August 16, 2018

VIA ELECTRONIC SUBMISSION

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Attn: EPA–HQ–OA–2018–0259

Re: Comment of the Environmental Defense Fund on the Environmental Protection Agency's *Proposed Rule: Strengthening Transparency in Regulatory Science,* 83 Fed. Reg. 18768 (Apr. 30, 2018) ("Proposal")

Environmental Defense Fund ("EDF") submits the following comments on EPA's April 30, 2018 proposed rule, "Strengthening Transparency in Regulatory Science" (the "Proposal").[1] Representing over two million members and supporters, EDF applies science, economics, and the law to solve our most urgent public health and environmental problems. EDF regularly engages in policy advocacy, regulatory proceedings, and litigation to secure and defend protections for human health and the environment under the Clean Air Act ("CAA"), Toxic Substances Control Act ("TSCA"), and other statutes administered by EPA—protections that save lives, improve well-being, and provide a more vibrant economy for all Americans, including our members. EDF and our members therefore have a profound stake in ensuring that EPA actions are anchored in the best available science, and are not distorted by policies and practices that seek to unjustifiably limit EPA's use of science for the purpose of weakening health and environmental protections.

For the reasons explained below, the Proposal would violate EPA's substantive and procedural obligations, is arbitrary and capricious, and must be withdrawn. Indeed, the Proposal is the classic wolf in sheep's clothing. Cloaked in vague platitudes about scientific quality and promoting "transparency," the Proposal would establish a sweeping new regulatory requirement prohibiting EPA from considering public health studies for which underlying data cannot be made "publicly available in a manner sufficient for independent validation."[2] This requirement would bar EPA from considering many vital public health studies that are based on confidential patient information that cannot be legally or ethically disclosed, and have been rigorously vetted using time-tested approaches that are widely accepted in the scientific community. Nowhere does the Proposal document what deficiencies in existing EPA regulatory science it is trying to solve, much less why such draconian restrictions on the use of science would improve the quality of EPA decision-making.

This wolf's true nature, however, cannot be covered up: the Proposal is in fact directed at excluding the best available science demonstrating significant health and welfare effects from

[1] *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18,768 (Apr. 30, 2018).
[2] *Id.* at 18,773 (proposed 40 C.F.R. § 30.5).

agency decision-making in order to thwart the agency's ability to protect the public health and welfare. As our comments document, the Administration hastily concocted this Proposal as a way of unilaterally implementing failed legislative proposals backed by prominent opponents of accepted climate change science and patterned on proposals put forward by the tobacco industry in the 1990s. According to records obtained from EPA through the Freedom of Information Act when this Administration's own political staff discovered that earlier versions of the Proposal might also restrict industry-funded science supporting the registration of pesticides and other chemicals, it decided to "thread this one real tight!" to ensure that *only* those studies supporting public health regulations would be subject to this new "transparency" rule.[3]

Ultimately, this Proposal does not "strengthen science." EPA's Science Advisory Board ("SAB") and the scientific community were not even consulted in its development, and a host of scientific authorities—including members of the SAB, editors of the nation's leading scientific journals, the National Academies, and numerous scientific and medical organizations—have raised fundamental concerns about the Proposal. Rather than strengthen science, the Proposal grants the Administrator vague and manipulable authority to *censor* science that by any scientific definition is the best simply because it conflicts with this Administration's political goals. We urge EPA to abandon this deeply destructive and misguided Proposal.

Respectfully submitted,

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[3] *See* discussion *infra* Section VII.

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OVERVIEW

The Proposal acknowledges that "[t]he best available science must serve as the foundation of EPA's regulatory actions."[4] But it then requires EPA to systematically ignore the best available science when it regulates to protect human health and welfare. This is counter to EPA's statutory mandates to use "best available science," and the proposal is a transparent attempt not to *strengthen* science, but rather to *censor* science that is inconvenient to the current Administration's political goals.

Since EPA was established nearly half a century ago, the Agency and its leadership—under Administrations of both parties—have recognized the central role that rigorous science plays in fulfilling the Agency's mission of protecting human health and the environment.[5] EPA's obligation to consider the best available science is not only a policy commitment that flows from the Agency's mission; it is a legal obligation enshrined in many of the fundamental public health and environmental statutes that EPA is charged with administering. The agency has established an array of mechanisms over the last five decades—including "rigorous review" by its scientific advisory boards "that goes beyond the typical journal peer review procedures"[6]—to ensure that the Agency's decisions are grounded in the best available science.

The Administrator's proposal does not build on this strong foundation; to the contrary, it crumbles it. The purpose and effect of the proposal would be to *degrade* the quality of science in EPA's decision making. While the proposal suggests that its aim is to improve transparency by increasing public availability of data, in actuality it proposes none of the steps that a proposal seriously aimed at that goal would propose, such as increasing funding for EPA grantees to undertake this effort, or proposing solutions to real concerns about patient confidentiality. Instead, the heart of the proposal is a bar on considering science simply because the underlying data is not publicly available, regardless of whether the science has been peer reviewed, reproduced, or contains other hallmarks of scientific quality. Indeed, the agency's recent communication to the Congressional Budget Office that a similar Congressional proposal could be implemented at "no cost" proves the point: EPA's aim here is not to make more data available (which costs money), but to rely on less science in decisionmaking.

The agency's arbitrary, single-minded focus on considering studies for which certain data and models are publicly available (but only the dose-response studies relevant to health

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[4] 83 Fed. Reg. at 18,769.

