Administrator of the functions transferred.” 85 Fed. Reg. at 15,397. According to a 2008 Office of Legal Counsel opinion, at “the time of the Reorganization Plan, such ancillary authority included the housekeeping authority conferred by 5 U.S.C. § 301 on the heads of those Departments to enable their subordinates to carry out efficiently the statutory functions transferred to the Administrator of the EPA.”⁶⁵ Thus, the Supplemental Notice claims that the housekeeping authorities were *implicitly* transferred to EPA as incidental powers.

This argument is unpersuasive. As discussed above, Congress has demonstrated that it knows how to update the list of “Executive departments” to include newly created departments.⁶⁶ Moreover, the Department of Homeland Security, like EPA, was created through the transfer and consolidation of various existing programs and authorities spread across several federal agencies. Indeed, similar to Reorganization Plan No. 3, the Homeland Security Act of 2002 lays out in minute detail those functions and authorities that were being transferred to the new department from the Departments of Agriculture, Energy, and Treasury.⁶⁷ However, unlike the Reorganization Plan, the Homeland Security Act specifically asserts that the Department of Homeland Security is an executive department within the meaning of the Housekeeping Statute:

⁶³ Part 11, *supra* note 57, at 2609 & 2614; *see also* Pub. L. 100-527, § 13(b), Oct. 25, 1988, 102 Stat. 2643 (adding Department of Veterans Affairs); Pub. L. 89-174, § 6(b), Sept. 9, 1965, 79 Stat. 667 (adding Department of Housing and Urban Development).

⁶⁴ Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970), <https://www.govinfo.gov/content/pkg/STATUTE-84/pdf/STATUTE-84-Pg2086.pdf#page=1>.

⁶⁵ Auth. of Env'tl. Prot. Agency to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Gov't Pers. Prop., 32 U.S. Op. Off. Legal Counsel 79, 2008 WL 4422366, at *4 (May 28, 2008).

⁶⁶ *See, e.g.*, Pub. L. 100-527, § 13(b).

⁶⁷ Pub. L. 107-296, 116 Stat. 2135 (Nov. 25, 2002), <https://www.govinfo.gov/content/pkg/STATUTE-116/pdf/STATUTE-116-Pg2135.pdf>.

“There is established a Department of Homeland Security, as an executive department of the United States within the meaning of title 5, United States Code.”⁶⁸ Thus, when Congress intends to grant housekeeping authority, it does so by amending Section 101 to include a newly created department. No such mandate exists in Reorganization Plan No. 3 for EPA.

This interpretation of Reorganization Plan No. 3 is confirmed by its legislative history. When describing EPA’s functions, Russell Train, Chairman of the Council on Environmental Quality, noted that “a reorganization plan cannot create any new legal authorities or functions;” thus, when EPA would come into being its functions *could only be* those of its constituent parts that were clearly transferred.⁶⁹ The Department of the Interior’s and Department of Agriculture’s housekeeping authorities were not so transferred.

Finally, although the Supplemental Notice cites certain court decisions in support of EPA’s claim of housekeeping authority, the decisions were not carefully reasoned and cannot overcome the plain language of the Housekeeping Statute. For example, in *Davis Enterprises v. U.S. Environmental Protection Agency*, the Third Circuit concluded—without any analysis—that “[t]he EPA’s authority to govern its internal affairs is *derived from* 5 U.S.C. § 301.”⁷⁰ In another case, the U.S. Court of Appeals for the Second Circuit stated that “the Federal Housekeeping Statute, 5 U.S.C. 301, *authorizes government agencies such as the EPA* to adopt regulations regarding ‘the custody, use, and preservation of [agency] records, papers, and property.’”⁷¹ While other federal courts have blindly followed these holdings in enforcing EPA’s *Touhy* regulations,⁷² both the Second and Third Circuits’ holdings show that the courts believed that EPA’s housekeeping authority derived from 5 U.S.C. § 301 *alone* because the EPA was a “government agency” within the meaning of the statute—a mistake in application that Congress attempted to avoid by enumerating the executive departments in Section 101. Such holdings are the type of “drive-by” rulings that the Supreme Court has cautioned against and deserve little to no weight.⁷³

⁶⁸ Pub. L. 107-296, 116 Stat., 2135, 2142, § 101.

⁶⁹ *Reorganization Plans Nos. 3 and 4 of 1970 Before the Subcomm On Executive Reorganization and Government Research of the S. Comm. On Government Operations* 91st Cong. 48 (1970) (Statement of Russel E. Train, Chairman, Council on Environmental Quality).

⁷⁰ 877 F.2d 1181, 1184 (3d Cir. 1989) (emphasis added).

⁷¹ *EPA v. General Elec. Co.*, 197 F.3d 592, 595 (2d Cir. 1999) (emphasis added).

⁷² See, e.g., *Boron Oil Co. v. Downie*, 873 F.2d 67, 68-69 (4th Cir. 1989) (not questioning EPA’s *Touhy* regulations promulgated under the authority of 5 U.S.C. § 301); *Bobreski v. EPA*, 284 F. Supp. 2d 67, 78 (D.D.C. 2003) (same). *Touhy* regulations concern a federal agency’s right to refuse a subpoena on behalf of its employees. See 40 C.F.R. § 2.402 *et seq.*

⁷³ See, e.g., *Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154, 161 (2010) (“Our recent cases evince a marked desire to curtail such ‘drive-by jurisdictional rulings.’”); *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 91 (1998) (holding that where jurisdiction was “assumed without discussion by the Court . . . drive-by jurisdictional rulings of this sort . . . have no precedential effect”).

C. The Transparency Rule is a Substantive Rule that May Not be Promulgated Under Section 301's Rulemaking Authority

Even assuming that EPA has Housekeeping Statute authority, the Proposal is a substantive rule outside the scope of the authority granted under that law. The purpose of the Housekeeping Statute is to delegate to executive and military departments the authority to prescribe rules related to their internal organization and operation; this authority does not extend to “substantive” rulemakings affecting the rights of parties and the department’s implementation of its statutory duties.⁷⁴

The Housekeeping Statute was originally enacted in 1789 to help “General Washington get his administration underway by spelling out the authority for executive officials to set up offices and file Government documents.”⁷⁵ In the legislative history of the 1958 amendments, Congress further made clear that the laws prescribed under the statute were limited to “day-to-day business” and recordkeeping.⁷⁶ Thus the Housekeeping Statute was never intended to be used as an authority to promulgate substantive rules with external legal consequences. The rule *only* authorizes what the APA “terms ‘rules of agency organization procedure or practice.’”⁷⁷

Although the APA does not define “substantive” rules, such rules may be recognized by negative inference from the statute’s definition of “interpretative rules” (commonly known as “interpretive rules”). Interpretive rules are “general statements of policy, or rules of agency organization, procedure, or practice.” 5 U.S.C. § 553(b)(A). The U.S. Supreme Court has therefore described a “substantive rule” as a “legislative-type rule” or as one “affecting individual rights and obligations.”⁷⁸ In coming to this definition, the Court relied heavily on the *Attorney General’s Manual on the Administrative Procedure Act* because neither the House nor Senate Report for the APA attempted to expound on the distinction between substantive and interpretive rules.⁷⁹ In a footnote, the Attorney General’s Manual describes “substantive” rules as those rules “other than organizational or procedural,” “issued by an agency pursuant to statutory authority and which implement the statute,” and having “the force and effect of law.”⁸⁰

⁷⁴ See, e.g., *Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979).

⁷⁵ H.R. Rep. No. 85-1461, 1958 U.S.C.C.A.N. 3352, 3352 (Mar. 6, 1958).

⁷⁶ See *id.*

⁷⁷ *Chrysler Corp.*, 441 U.S. at 310.

⁷⁸ *Id.* at 302 (quoting *Morton v. Ruiz*, 415 U.S. 199, 232 & 236 (1974)).

⁷⁹ See *id.* at 302 n. 31.

⁸⁰ Tom C. Clark, U.S. Dep’t of the Attorney General, *Attorney General’s Manual on the Administrative Procedure Act*, at 30 n.3 (1947), <https://heinonline.org/HOL/P?h=hein.agopinions/atgmanp0001&i=30>. A reprinted version of the Attorney General’s Manual is also available at <https://archive.org/details/AttorneyGeneralsManualOnTheAdministrativeProcedureActOf1947>.

Consistent with this definition, courts have forbidden executive departments from using Section 301 to implement substantive regulations.⁸¹ For example, last year, in *New York v. U.S. Department of Health and Human Services*, a district court found that the Department of Health and Human Services' ("HHS") "conscience rule," recognizing the right of HHS funding recipients to abstain from participating in medical procedures on account of religious or moral objections, was a substantive rule impermissibly promulgated under the Housekeeping Statute.⁸² In coming to this conclusion, the court explained that although the rule had "housekeeping features," it was "largely substantive—and, indeed, in key respects transformative."⁸³ Specifically, the court found that the rule was substantive as the "conscience rule" would "effectively supersede Title VII in the health care field" by bypassing the undue hardship exception,⁸⁴ "newly restrict[] the ability of employers to inquire about employees' conscience objections,"⁸⁵ newly define the term "health care entity" to apply to pharmacists and medical laboratories, and construe "the Weldon Amendment and the [Affordable Care Act], for the first time, to apply to health care plan sponsors and third-party administrators."⁸⁶ The court held that "contrary to HHS's depiction of [the "conscience rule"] as mere housekeeping, the Rule relocates the metes and bounds—the who, what, when, where, and how—of conscience protection under federal law."⁸⁷

The Proposal is similarly substantive as it "relocates the metes and bounds" of "best available science" requirements under the multiple environmental statutes that EPA implements. Specifically, the Proposal not only changes "how" EPA performs environmental decision-making under these statutes, but it also changes "what" studies EPA must consider as "best available science" when issuing influential scientific information and making significant regulatory decisions. Indeed, the Supplemental Notice acknowledges that the purpose of the proposed rule is "to establish an agency-wide approach to ensure that the data and models underlying EPA's significant regulatory decisions are publicly available." 85 Fed. Reg. at 15,398.

The Supplemental Notice's claim that the Proposal is not "substantive" rests on the assertion that the rule "would not regulate the conduct or determine the rights of any entity outside the federal government" and that "it exclusively pertains to the internal practices of EPA." 85 Fed. Reg. at

⁸¹ *Chrysler Corp.*, 441 U.S. at 310 ("[T]here is nothing in the legislative history of § 301 to indicate it is a substantive grant of legislative power to promulgate rules authorizing the release of trade secrets or confidential business information."); *Koopmann v. U.S. Dep't of Transportation*, 335 F. Supp. 3d 556, 560-64 (S.D.N.Y. 2018) (holding that Department of Transportation regulations forbidding former agency employees from testifying was substantive regulation outside of the Housekeeping Statute's rulemaking authority).

⁸² *New York v. U.S. Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 512-16 (S.D.N.Y. 2019).

⁸³ *See id.* at 513.

⁸⁴ *See id.* Under Title VII, which prohibits religious discrimination against employees, an employer may avoid liability by showing that accommodating the employee's religious objection would work as an "undue hardship" on the employer and that the employer has offered the employee a "reasonable accommodation." *Id.* at 536.

⁸⁵ *See id.* at 515.

⁸⁶ *See id.*

⁸⁷ *See id.* at 516.

15,398. Past court decisions, however, have found that EPA's refusal to consider certain scientific studies in its regulatory decision-making processes carry the force and effect of law.