[5] Brady Dennis, *Outgoing EPA chief: Science is 'fundamental to absolutely everything we do'*, Washington Post (Dec. 21, 2016) (quoting former EPA Administrator Gina McCarthy as saying, "Science is everything. Almost every action we take is bounded by what the science tells us. It's based on a factual record of where the world is today and what is our obligation under our mission. Science needs to be protected. Any effort to undermine that science in a way that would give undue influence to folks that aren't scientists is a really big problem."), https://www.washingtonpost.com/news/energy-environment/wp/2016/12/21/outgoing-epa-chief-science-is-everything-it-is-fundamental-to-absolutely-everything-we-do/?utm_term=.6f1e45472169; Christine Todd Whitman, *No room for science in Trump Administration*, CNN (May 15, 2017), https://www.cnn.com/2017/05/15/opinions/no-science-in-trump-administration-whitman/index.html (describing Administrator Pruitt's actions as a "trend away from science as the backbone of the EPA and other key federal agencies").

[6] Memorandum by Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science 4 (May 12, 2018) (observing that the Proposal "fails to mention that EPA has mechanisms for vetting science through several expert panels," including the SAB and others).

protective regulation, not the ones supporting registration of chemicals) stands in stark contrast to the way the scientific community validates research findings. The scientific community, and scientific journals look to a range of attributes when assessing the quality of a scientific study, including whether the study has been peer reviewed, whether the scientists used rigorous scientific methods, and whether the study's results have been reproduced or replicated. While scientific journals and other institutions have encouraged making data and models publicly available, there is widespread recognition in the scientific community that doing so is often legitimately constrained due to legal and ethical protections on the confidentiality and privacy of data, or because the data is unavailable. Moreover, no scientist or scientific organization supports the Proposal's approach of *excluding* research for which the underlying data cannot be disclosed. Indeed, *none* of the materials EPA cites support such an extreme approach. To the contrary, the scientific community recognizes that the quality of a study is not determined by whether the underlying data is publicly available and has long utilized a variety of tools for ensuring the integrity and rigor of research findings.[7]

For all these reasons, numerous representatives of the scientific community—including editors of the very scientific journals whose policies EPA cites to in the Proposal, the American Association for the Advancement of Science, members of the SAB, and other scientists cited to by EPA—have already voiced serious concerns about the Proposal.[8] As these experts have recognized, it is not consistent with good scientific practice, and certainly not consistent with the Agency's responsibility to utilize "best available science," to deem certain scientific studies unworthy of consideration simply because these studies cannot meet an arbitrary public availability requirement.[9] Far from promoting the integrity of Agency decisions, the Proposal's simplistic approach would impoverish the Agency's decision-making by excluding the consideration of scientific studies that, standing alone or in combination with other studies, have significant bearing on vital public health and environmental protections. This, in turn, would result in regulations that are *not* based on "best available science" and that will provide inadequate protection for the very public health and welfare that EPA has been charged by Congress to safeguard.

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[7] *See id.* at 4 ("The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods.").

[8] *E.g.*, Anne Q. Hoy, *Scientific Leaders Speak Out on EPA's Proposed "Transparency Rule,"* https://www.aaas.org/news/scientific-leaders-speak-out-epa-s-proposed-transparency-rule; Jeremy Berg et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116; Letter to Acting Administrator Wheeler 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 (July 16, 2018) (Warning that "overly stringent requirements for transparency may cause valid evidence to be discarded and thereby pose a threat to the credibility of regulatory science," and stating that "The National Academies have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data.").

[9] *See* John Ioannidis, *All science should inform policy and regulation*, 15 PLOS 5 (May 3, 2018) ("Past collected and analyzed information can and should still be used for decision-making, taking into account any relevant imperfections. While fully transparent and reproducible information should certainly be valued more highly, studies with weaknesses can still offer insights.").

That, of course, appears to be the current Administration's goal. A close examination of the history of this Proposal confirms that its purpose is not to strengthen science at EPA, but to undermine public health and environmental protections by arbitrarily blinding the agency to vital research. Indeed, the Proposal resembles proposals advanced by the tobacco industry for the specific purpose of suppressing public health science warning about the dangers of tobacco smoke.[10] The Proposal also resembles failed legislation in Congress that was similarly advanced by industry interests seeking to undermine public health and environmental protections, and criticized by scientific experts.[11] EPA documents released in response to Freedom of Information Act (FOIA) requests relating to the Proposal show that Trump Administration appointees deliberately tailored the scope of the Proposal in order to promote industry interests.

EPA's purpose and mission is to protect human health and welfare, *not* to promote the agendas of the worst polluters and their allies in order to weaken health and welfare protections. EPA should withdraw this misguided and harmful proposal.

Terminology

At the outset, it is useful to review relevant terminology, which the Proposal appears to confuse and conflate. A recent National Academy of Sciences workshop produced the following definitions of "reanalysis," "replication," and "reproduction," each of which has a different scientific meaning and different applications and implications.[12] Let's consider each of these definitions separately.

> *A **reanalysis** is when you conduct a further analysis of data. A person doing a reanalysis of data may use the same programs and statistical methodologies that were originally used to analyze the data or may use alternative methodologies, but the point is to analyze exactly the same data to see if the same result emerges from the analysis.*

A reanalysis does validate or invalidate a study findings. If all credible methods of reanalysis yield effectively the same results as the original analysis, this does strengthen the original findings. The use of differing statistical models should be assessed with care and demonstrate that the assumptions supporting a new method of analysis is significantly more credible than the original analysis. It is easy to develop methods of analysis that can demonstrate

[10] Emily Atkin, *The EPA is Acting Like Big Tobacco*, The New Republic (Apr. 26, 2018), https://newrepublic.com/article/148126/epa-acting-like-big-tobacco (describing the role of Steve Milloy, a leading public proponent of the Proposal who has taken credit for its existence, in crafting similar policy proposals on behalf of the tobacco industry-funded Advancement of Sound Science Coalition).