In *CropLife America v. U.S. Environmental Protection Agency*, for example, pesticide manufacturers and trade associations sought judicial review of an EPA directive that provided that the agency, contrary to its established practice, would no longer consider or rely on third-party human studies in evaluating the safety of pesticides under FIFRA.⁸⁸ Petitioners argued, and the D.C. Circuit agreed, that this directive was a substantive rule with the force of law, that the rule violated FIFRA's requirement that EPA "consider all relevant reliable data," and that the rule was arbitrary and capricious in violation of the APA.⁸⁹

Specifically, in *CropLife*, the D.C. Circuit held that:

The disputed directive constitutes a binding regulation that is directly aimed at and enforceable against petitioners. It provides that "the Agency will not consider or rely on any [third-party] human studies in its regulatory decision making." This clear and unequivocal language, which reflects an obvious change in established agency practice, creates a "binding norm" that is "finally determinative of the issues or rights to which it is addressed."⁹⁰

The Proposal would limit EPA's consideration of scientific studies whose data and models are not sufficiently available to the public for reanalysis. It is therefore directly analogous to the directive at issue in *CropLife* regarding "best available science" requirements in that it creates a binding norm.

Moreover, in *CropLife*, the D.C. Circuit determined that the directive was a substantive rule with binding effect as it not only impacted private parties, but also the agency's regulatory actions (as opposed to its internal practices). In particular, the court found that "there [was] little doubt" that the directive prohibiting EPA from considering third-party studies:

"binds private parties [and] the agency itself with the 'force of law,'" and thus constitutes a regulation rather than a policy statement. The directive clearly establishes a substantive rule declaring that third-party human studies are now deemed immaterial in EPA regulatory decisionmaking under [the Federal Food, Drug and Cosmetic Act] and FIFRA.⁹¹

The Proposal is similarly substantive because it would establish a rule declaring that studies whose data and models are not "publicly available in a manner sufficient for independent validation" are deemed immaterial (or given less weight). 85 Fed. Reg. at 15,405. Such a rule would not only impact the ability of private parties to challenge the scientific bases for EPA's

⁸⁸ *CropLife America, et al. v. EPA et al.*, 329 F.3d 876, 878 (D.C. Cir. 2003).

⁸⁹ *See id.* at 879.

⁹⁰ *See id.* at 881 (quoting *Chamber of Commerce v. U.S. Dep't of Labor*, 174 F.3d 206, 212 (D.C. Cir. 1999) (quoting *Pacific Gas & Elec. Co. v. FPC*, 506 F.2d 33, 38 (D.C. Cir. 1974))).

⁹¹ *See id.* at 883 (internal citations omitted).

regulatory actions going forward, but would also plainly restrict the agency's use of science in its determination of influential scientific information and regulatory decisions.

Additionally, the Proposal is a substantive rule because it will impose significant burdens on researchers. As discussed above,⁹² the burden of implementing the tiered-access proposal will largely fall on researchers and universities. In particular, researchers will be responsible for determining which data and models can be made publicly available and managing the logistics of making the data and models available in a manner that complies with the rule. As the Proposal would place the bulk of the responsibility and costs for managing public access to data and models on people outside of the agency, it clearly has a binding external impact, and is substantive in effect.

VIII. RCRA, CERCLA, AND THE CWA DO NOT GRANT EPA AUTHORITY TO PROMULGATE THE PROPOSAL

None of the other statutory provisions identified by the Supplemental Notice authorize EPA to promulgate the Proposal. The Supplemental Notice asserts that Resource Conservation and Recovery Act ("RCRA") Section 8001, 42 U.S.C. § 6981, Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") Section 115, 42 U.S.C. § 9615, and Clean Water Act ("CWA") Section 501, 33 U.S.C. § 1361, empower EPA to promulgate the Proposal. 85 Fed. Reg. at 15,397. However, there are two major problems with these assertions of statutory authority. First, the Supplemental Notice does not provide any explanation for how these provisions purportedly authorize the Proposal. Second, an examination of the cited provisions demonstrates that they provide no support for the Proposal; indeed, the Proposal would actively hinder, rather than promote, the statutory purposes of RCRA, CERCLA, and the CWA.

A. The Supplemental Notice Provides no Explanation of How the Cited Provisions Authorize the Promulgation of the Proposal

The Supplemental Notice makes no effort at all to tie the Proposal to the statutory schemes of RCRA, CERCLA, or the CWA. Instead, it merely asserts that the cited provisions authorize the Proposal without any explanation of how the Proposal relates to the language or purposes of the three statutes. Additionally, both the Initial Proposal and the Supplemental Notice refer to a range of different provisions from different statutes. 83 Fed. Reg. at 18,769; 85 Fed. Reg. at 15,397. EPA must explain how distinct provisions in multiple statutes can authorize the agency to promulgate precisely the same rule for its review of science under all of these schemes, as well as how the Proposal would comply with each statutory scheme.⁹³

⁹² See Section V, *supra*.

⁹³ 5 U.S.C. § 553(b)(2) (requiring that notice of proposed rulemaking include "reference to the legal authority under which the rule is proposed"); see also *Iowa League of Cities v. EPA*, 711 F.3d 844, 877 (8th Cir. 2013) (noting that an agency regulation will only survive *ultra vires* allegations if a court can "reasonably conclude that the grants of authority in the statutory provisions cited by the government contemplate the issuance" of the regulation).

B. The Cited Provisions Do Not Authorize EPA to Promulgate the Proposal

“[I]t is ‘axiomatic’ that ‘administrative agencies may act only pursuant to authority delegated to them by Congress.’”⁹⁴ None of the cited provisions, however, provide EPA with authority to ignore relevant scientific information. RCRA Section 8001 relates only to research and research funding, and the cited provisions of CERCLA and the CWA only authorize rulemakings that are necessary to achieve the statutes’ broader purposes. The Proposal, however, is not related to EPA research or research funding, and will actively hinder EPA’s ability to achieve the statutes’ underlying goals by limiting EPA’s ability to rely on the best available science.