[11] Letter by U.S. Science, Engineering, and Academic Institutions to Kevin McCarthy, House Majority Whip (Mar. 16, 2015) (opposing "Secret Science Reform Act, H.R. 1030"), https://sciencepolicy.agu.org/files/2013/07/AAAS-Secret-Science-letter-McCarthy-2015.pdf; Letter by Barry Nussbaum, American Statistical Association to Sen. Mike Rounds and Sen. Kamala Harris (May 25, 2017) (opposing HONEST Act, H.R. 1430), https://www.amstat.org/asa/files/pdfs/POL-HONEST_ActLetter.pdf.

[12] National Academies of Sciences, Engineering, and Medicine, *Principles and obstacles for sharing data from environmental health research: Workshop summary*, The National Academies Press (2016), https://www.nap.edu/catalog/21703/principles-and-obstacles-for-sharing-data-from-environmental-health-research.

a different finding, but are created solely for that purpose and these should not be given greater weight in evaluating a particular study.

> ***Replication*** *means that you actually repeat a scientific experiment or a trial to obtain a consistent result. The second experiment uses exactly the same protocols and statistical programs but with different data from a different population*[13]*. The goal is to see if the same results hold with data from a different population.*

Replication predominantly applies to laboratory studies and randomized control trials since you are able to control almost all of the experimental details making replication possible. Replication does not enhance transparency. In environmental epidemiology, randomized control trials are not feasible or ethical, and replication of observational studies is virtually impossible since it is not possible to create the same conditions as seen in the original study. Even in laboratory experiments, replication can be difficult due to uncontrolled factors like genetic drift in cell lines and animal strains. Finally, if you do have replicate studies and one has a positive finding and another has a negative finding, there would have to be additional criteria used to determine which study was correct; thus a failure to replicate should not immediately lead to the conclusion that there is no effect. Rather than replicating a study, it is far better to develop a better study that replicates the results while providing greater insight into the basis underlying any toxicity.

> *And then, finally, when you* ***reproduce*** *a scientific experiment, you are producing something that is very similar to that research, but it is in a different medium or context. For example, a researcher who is reproducing an experiment addresses the same research question but from a different angle than the original researcher did.*

Here, reproduction refers to a body of evidence addressing the same hypothesis, but using different populations, methods, etc. Reproduction does not enhance transparency. The majority of research on the health effects of environmental hazards fall into this category. Here, a series of studies that address the same hypothesis and give the same basic result does indeed strengthen findings of toxicity.

None of these concepts discusses the scientific quality of the study; this is critical. The ability to replicate a study with very poor scientific quality does not strengthen the scientific belief that any toxicity is present. Similarly, studies that attempt to reproduce the same findings must have their quality clearly established before comparisons can be made across the multiple studies.

An example of how some of these different techniques work in practice is the scientific evidence on air pollution and premature death which include the Harvard Six Cities Study and the American Cancer Society Cancer Prevention Study II (ACS CPSII). The extent to which these studies have been reanalyzed and reproduced is extraordinary and by no means necessary. But they provide a good case study of how these techniques work in practice.

[13] "Different population" in this context means a different set of the same test subjects (e.g., same animal species and strain, same cell lines).

The original Harvard Six Cities and ACS CPSII studies on mortality were published in 1993 and 1995 respectively.

- The Harvard Six Cities study assessed the long-term effects of fine particle pollution (PM2.5) over 12 to 14 years (1974–1989) on premature mortality among 8,111 adult participants who lived in 6 different cities: Watertown, MA; Harriman, TN; St. Louis, MO; Steubenville, OH; Portage, WI; and Topeka, KS. After accounting for cigarette smoking, level of education, body mass index, and occupational exposure to dusts, gases, and fumes, the authors of this study found that for members of the same age and sex group there was a 26% higher risk of premature mortality between the study participants living in the city with the highest levels of particles (Steubenville) and the city with the lowest levels (Portage).[14]

- The investigators of the Harvard Six Cities study, along with others, **reproduced** their finding in a separate assessment of the association between fine particle levels and mortality among 295,223 adults who lived in 50 metropolitan areas across the United States, over a period of 7 years (1979-1983) in the ACS CPSII study. After accounting for smoking, education, body mass index, alcohol consumption, and self-reported occupational exposure to a number of substances, the scientists found that for participants of the same age, race and sex there was a 17% increased risk of mortality with every 25.4 microgram per meter cube change in PM2.5.[15]

The Harvard Six Cities Study and the ACSCPSII were **reanalyzed** by the Health Effects Institute, a nonprofit independent research corporation funded by EPA and the motor vehicle industry, under a data sharing agreement. A research team evaluated the consistency and accuracy of the data and then undertook a series of comprehensive analyses to test the validity of the findings first using the same statistical analyses and then testing the robustness of the original findings and interpretations to alternative analytic approaches. The results of the reanalysis were resoundingly similar to the original studies. For the Harvard Six cities study the reanalysis found a 28% increased risk of mortality per 18.6 microgram per meter cube of PM2.5 in comparison to 26% found in the original study. For the ACS CPSII study the showed that for every 25.4 microgram per meter cube change in PM2.5 there was an associated 18% increased risk of mortality (results of the independent reanalysis) vs 17% reported by the original study.[16]

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[14] Dockery, D.W., Pope, C.A., Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris Jr, B.G. and Speizer, F.E., *An Association Between Air Pollution and Mortality in Six US Cities*, 329(24) New England Journal of Medicine 1753-1759 (1993).

[15] Pope, C.A., Thun, M.J., Namboodiri, M.M., Dockery, D.W., Evans, J.S., Speizer, F.E. and Heath, C.W., *Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of US Adults*, 151(3) American Journal of Respiratory and Critical Care Medicine 669-674 (1995).

[16] Krewski, Daniel, et al., *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality*, footnote on 249 Health Effects Institute (2000). See also Letter to Andrew Wheeler from Harvard University (Docket ID No. EPA-HQ-OA-2018-0259) (reanalysis and "releasing raw data will not improve the quality of the resulting report/study/analysis, and therefore will do nothing to render any individual study 'better.'").

A large body of literature also shows that this association of fine particle pollution and mortality has been **reproduced** in different populations across the globe,[17] over different periods of time, contexts and using different methods. Most recently, a study of 61 million elderly people enrolled in Medicare across the entire United States followed over 13 years found a strong association between particle pollution and increased risk of mortality, at even the current levels of air pollution and below the current air quality standards for PM2.5.[18] It is this accumulation of evidence of reproducible effects in multiple studies that is critical in determination of causality and validation of an effect and is already an integral part of the EPA process of supporting causality.[19]

Through these different methods, the original findings of the Harvard Six Cities Study have been validated many times over, and they have been used to inform countless EPA rule makings that address particulate matter pollution. Notably, however, the Proposal would appear to preclude EPA from using them because—while the Study has been reanalyzed and reproduced—the underlying data is not publicly available because of patient confidentiality protections bound by individual contractual agreements between the scientists and the research participants and by the Health Insurance Portability and Accountability Act. These reasons are unrelated to the validity, integrity or quality of the Harvard Six Cities Study. Indeed, the Office of Management and Budget's data quality guidelines specifically point to the Harvard Six Cities Study as an example of how data may be validated or corroborated without public release of the underlying raw data.[20] It is critically important to note that reanalysis projects are not simple or inexpensive.[21] The reanalysis of just the Harvard Six Cities Study and the ACS CPSII took three years to complete and cost $899,046 in direct expenditures,[22] without accounting for costs incurred by Health Effects Institute for oversight and review as well as staff compensation.

In summary, reanalysis is a tool to demonstrate the robustness of an effect to changes in the statistical model underlying an analysis of a single data set. However, it is easy to develop methods of reanalysis that can demonstrate a different finding. Therefore, care must be taken to understand the assumptions underlying models applied in reanalysis in order to judge their relevance. Replication in the environmental health context is primarily limited to laboratory studies and, without additional information to guide a decision, provides little information that can be used to decide between replicate studies with differing results. Reproducing effects in multiple studies that are not identical is the basis for almost all scientific decisions on environmental issues and should be the focus of the EPA's approach to regulatory science. Finally, none of these issues address other key aspects of scientific quality such as

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[17] EPA, NCEA, *Integrated Science Assessment for Particulate Matter*, EPA/600/R-08/139F (2009); Beelen, Rob, et al., *Effects of long-term exposure to air pollution on natural-cause mortality: an analysis of 22 European cohorts within the multicentre ESCAPE project*, 383.9919 The Lancet 785-795 (2014).

[18] Di, Qian, et al., *Air pollution and mortality in the Medicare population*, 376.26 New England Journal of Medicine 2513-2522 (2017).

[19] EPA, *Preamble to the Integrated Science Assessments (ISA)* (EPA/600/R-15/067) (2015).

[20] *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information*, 67 Fed. Reg. 8,452, 8,456 (Feb. 22, 2002).

[21] Comments of Daniel Greenbaum, President, Health Effects Institute (HEI), on Proposed Rule EPA–HQ–OA–2018–0259 (July 17, 2018).

[22] Krewski, Daniel, et al., *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality*, footnote on 249 Health Effects Institute (2000).

generalizability and bias; how these characteristics of any scientific study are assessed by the EPA directly relate to the transparency of any decisions they might make.

I. EPA's Proposed Rule Violates Numerous Substantive Statutory Requirements.

A. EPA Does Not Have Authority to Issue the Proposed Rule.

Agencies are creatures of Congress; "an agency literally has no power to act . . . unless and until Congress confers power upon it." *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); *see Am. Library Ass'n v. FCC*, 406 F.3d 689, 691 (D.C. Cir. 2005) ("It is axiomatic that administrative agencies may issue regulations only pursuant to authority delegated to them by Congress."). EPA points to a smattering of statutes as allegedly authorizing the Proposal.[23] None of these authorities, however, authorize EPA to promulgate a one-size-fits-all regulation governing how the agency will consider science under its various statutory authorities, which is perhaps why EPA solicits comment on whether additional authorities might exist to authorize its Proposal. The varied statutes that the Proposal cites have different requirements as to the agency's obligations when considering science. *Compare* CAA § 108(a) (standards must "reflect the latest scientific knowledge useful in indicating" health and welfare effects)[24] *with* TSCA § 4(f) (Administrator must consider "*any other information available*")[25] *with* Safe Drinking Water Act ("SDWA") § 1412(b)(1)(B)(ii)(II) (Administrator must consider "the best available public health information").[26] The Proposal gives no explanation of how *any* of the provisions it cites provide authority for the Proposal, much less how all of them authorize identical requirements.