EPA has long accepted that its decisions must be guided by the best available science. For example, in 2002, EPA issued Information Quality Guidelines in which it took the position that the standard set forth in the Safe Drinking Water Act—to use “the best available, peer-reviewed science”—should apply to all of the agency’s risk assessments.⁹⁵ EPA even reiterated its commitment to this standard in the Initial Proposal. 83 Fed. Reg. at 18,769. However, the Proposal would directly undermine this longstanding commitment to use the best available science. As we pointed out in a comment letter in response to the Initial Proposal, the Proposal would prevent EPA from relying on crucial studies that underlie a number of past, present, and future regulations.⁹⁶ This radical departure from EPA’s standard practice cannot be justified by any of the statutes EPA identifies because it is contrary to the goals of those statutes.

1. *RCRA Section 8001 Only Authorizes EPA to Aid and Conduct Research*

RCRA Section 8001, 42 U.S.C. § 6981, only empowers EPA to assist and conduct research; it says nothing about EPA’s use of data in its regulatory capacity and certainly does not authorize EPA to *limit* its ability to rely on certain scientific data. In relevant part, RCRA Section 8001 grants EPA the authority to “conduct, and encourage, cooperate with, and render financial and other assistance” to institutions and individuals conducting research. 42 U.S.C. § 6981(a). The section also confers on EPA the authority to “establish a management program or system to insure the coordination of all such authorities,” 42 U.S.C. § 6981(b), and to “make grants to or enter into contracts (including contracts for construction) with, public agencies and authorities or private persons” for the development of research. 42 U.S.C. § 6981(c).

None of these provisions empower EPA to issue a broad rulemaking whose primary effect will be to limit the agency’s ability to rely on the best available science. Nothing in the statutory text purports to confer this power. On the contrary, the powers to “conduct,” “encourage,” “cooperate with,” and assist in research efforts have nothing to do with the power to ignore

⁹⁴ *Clean Air Council v. EPA*, 862 F.3d 1, 9 (D.C. Cir. 2017) (citation omitted).

⁹⁵ EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* 21-23 (2005), <https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf>; see also *Our Mission and What We Do*, EPA, <https://www.epa.gov/aboutepa/our-mission-and-what-we-do> (last visited May 14, 2020) (identifying EPA’s mission to include ensuring that “[n]ational efforts to reduce environmental risks are based on the best available scientific information”).

⁹⁶ ELPC Science Comments, *supra* note 2, at 6-12.

research when acting in a regulatory capacity. The Supplemental Notice makes no attempt to connect the Proposal to the language of this provision or RCRA’s statutory purposes.

2. *The Proposal is Inconsistent with CERCLA’s Statutory Purposes*

Section 115 of CERCLA, 42 U.S.C. § 9615, only authorizes the President, and by extension EPA, to promulgate regulations that are “*necessary* to carry out the provisions of this subchapter.” 42 U.S.C. § 9615 (emphasis added). Section 115 does not authorize EPA to promulgate the Proposal for two related reasons.

First, the Supplemental Notice does not offer any reason why the Proposal is *necessary* to achieve CERCLA’s purposes. Provisions in other environmental statutes with language identical to that in Section 115 have been interpreted to limit the Administrator’s discretion in promulgating regulations.⁹⁷ Similarly, the language of Section 115 of CERCLA is clear on its face: the provision only authorizes regulations that are necessary to achieve the statutory purposes of CERCLA. EPA, however, offers no justification for why the Proposal is necessary to achieve CERCLA’s goals; indeed, it makes no effort to tie the Proposal to CERCLA’s legislative purposes at all.

Second, Section 115 does not authorize EPA to promulgate the Proposal because it would hinder, rather than advance, CERCLA’s underlying purposes. The discretion afforded to EPA under CERCLA only extends to actions that further the statute’s goals, which include the “timely cleanup of hazardous waste sites” and ensuring that polluters are held financially responsible for cleanup efforts.⁹⁸ In *Eagle-Picher Industries, Inc. v. U.S. Environmental Protection Agency*, for example, the D.C. Circuit Court of Appeals upheld EPA’s use of a particular model to determine priority sites only because the model was “reasonable and consistent with congressional intent.”⁹⁹

Allowing EPA to limit its use of scientific data, however, would hinder rather than further CERCLA’s purposes by precluding EPA from relying on studies merely because their underlying data and models cannot be made available to the public for privacy or confidentiality reasons. Indeed, courts have recognized that valid scientific data is crucial in promulgating regulations under CERCLA.¹⁰⁰ In *City of Stoughton, Wisconsin v. U.S. Environmental*

⁹⁷ See, e.g., *Citizens to Save Spencer Cty. v. EPA*, 600 F.2d 844, 873 (D.C. Cir. 1979) (holding that section 301 of the Clean Air Act “does not provide the Administrator with Carte blanche authority to promulgate any rules, on any matter relating to the Clean Air Act, in any manner that the Administrator wishes”); see also *In re Permanent Surface Min. Regulation Litig.*, 653 F.2d 514, 523 (D.C. Cir. 1981) (quoting *Citizens to Save Spencer County* to reach the same conclusion under the Surface Mining Control and Reclamation Act); *Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063 (D.C. Cir. 2014) (“[W]e have consistently held that EPA’s authority to issue ancillary regulations is not open-ended, particularly when there is statutory language on point.”).

⁹⁸ *Burlington Northern and Santa Fe Ry. Co. v. U.S.*, 556 U.S. 599, 602 (2009).