For example, EPA cites the Clean Air Act, § 301, 42 U.S.C. § 7601, as purportedly granting authority for the Proposal.[27] The authority granted by section 301(a), however, applies only to the Clean Air Act and, in any event, is not broad enough to encompass this Proposal. Section 301 provides that "[t]he Administrator is authorized to prescribe such regulations subject to section 307(d) as are *necessary* to carry out his [or her] functions under this Act."[28] The courts have consistently "decline[d] to read … open-ended power into section 301,"[29] and instead have required that regulations promulgated under section 301 be both necessary and appropriate.[30] As

[23] 83 Fed. Reg. at 18769.
[24] 42 U.S.C. § 7408(a).
[25] 15 U.S.C. § 2603(f).
[26] 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II), (b)(1)(A)(i); *see also*, 42 U.S.C. § 300g-1(b)(3)(A)(i) ("the Administrator shall use. . . the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices").
[27] 83 Fed. Reg. at 18769.
[28] 42 U.S.C. § 7601(a)(1) (emphasis added).
[29] *Nat. Res. Def. Council v. Reilly*, 976 F.2d 36, 41 (D.C. Cir. 1992).
[30] *E.g.*, *Alabama Power Co. v. Costle*, 636 F.2d 323, 403 (D.C. Cir. 1979) (finding an EPA rule unauthorized under section 301, and concluding that "[a]n extension of PSD permit requirements beyond the wording of the Act is therefore neither necessary nor appropriate to carry out EPA's functions under the Act."); *Nat. Res. Def. Council v. EPA*, 22 F.3d 1125, 1148 (D.C. Cir. 1994) ("[S]ection 301 does not provide the Administrator '*carte blanche* authority to promulgate any rules, on any matter relating to the Clean Air Act, in any manner that the Administrator wishes,'" and instead "allow[s] the promulgation of rules that are necessary and reasonable to effect the purposes of

discussed in more detail below, EPA's Proposal here is not necessary, and instead directly conflicts with several other provisions of the Clean Air Act. It is axiomatic that a "general grant of authority cannot trump specific statutory provisions."[31]

Nor does Congressional authorization to *conduct* or *fund* research authorize EPA to *ignore* research in regulatory decision-making. Accordingly, provisions like TSCA § 10, which directs that the "Administrator shall … conduct such research, development, and monitoring as is necessary to carry out the purposes of this [Act],"[32] and CAA § 103, which authorizes the agency to conduct and support research,[33] plainly do not authorize the Proposal.

B. The Proposed Rule Violates EPA's Statutory Authorities.

Not only is there no authority for EPA's pan-statutory Proposal, the Proposal would violate explicit statutory commands. Though EPA admits that "[t]he best available science must serve as the foundation of EPA's regulatory actions,"[34] proposed section 30.5 would ***prohibit*** EPA from considering high quality and critically important scientific studies—precisely that "best available science"—when undertaking regulatory actions. Specifically, section 30.5 would prevent EPA from considering any scientific study for which the underlying "dose response data and models" are not "publicly available in a manner sufficient for independent validation."[35] This would be true even if that scientific study constituted "information available to the Administrator" in a TSCA § 4(f) rulemaking, 15 U.S.C. § 2603(f)(2); "reflect[ed] the latest scientific knowledge useful in indicating" health and welfare effects in a CAA § 108 rulemaking, 42 U.S.C. § 7408(a)(2); or reflected "the best available public health information" in a SDWA rulemaking, 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II). Accordingly, this proposed prohibition would contravene an array of statutes governing EPA's consideration of science when promulgating rules, such as requirements to consider the "best available science" when setting environmental protection standards. *See, e.g.*, SDWA, 42 U.S.C. § 300g-1(b)(3)(A) (EPA must use "[t]he best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" and "[d]ata collected by accepted methods or best available methods"); TSCA, 15 U.S.C. § 2625(h) ("[T]he Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science."); CAA, 42 U.S.C. § 7408(a) (EPA shall establish air quality criteria that "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be

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the Act.") (quoting *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 873 (D.C. Cir. 1979)); *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."); *North Carolina v. EPA*, 531 F.3d 896, 922 (D.C. Cir. 2008), *on reh'g in part*, 550 F.3d 1176 (D.C. Cir. 2008) (striking down a regulation promulgated under Section 301 because EPA could not demonstrate that it was "necessary" to fulfill the purposes of the Act).

[31] *Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063-64 (D.C. Cir. 2014); *API v. EPA*, 52 F.3d 1113, 1119 (D.C. Cir. 1995) (same).

[32] 15 U.S.C. § 2609(a), cited at 83 Fed. Reg. at 18769.

[33] 42 U.S.C. § 7403, cited at 83 Fed. Reg. at 18769.

[34] 83 Fed. Reg. at 18769.

[35] 83 Fed. Reg. at 18773-74.

expected from the presence of such pollutant in the ambient air, in varying quantities."). And, by excluding science that meets these statutory criteria from supporting regulations to protect public health and welfare, the Proposal would frustrate Congress's policy in these statutes and frustrate EPA from achieving its fundamental mission.[36]

1. EPA's statutory authorities generally require the agency to consider *all* available data when undertaking significant rulemakings.

As just noted, EPA's statutory authorities mandate a variety of requirements for what scientific information EPA must consider in rulemaking. These statutes are discussed in detail, *infra* at Section I.B.3. To take one example that appears in numerous statutes, including TSCA, CAA, SDWA, and the Endangered Species Act, Congress has often required agencies to act on the "best available science." For an agency to comply with this obligation, the agency must at least consider all available scientific information. "Best" means "of the most excellent, effective, or desirable type or quality."[37] "Available" means "able to be used or obtained."[38] And "science" means "the intellectual and practical activity encompassing the systematic study of the structure and behavior of the physical and natural world through observation and experiment."[39] Assessing which science is "best" requires consideration of the overall quality of the science, and the public availability of underlying data is, at best, one of many aspects that should inform that assessment of overall quality.

An agency "cannot ignore available. . . information."[40] Numerous courts have indicated that a plaintiff or petitioner can establish a violation of the "best available science" requirement by "point[ing] to any scientific evidence that the agency failed to consider."[41] "The best available data requirement. . . prohibits [an agency] from disregarding available scientific evidence that is in some way better than the evidence [it] relies on.'"[42] "An agency does. . . have an obligation to deal with newly acquired evidence in some reasonable fashion."[43] EPA's proposal will result in EPA precluding itself from considering certain studies that are "available," thus violating the requirement that EPA rely on the best available science.

In addition, the requirement that agencies use "best available" science or information often means that the agency must act *even if* the available science or information is imperfect.

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[36] *See, e.g., Shays v. FEC*, 528 F.3d 914, 919 (D.C. Cir. 2008) ("[W]e 'must reject administrative constructions of [a] statute that frustrate the policy that Congress sought to implement.'") (*quoting Cont'l Air Lines, Inc. v. Dep't of Transp*, 843 F.2d 1444, 1453 (D.C. Cir. 1988)).
[37] *Oxford American Dictionary* 159 (3d ed. 2010).
[38] *Id.* at 111.
[39] *Id.* at 1564.
[40] *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988); *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 602 (9th Cir. 2014) (quoting *Kern Cnty.*, 450 F.3d at 1080-81 (quoting *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988)).
[41] *Safari Club Int'l v. Salazar (In re Polar Bear Endangered Species Act Listing & Section 4(d) Rule Litig. - MDL No. 1993)*, 709 F.3d 1, 9 (D.C. Cir. 2013).
[42] *Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1080 (9th Cir. 2006) (quoting *Sw. Ctr. for Biological Diversity v. Babbitt*, 215 F.3d 58, 60 (D.C. Cir. 2000)).
[43] *Catawba County v. EPA*, 571 F.3d 20, 45 (D.C. Cir. 2009) (quoting *American Iron & Steel Institute v. EPA*, 115 F.3d 979, 1007 (D.C. Cir. 1991)).

"Even if the available scientific and commercial data were quite inconclusive, [the agency] may—indeed must—still rely on it" when the agency has a duty to act.[44] "[W]here the information is not readily available, we cannot insist on perfection."[45] Just as the Courts have recognized that they cannot expect perfection, agencies cannot choose to ignore certain studies or sources of information based solely on whether the data is publicly available—especially where the validity of those studies has been established using techniques that do not rely on public availability of underlying data.

EPA cannot reasonably elevate the interest in public availability of all underlying information above all other factors in assessing the "best available science." Textually, EPA's approach is unlawful.

2. The proposal violates these statutory commands by requiring EPA to ignore science when undertaking significant rulemakings.

In direct violation of statutory requirements to consider, for example, "any other information available" or "the latest scientific knowledge [that is] useful" or "best available science," the Proposal would *prohibit* EPA from considering relevant and high quality science whenever the underlying data for a study is not publicly available. Through the Proposal, EPA unlawfully tries to engraft an additional statutory requirement onto each of these statutes, requiring that to be considered a study's underlying data must be publicly available.[46] For EPA's Proposal to succeed, EPA must demonstrate that a study *cannot* be "other information available to the Administrator" or the "latest scientific knowledge useful in indicating" health or welfare effects or the "best available science," or any of a number of other statutory formulations if the underlying data is not publicly available. EPA's Proposal fails to do so, and it could not do so.

As explained *infra* at Section II.A.1, there are many reasons that underlying study data may not be available that have no bearing on the quality or validity of the study. These include legal restrictions or concerns about privacy (especially with respect to studies involving human subjects), confidentiality, confidential business information, or national security. Further, if this requirement were applied retroactively to existing studies, it may no longer be possible to make underlying data and models publicly available. EPA acknowledges these impediments in proposed section 30.9, which provides the Administrator with discretion—but not an obligation—to allow the agency to consider a study for which underlying data or models are not publicly available if he determines that public disclosure is infeasible. But where the Administrator fails to exercise his discretion to grant an exemption pursuant to proposed section 30.9, or where data or models are unavailable for reasons that do not satisfy the infeasibility standard, proposed section 30.5 would prohibit EPA from considering such studies, regardless of whether they meet the statutory criteria for consideration.

The only way that this prohibition could comport with EPA's statutory obligations is if a study for which underlying data is not available *cannot* be, for example, "other information

[44] *Southwest Ctr. for Biological Diversity v. Babbitt*, 215 F.3d 58, 60 (D.C. Cir. 2000) (quoting *City of Las Vegas v. Lujan*, 891 F.2d 927, 933 (D.C. Cir. 1989)).
[45] *San Luis*, 747 F.3d at 602.
[46] *See Nat'l Ass'n of Homebuilders v. Defenders of Wildlife*, 551 U.S. 644, 663-64 (2007).

available" or "the latest scientific knowledge [that is] useful" or "best available science"—i.e., if the public unavailability of a study's underlying dose response data and models makes the study ineligible to meet these criteria, regardless of whether the study has been peer reviewed, is based on rigorous methodologies, or has been published in a leading journal, and regardless of the reason for the public unavailability. EPA makes no such demonstration—nor could it. There is simply no support for such a proposition; to the contrary, all of the evidence shows that studies may be "best available science," and certainly "other information available" regardless of whether the data underlying them is publicly available.