⁹⁹ 759 F.2d 905, 909 (D.C. Cir. 1985).

¹⁰⁰ See, e.g., *City of Stoughton, Wis. v. EPA*, 858 F.2d 747, 750-51 (D.C. Cir. 1988); see also *Eagle-Picher Indus., Inc. v. EPA*, 822 F.2d 132, 151 (D.C. Cir. 1987).

Protection Agency, for example, the D.C. Circuit Court of Appeals underscored that EPA must rely on valid data as a basis for administrative action under CERCLA.¹⁰¹

The Proposal, if finalized, would also undermine specific actions that EPA has considered taking under CERCLA. For example, at the time of the Initial Proposal in 2018, EPA was planning to designate two chemicals—perfluorooctanoic acid (“PFOA”) and perfluorooctane sulfonate (“PFOS”)—as hazardous chemicals under CERCLA.¹⁰² Then-Administrator Pruitt had announced that EPA viewed these contaminants as public health risks and intended to develop maximum contaminant levels for them.¹⁰³ However, this determination was based on epidemiological studies generated, *e.g.*, by the C8 Health Project,¹⁰⁴ all of which included confidential human health data.¹⁰⁵ The Proposal would severely weaken EPA’s effort to promulgate maximum contaminant levels for PFOA and PFOS because it would limit the agency’s ability to rely on studies whose underlying health data cannot be made publicly available.

3. *The Proposal is Inconsistent with the CWA’s Statutory Purposes*

Section 501 of the CWA, 33 U.S.C. § 1361, does not authorize the Proposal for the same reasons. First, like Section 115 of CERCLA, Section 501(a) of the CWA only authorizes the EPA administrator to promulgate regulations “as are necessary to carry out his functions under this chapter.” 33 U.S.C. § 1361(a). The EPA Administrator’s discretion to promulgate regulations is limited by the goal of the Clean Water Act to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.”¹⁰⁶ EPA, however, makes no effort to explain why the Proposal is necessary to further the CWA’s goals. On the contrary, the Proposal will limit the agency’s ability to rely on the best available science in promulgating regulations under the CWA.

¹⁰¹ 858 F.2d at 750.

¹⁰² 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>.

¹⁰³ 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>.

¹⁰⁴ 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.

¹⁰⁵ 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), <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-018-0405-y>.

¹⁰⁶ 33 U.S.C. § 1251(a); *see, e.g., American Frozen Food Institute v. Train*, 539 F.2d 107, 129 (D.C. Cir. 1976) (Under Section 501(a), “the Administrator has no more important function than carrying out the fundamental purposes of the Act.”); *E. I. du Pont de Nemours & Co. v. Train*, 430 U.S. 112, 131-32 (1977) (Section 501 gives EPA the authority “to achieve with reasonable effectiveness the purpose for which [Congress] has acted.”); *see also Am. Petroleum Inst. v. EPA*, 540 F.2d 1023, 1029 (10th Cir. 1976) (Section 501 is directed towards “the attainment of the congressional intent to protect and preserve water purity.”).

Second, the Proposal is contrary to the broader statutory scheme of the Clean Water Act. Like many other environmental statutes, the CWA embraces science and seeks to incorporate the best available science into EPA's decision-making. For example, in developing water quality criteria under the CWA, EPA must "accurately reflect[] the latest scientific knowledge." 33 U.S.C. § 1314(a)(1). The Proposal, by arbitrarily blocking EPA from considering relevant scientific studies, is inconsistent with this mandate.

IX. EVEN AS MODIFIED BY THE SUPPLEMENTAL NOTICE, THE PROPOSED WAIVER AUTHORITY UNDER 40 C.F.R. 30.9 LEAVES THE EPA ADMINISTRATOR WITH IMPERMISSIBLY BROAD DISCRETION

It is well-established that a waiver provision cannot save an otherwise impermissible rule. In *ALLTEL Corp. v. Federal Communications Commission*, for example, the D.C. Circuit explained that "the FCC cannot save an irrational rule by tacking on a waiver procedure."¹⁰⁷ The Proposal is not authorized by any of the statutory authorities cited in the Supplemental Notice and actively hinders EPA's ability to effectuate the statutes that it is charged with implementing. The waiver provision cannot save a rule that is otherwise unlawful simply by creating an exemption mechanism.

In addition, even as modified by the Supplemental Notice, the waiver provision does not clearly explain how the Administrator will determine when to grant an exemption, and leaves room for arbitrary decision-making. The Initial Proposal allowed EPA to grant exemptions to studies on a case-by-case basis. 83 Fed. Reg. at 18,772. While the Initial Proposal identified factors for EPA to consider in exercising this authority—providing that public disclosure must be done "in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security"—these factors merely reiterated the main reasons that data underlying scientific studies are commonly not disclosed. *Id.* at 18,773. The Proposal offered no guidance for how the EPA Administrator should evaluate these factors or determine when they would be sufficient to warrant an exemption. If, on the one hand, EPA always allowed data to be withheld for these reasons, the Proposal would be meaningless and have no effect. If, on the other hand, EPA would pick and choose when these reasons were sufficient, it would be exercising impermissibly broad, standardless discretion.