What the Proposal fails to recognize is that disclosure of data addresses only *one* method of validating scientific research—and a relatively less important aspect at that. Disclosure of data for a given study—the focus of the Proposal—permits independent researchers to determine whether the data and methodology *used in that study* can be applied to generate the *same* results. This may help protect against sources of error or misrepresentation in a particular study. However, both EPA and independent researchers have recognized that such reanalysis does not by itself *validate* a particular study.[47] Rather, a study's evidentiary weight rests both on the strength of its methodology, as well as whether similar results can be obtained by applying the study's methodology to a relevant, but *different* dataset or population, or by using a distinct methodology to interrogate the same hypothesis.[48]

a) The scientific community

Publication in a peer-reviewed scientific journal is the way that scientists communicate their findings to other scientists and is considered the hallmark of scientific quality. Notably, the editors in chief of the world's top scientific journals have notified EPA that "[i]t does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making."[49] In response to EPA's Proposal, the editors-in-chief of *Science* and *Nature*, and other leading scientists explained that though "[d]ata sharing is a feature that contributes to the robustness of published scientific results. . . in not every case can all data be fully shared."[50] For example, full

[47] *See* EPA, *Preamble to the Integrated Science Assessment* at 20 (2015) ("An inference of causality is strengthened when a pattern of elevated risks is observed across several independent studies. *The reproducibility of findings constitutes one of the strongest arguments for causalit*y. . . ") (emphasis added); National Academies, *Principles and Obstacles for Sharing Data From Environmental Health Research* 6 (2016) (quoting researcher Lynn Goldman's observation that reproducibility and replicability across independent studies – as distinct from reanalysis of a single set of data using the same methodology – are the most convincing ways of validating a research finding); Lynn R. Goldman & Ellen Silbergeld, *Correspondence on Access to Chemical Data Used in Regulatory Decision Making*, 121 Environmental Health Perspectives A111 (Apr. 2013), https://ehp.niehs.nih.gov/wp-content/uploads/121/4/ehp.1206438.pdf ("Replication in science is quite different; it involves performance of an independent study with the same hypothesis and then testing the extent to which this independent study reaches the same conclusions. . . Designing and conducting a replication study does not require access to raw data from the original study; this would abrogate the concept of independence.")

[48] *See* National Academies, *Principles and Obstacles* at 6.

[49] Jeremy Berg et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

[50] *Id.*

sharing is not possible when data sets include "personal identifiers."[51] The scientists confirm that even under circumstances where underlying data cannot be made generally available, it is possible to evaluate the merits of a study, explaining:

> Importantly, the merits of studies relying on data that cannot be made publicly available can still be judged. Reviewers can have confidential access to key data and as a core skill, scientists are trained in assessing research publications by judging the articulation and logic of the research design, the clarity of the description of the methods used for data collection and analysis, and appropriate citation of previous results.[52]

They conclude that EPA's proposal to exclude relevant studies from EPA's consideration based solely on the fact that underlying data or methods cannot be made available to the public "will adversely affect decision-making processes."[53]

In a letter filed in this docket, the Presidents of the National Academies of Science, Engineering, and Medicine similarly observe that the public availability of data is not necessary to ensure the integrity of regulatory science and is not a sufficient criterion for excluding a particular study from consideration. The Presidents' letter notes: "The National Academies have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data." [54] The letter goes on to explain: "If the study data are not available, their absence may affect how the study is rated and used in the [agency's] analysis, but the study should not necessarily be eliminated from the assessment."[55]

b) EPA policy and practice

EPA has previously stated in several different forums that a scientific study can be valid even if the underlying dose response data and models are not publicly available. For example, EPA recently explained in its own *Plan to Increase Access to Results of EPA-Funded Scientific Research* that even though "some research data cannot be made fully available to the public but instead may need to be made available in more limited ways," the lack of full public availability "does not affect the validity of the scientific conclusions from peer-reviewed research publications."[56] Under the plan, EPA must make publications resulting from EPA-funded research publicly accessible on National Institute of Health's PubMed Central (PMC).[57] The plan

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[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] Letter to Acting Administrator Wheeler 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 2 (July 16, 2018), http://www.nationalacademies.org/includes/EPA%20Proposed%20Rule%20Docket%20EPA-HQ-OA-2018-0259%20NASEM%20Comment.pdf.
[55] *Id.* at 2-3.
[56] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* 4-5 (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.
[57] *Id.* at 8.

aims to "maximize access, by the general public and without charge, to digitally formatted data resulting from EPA funded research, *while protecting confidentiality and personal privacy, recognizing proprietary interests, business confidential information and intellectual property rights, and preserving the balance between the relative benefits and costs of long-term preservation and access.*"[58] The plan recognizes important exceptions for when "the research data cannot be released due to one or more constraints, such as requirements to protect confidentiality, personal privacy, proprietary interest, or property rights."[59] It specifically declares: "The validity of scientific conclusions drawn from research publications or their associated research data, or EPA's ability to consider those conclusions and data in its actions, does not depend on compliance with this Plan."[60]

Likewise, EPA's Science Policy Council explains in *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* that EPA's determination as to the quality and reliability of a particular scientific study does not depend on one single factor (e.g., the public availability of underlying data), but instead turns on the agency's consideration of five general factors.[61] Congress implicitly endorsed this approach by including a directive for EPA to use these same five factors in evaluating science under the Toxic Substances Control Act Amendments passed in 2016,[62] and just last year this Administration included these same factors in a recent regulation implementing TSCA.[63] The factors comprise: (1) soundness; (2) applicability and utility; (3) clarity and completeness; (4) uncertainty and variability; and (5) evaluation and review.[64] Of these, the only ones with any possible direct relevance to EPA's proposed approach are the third and fifth factors, but neither supports the elevation of public availability of data above all other considerations or the exclusion of studies with non-public data. The third factor, "clarity and completeness" requires EPA to consider "[t]he degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented." The fifth factor, "evaluation and review," requires EPA to consider "[t]he extent of independent verification, validation and peer review of the information or of the procedures, measures, methods or models." Even clear and complete "documentation" of the data used does not require that the data be made publicly available. Nor does factor five require either that a study's findings must have been replicated using the same data, or that the data must be available