The changes in the Supplemental Notice do not cure this defect and still leave the Administrator with impermissibly broad discretion to grant exemptions. While the notice adds that the Administrator may conclude that compliance is impracticable when "technological barriers render the sharing of the data or models infeasible," it does not clarify what sort of standards are meant to govern the Administrator's discretion in determining when data sharing is "infeasible." 85 Fed. Reg. at 15,403. Moreover, as with the Initial Proposal, the Supplemental Notice does not explain how the Administrator will evaluate or weigh this factor or the others. Technological barriers are already one of many reasons why researchers may not disclose a study's underlying data or models. On the one hand, if EPA always allows data to be withheld when the study faces technological barriers to disclosure, the rule will be meaningless and have no effect. If, on the

¹⁰⁷ 838 F.2d 551, 561 (D.C. Cir. 1988); see *United States Telecom Ass'n v. FCC*, 359 F.3d 554, 571 (D.C. Cir. 2004) ("[T]he mere existence of a safety valve does not cure an irrational rule."); *Dimension Financial Corp. v. Board of Governors of Federal Reserve System*, 744 F.2d 1402, 1410 (10th Cir. 1984).

other hand, EPA intends to pick and choose when it will hold technological barriers sufficient to grant an exemption, it will be exercising impermissibly broad discretion. Without further standards to guide the Administrator's decision regarding when technological barriers render disclosure infeasible, the Proposal still does not offer a clear picture of how EPA will actually implement its exemption authority. As a result, the waiver provision remains impermissibly broad and leaves room for arbitrary decision-making.¹⁰⁸

X. THE PROPOSAL DOES NOT COMPLY WITH MULTIPLE STATUTORY AND EXECUTIVE ORDER REQUIREMENTS

The Proposal is inconsistent with EPA's duties under multiple statutes and executive orders. We pointed out many of these conflicts in comments on the Initial Proposal,¹⁰⁹ but the Supplemental Notice continues to make the same errors. Moreover, some changes introduced in the Supplemental Notice exacerbate the problems.

A. EPA has not Consulted Adequately with the SAB and the FIFRA SAP

The Proposal is also inconsistent with the requirements of FIFRA. The Supplemental Notice continues to rely on the rulemaking provision of FIFRA as a source of authority for the Proposal. 85 Fed. Reg. at 15,397. This provision mandates that EPA seek comments from the Secretary of Agriculture and the FIFRA Scientific Advisory Panel on draft regulations. 7 U.S.C. § 136w. Yet there is no evidence in the rulemaking docket that EPA has sought such input.

EPA's consultation with the SAB has also been inadequate, in violation of the Environmental Research, Development, and Demonstration Authorization Act of 1978 ("ERDDAA"). EPA is required to consult with the SAB on the Proposal, 42 U.S.C. § 4365, a fact that EPA has now acknowledged. Even though the SAB has now been able to offer a belated report on the Proposal—something it was not able to do before the initial notice in 2018—EPA's consultation with the SAB is nevertheless inadequate.

First, EPA has not allowed adequate time for the SAB to review the Supplemental Notice. The SAB last met as a group to discuss the Proposal in a public teleconference on January 21, 2020, when it reviewed a draft report that commented on the initial version of the Proposal from 2018. The Supplemental Notice was not issued until March 3, 2020, after this meeting. Although the SAB subsequently issued its final report on April 24, 2020, it had no opportunity to hold a meeting to discuss the Supplemental Notice. Therefore, it is not clear that the SAB was genuinely able to consult as a body on the contents of the Supplemental Notice. In addition, even the SAB Report itself indicates only that it addresses certain "aspects of the supplemental notice."¹¹⁰ In other words, the SAB indirectly acknowledges that it was not able to provide input on all parts of the Supplemental Notice.

¹⁰⁸ The SAB recently noted in its final report on the Proposal that "[c]ase-by-case exceptions without [specific] criteria may create public concerns about inappropriate exclusion of scientifically important studies." SAB Report, *supra* note 19, at 4.

¹⁰⁹ See ELPC Multi-Clinic Comments, *supra* note 2, at 5-8.

¹¹⁰ SAB Report, *supra* note 19, at 1.

Second, the multiple gaps and ambiguities in the Proposal, as described above, also made it impossible for the SAB to weigh in adequately. As the SAB itself indicated, “[g]iven the relatively skeletal nature of the Proposed Rule, it is not possible to define the implications of the rule with confidence.”¹¹¹

B. EPA Has Failed to Address Impacts under the Paperwork Reduction Act

The Paperwork Reduction Act (“PRA”) requires that the White House Office of Management and Budget (“OMB”) review federal rules that impose information collection requirements on “persons,” including individuals and corporations. 44 U.S.C. § 3502(10). Such collection of information includes “obtaining, causing to be obtained, soliciting, or *requiring the disclosure to third parties or the public*, of facts or opinions by or for an agency, regardless of form or format” through the use of “reporting or recordkeeping requirements.” *Id.* § 3502(3)(A)(i) (emphasis added). The Supplemental Notice asserts that it “does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.” 85 Fed. Reg. at 15,404.

It is clear, however, that the Proposal would create new reporting requirements that would apply to multiple “persons.”¹¹² Specifically, for EPA to consider a scientific study in its rulemakings or when producing influential scientific information, someone will have to make the underlying data available, either to the public in general, or through a tiered access system. Such reporting and data management procedures are costly and, in some instances, inconsistent with other federal policies governing information use and dissemination. This aspect of the Proposal must be addressed by OMB as required by the PRA.

C. EPA Has Failed to Produce the Estimate of Costs and Benefits Required under Executive Order 12,866

EPA’s failure to produce any estimate of the costs and benefits of the Proposal is a violation of Executive Order 12,866. That Executive Order requires that agencies provide to the White House Office of Information and Regulatory Affairs, and the public, an “assessment” and the “underlying analysis” of the anticipated benefits and costs of all significant regulatory actions. E.O. 12,866, § 6(a)(3)(B)-(C), (E)(i). The Supplemental Notice acknowledges that the Proposal is a significant regulatory action. 85 Fed. Reg. at 15,404. Nevertheless, EPA has not prepared any cost-benefit analysis for the Proposal.

This failure is particularly glaring, because our comments (and others) pointed out the need for a cost-benefit analysis on the Proposal *almost two years ago* and yet EPA still has not completed the required analysis. Moreover, as described above,¹¹³ the implementation of the Proposal will likely impose significant costs on EPA, other agencies, and researchers. Indeed, a CBO analysis of a similar legislative proposal concluded that it could cost hundreds of millions of dollars a

¹¹¹ *Id.* at 2.

¹¹² The Proposal would certainly apply to more than the minimum ten persons required by the PRA. *See* 44 U.S.C. § 3502(3)(A)(i).

¹¹³ *See supra* at text accompanying note 34.

year.¹¹⁴ This continuing failure to comply with Executive Order 12,866 is unacceptable and the Proposal should be withdrawn until EPA completes the required cost-benefit analysis.

D. EPA Has Failed to Conduct the Analyses Required under Executive Orders 13,045 and 12,898

As we explained in a comment letter on the Initial Proposal, the Proposal will hinder EPA's ability to conduct accurate risk assessments for regulations that address public health risks with disproportionate effects on young children or on minority and low-income populations.¹¹⁵ Nevertheless, the Supplemental Notice continues to assert that EPA is not required to conduct an analysis under either Executive Order 13,045 or Executive Order 12,898. 85 Fed. Reg. at 15,404. These continuing failures to comply with the executive orders is unacceptable and the Proposal should be withdrawn until EPA completes the required analyses.

XI. THE COMMENT PERIOD IS INSUFFICIENT IN LIGHT OF THE GLOBAL PANDEMIC

The comment period for the Supplemental Notice is inadequate. Many of the public health and medical experts whose research is most affected by the Proposal and who are best positioned to comment on it are on the front lines of the response to the COVID-19 pandemic, working around the clock to save lives. That is just as true on May 18th (the current deadline) as it was on the April 17th (the original deadline).

The Clinic submitted a comment on the initial proposal on August 7, 2018, on behalf of Harvard faculty and leadership, including doctors and researchers at Boston-area hospitals.¹¹⁶ Those signatories have a strong interest in the consequences of the Proposal given its implications for research in their fields. Those same researchers are now at the center of the COVID-19 crisis. They are working tirelessly to keep our communities safe and healthy. Some of the signatories are providing emergency medicine and critical care to coronavirus patients at Beth Israel Deaconess Medical Center,¹¹⁷ Massachusetts General Hospital,¹¹⁸ and the Mount Auburn

¹¹⁴ CBO Analysis, *supra* note 34, at 2.

¹¹⁵ ELPC Multi-Clinic Comments, *supra* note 2, at 7-8.

¹¹⁶ ELPC Science Comments, *supra* note 2.

¹¹⁷ Chief, Emergency Medicine Richard Wolf, MD; Chief, Dept. of Anesthesia, Pain Management and Critical Care, Daniel Talmor, MD, MPH.

¹¹⁸ Chief, Dept. of Emergency Medicine, David F.M. Brown MD; Professors of Emergency Medicine, Carlos Camargo Jr. MD, Dr.PH, MPH, Joshua Goldstein MD PhD; Associate Professor of Emergency Medicine, N. Stuart Harris MD; Associate Professor of Emergency Medicine and Direct of Center for Vascular Emergencies Christopher Kabrhel MD, MPH; Associate Professor of Emergency Medicine and Director of the Center for Ultrasound Research and Education, Andrew Liteplo MD; Associate Professor of Emergency Medicine and Director of Emergency Medicine Research Program, John T Nagurney MD; Associate Professor of Emergency Medicine, Hamid Shokoohi, MD; Assistant Professors of Emergency Medicine Emily Miller MD, Brian Yun MD MBA MPH and; Instructors of Emergency Medicine Sayon Dutta MD, Kamal Medlej MD, Renee N. Salas MD MPS MS, Jonathan Slutzman MD.

Hospital.¹¹⁹ Other signatories are leaders in public health and epidemiology, and are therefore contributing to the broader fight against the coronavirus pandemic.

One signatory, Dr. David F.M. Brown in the Emergency Department at Massachusetts General Hospital wrote an article describing a typical day on the frontlines, fighting COVID-19.¹²⁰ Dr. Brown's days begin at 5 am, when he wakes up and immediately checks in with his team at the hospital, and end when he arrives home at 8:30 pm. He notes that his department is seeing "an unprecedented volume of critically ill patients."¹²¹ Dr. Brown and his colleagues, like many of the signatories, cannot be expected to have time to consider EPA's revisions to the Initial Proposal in a meaningful manner at this time. Rather, he and many other medical professionals are devoting their energy to saving lives in this unprecedented crisis.

Public health experts also play a crucial role in assisting the public and governments in responding to this crisis. For example, Harvard University is working in partnership with the Massachusetts Department of Public Health, the Executive Office of Health and Human Services COVID-19 Command Center, and other schools in Massachusetts to respond to the coronavirus crisis.¹²² Additionally, signatories who are public health experts at Harvard have been instrumental in carrying out research on COVID-19 and interpreting data and studies for the public. For example, Francesca Dominici is one of the authors of a recent manuscript identifying a relationship between greater exposure to fine particulate matter pollution and a higher death rate from COVID-19.¹²³ Marc Lipsitch was one of the authors of a recent study in *Science* projecting different scenarios for the course of the pandemic in the coming months and years.¹²⁴ Joseph Allen penned an article in the Washington Post that corrected public misperception of the risks of catching coronavirus from inanimate objects.¹²⁵ Ashish Jha has appeared frequently on news outlets including NBC, CNN, and NPR. He, like many of the other signatories, has also

¹¹⁹ Instructor in Emergency Medicine, Mount Auburn Hospital, Justin Pitman MD.

¹²⁰ David F. M. Brown, MD, *COVID-19: A View from the Frontlines*, Giving News, MASSACHUSETTS GENERAL HOSPITAL (Apr. 9, 2020), <https://giving.massgeneral.org/covid-19-emergency-medicine/>; see also Renee Salas, MD, *On the Hospital Frontlines, Conquering Fear and Finding Hope*, U.S. NEWS & WORLD REPORT (Mar 30, 2020, 12:54 PM), https://www.usnews.com/news/healthiest-communities/articles/2020-03-30/conquering-coronavirus-fear-and-finding-hope-on-the-hospital-front-lines?utm_source=usn_tw.

¹²¹ David F. M. Brown, MD, *COVID-19: A View from the Frontlines*, *supra* note 120.

¹²² *Collaborating to Support Local Public Health Departments with COVID-19 Response*, ASS'N OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH (ASPPH) (Apr. 9, 2020), <https://www.aspph.org/harvard-collaborating-to-support-local-public-health-departments-with-covid-19-response/>.

¹²³ Xiao Wu et al., *Exposure to air pollution and COVID-19 mortality in the United States*, MEDRXIV 2020.04.05.20054502, <https://doi.org/10.1101/2020.04.05.20054502>

¹²⁴ Stephen Kissler, et al, *Projecting the transmission dynamics of SARS-CoV-2 through the post pandemic period*, SCIENCE, (Apr. 14, 2020), <https://science.sciencemag.org/content/early/2020/04/14/science.abb5793>.

¹²⁵ Joseph G. Allen, *Don't panic about shopping, getting delivery, or accepting packages*, WASH. POST, (Mar. 26, 2020, 5:10 AM PDT), <https://www.washingtonpost.com/opinions/2020/03/26/dont-panic-about-shopping-getting-delivery-or-accepting-packages/>. There, Prof. Allen responded to an article that was misunderstood by the public and leading to widespread panic and anxiety about getting packages delivered. See Neeltje van Doremalen et al., *Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1*, 382 NEW ENGLAND J. MEDICINE, 1564 (Apr. 16, 2020), <https://www.nejm.org/doi/full/10.1056/NEJMc2004973> (originally published online on March 17, 2020).

published articles and has been quoted in various news media outlets.¹²⁶ Dr. Jha also testified before the House of Representatives Select Subcommittee on the Coronavirus Crisis on May 13, 2020.¹²⁷ Given their expertise in public health, the signatories are uniquely positioned to guide government offices and advise the public on how to respond to this unprecedented pandemic. This responsibility is significant and thus demands the full attention of public health and medical experts.

The timing of the comment period could not have been worse as it has overlapped with the most critical moment in our country's response to the COVID-19 pandemic so far. The Supplemental Notice was published in the Federal Register on March 17, 2020. Less than a week later on March 23, 2020, Massachusetts ordered all non-essential businesses to close and ordered residents to shelter in place.¹²⁸ That order remains in place at least until May 18th, the last day of the comment period.¹²⁹ Even as the end of the comment period draw nears, COVID-19 cases and hospitalizations have continued to rise in many parts of the country.¹³⁰

While a sixty-day comment period for a supplemental notice may sometimes be sufficient in ordinary times, the present conditions in hospitals around the country, including where the signatories work, demonstrate that times are anything but ordinary. Medical and public health experts should be given a meaningful opportunity to provide comment to EPA's proposed supplemental rule. Such a meaningful opportunity would require that our nation be *not* enduring a pandemic with our medical experts on the front lines. Specifically, EPA should not finalize the rule without reopening the docket for public comments for at 30 days after social distancing restrictions have been lifted in most if not all urban areas in the United States.

¹²⁶ See e.g., Dr. Ashish K. Jha, *To Get Our Economy Moving, Focus on Testing for Coronavirus*, FORBES (Apr. 8, 2020, 6:00 AM EDT), <https://www.forbes.com/sites/steveforbes/2020/04/08/to-get-our-economy-moving-focus-on-testing-for-coronavirus/#35f6771d73f2>; see also Michelle A. Williams et al., *The COVID-19 Crisis Is Going to Get Much Worse When it Hits Rural Areas*, WASH. POST (Apr. 6, 2020, 6:00 AM PDT), <https://www.washingtonpost.com/opinions/2020/04/06/covid-19-crisis-is-going-get-much-worse-when-it-hits-rural-areas/>; Jane J. Kim & Michelle A. Williams, *There will be another pandemic after the coronavirus—and it's time to start preparing now*, FORTUNE (Mar. 29, 2020, 9:00 AM EDT), <https://fortune.com/2020/03/29/coronavirus-pandemic-public-health-preparedness/>; Michelle A. Williams & Shekhar Saxena, *5 Ways to Manage Your Coronavirus Stress*, THRIVE GLOBAL (Mar. 22, 2020), <https://thriveglobal.com/stories/harvard-michelle-williams-shekhar-saxena-how-manage-anxiety-stress-coronavirus/>.

¹²⁷ *Member Briefing On Testing, Tracing, And Targeted Containment*, House of Representatives Select Subcommittee on the Coronavirus Crisis (May 13, 2020), <https://coronavirus.house.gov/member-briefing-testing-tracing-and-targeted-containment>.

¹²⁸ Press Release, Governor Charlie Baker Orders All Non-Essential Businesses To Cease In Person Operation, Directs the Department of Public Health to Issue Stay at Home Advisory For Two Weeks (Mar. 23, 2020), <https://www.mass.gov/news/governor-charlie-baker-orders-all-non-essential-businesses-to-cess-in-person-operation>.

¹²⁹ Order Further Extending the Closure of Certain Workplaces and the Prohibition of Gatherings of More than 10 People (Apr. 28, 2020), <https://www.mass.gov/doc/signed-second-extension-of-essential-services-order/download>.

¹³⁰ *Coronavirus in the U.S.: Latest Map and Case Count*, N.Y. Times, <https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html> (last visited May 14, 2020).

For all of the foregoing reasons, the Proposal should be withdrawn.

Thank you for your attention to these comments.

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