[58] *Id.* at 11 (emphasis added).
[59] *Id.*
[60] *Id.* at 6.
[61] EPA Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*, EPA 100/B-03/001 (June 2003) https://www.epa.gov/risk/summary-general-assessment-factors-evaluating-quality-scientific-and-technical-information.
[62] *Id.* at 7.
[63] EPA Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*; 15 U.S.C. § 2625(h)(1)-(5); 82 Fed. Reg. 33,726, 33,731 (July 20, 2017), 42 U.S.C. § 300g-1(b)(3)(A).
[64] Note that TSCA and the regulations do not include the headers for the five factors ("soundness," "applicability and utility," etc.) included in the Science Policy Council guidance, but the description of each factor to be considered is largely identical.

to allow for such replication. Moreover, these are only portions of two of five key factors to consider.[65]

Similarly, EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of the Information Disseminated by the Environmental Protection Agency*,[66] ("EPA Information Quality Guidelines") issued pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658) (the "Data Quality Act") make it clear that the public unavailability of underlying data or models does not render a study inappropriate for EPA's consideration. Specifically, the EPA Information Quality Guidelines acknowledge that even with respect to science that will have "a clear and substantial impact on important public policies or private sector decisions," there will be circumstances where "access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections."[67] Significantly, the Guidelines do not instruct EPA to ignore such science. Rather, the Guidelines instruct that if underlying data or methods are unavailable, "EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken."[68] The Guidelines further explain: "Original and supporting data may not be subject to the high and specific degree of transparency provided for analytic results; however, EPA should apply, to the extent practicable, relevant Agency policies and procedures to achieve reproducibility, given ethical, feasibility, and confidentiality constraints."[69]

Far from instructing EPA not to consider scientific studies for which underlying data or models are unavailable, the EPA Information Quality Guidelines expressly acknowledge that EPA must balance a variety of important aims to fulfill its statutory obligations to protect public health and the environment. EPA explains in the guidelines that "most environmental statutes obligate EPA to act to prevent adverse environmental and human health impacts" and that "[f]or many of the risks that we must address, data are sparse and consensus about assumptions is rare."[70] Thus, rather than set rigid rules regarding what science and information EPA can rely upon in its rulemakings, EPA "seek[s] to strike a balance among fairness, accuracy, and efficient implementation."[71] EPA states: "Refusing to act until data quality improves can result in substantial harm to human health, safety, and the environment."[72]

As discussed *infra* at Section I.B.3.b)ii, even this Administration, in the context of promulgating regulations under TSCA, has adopted a regulatory definition of "best available

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[65] *See* EPA Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*.
[66] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA* (2002), https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.
[67] *Id.* at 21.
[68] *Id.*
[69] *Id.*
[70] *Id.* at 52.
[71] *Id.*
[72] *Id.*

science" expressly incorporating a multi-factor analysis, and that definition recognizes that public unavailability of data does not render a study incapable of being "best available science."

c) The courts

As EPA acknowledges in footnote 3 of the Proposal, in at least two instances the D.C. Circuit Court of Appeals has recognized that studies for which underlying data is not publicly available may constitute "best available science."[73] The D.C. Circuit's decisions in these cases further demonstrate that the public unavailability of a study's underlying data does not render a study incapable of constituting "best available science" otherwise unworthy of EPA's consideration.

In *American Trucking Associations* v. *EPA*, the petitioner challenged EPA's reliance on scientific studies for which underlying data was not publicly available in deciding to strengthen the national ambient air quality standards for particulate matter.[74] The Court held that the Clean Air Act did not require EPA to make public underlying data where EPA relied on the study itself and not the raw data underlying the study. The Court agreed with EPA's position that requiring agencies to obtain and publicize the data underlying all studies on which they rely "would be impractical and unnecessary."[75] Importantly, the Court concluded that:

> If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, *then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment*. . . . Such data are often the property of scientific investigators and are often not readily available because of. . .proprietary interests. . . or because of [confidentiality] arrangements [with study participants].[76]

The court accordingly recognized that ignoring relevant scientific information simply because the underlying data is not available would violate EPA's obligations to consider "best available science." *Coalition of Battery Recyclers Association v. EPA* involved another challenge to EPA's reliance on a scientific study for which the underlying data was not publicly available.[77] In that case, EPA had relied upon the study in question to determine the "concentration-response relationship between blood lead levels and IQ changes."[78] The D.C. Circuit again upheld EPA's reliance on studies without making the underlying data publicly available and explained, "raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants."[79] Likewise, in *City of Waukesha v. EPA* the

[73] 83 Fed. Reg. at 18769.
[74] 283 F.3d 355, 372 (D.C. Cir. 2002).
[75] *Id.* at 372 (quoting National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,689 (July 18, 1997).
[76] *Id.* (emphasis added).
[77] 604 F.3d 613, 622-23 (D.C. Cir. 2010).
[78] *Id.* at 622.
[79] *Id.* at 623.

D.C. Circuit concluded that agency peer review satisfies the requirement to use best, peer-reviewed science and supporting studies.[80]

d) The Proposal

Finally, even the Proposal appears to concede that studies for which data is not publicly available could constitute the "best available science" that EPA is statutorily required to consider. The proposed exemption provision in section 30.9 makes it clear that EPA does not consider a study to be invalid or unsuitable for EPA's consideration based only on the public unavailability of underlying data or models. Specifically section 30.9 would give the Administrator discretion to authorize consideration of a scientific study where "[i]t is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available." Of course, EPA could not have intended for proposed section 30.9 to provide the Administrator with discretion to take a study that is not "best available science" into consideration when promulgating a rulemaking. If the Administrator has discretion to allow consideration of a study for which it is infeasible to make the study's underlying data and models publicly available, then it obviously is not necessary for such underlying data and models to be publicly available for a scientific study to constitute "best available science." Yet, unless the Administrator elects to exercise his discretion under proposed section 30.9 and find that it is "infeasible" to make a study's underlying data and models publicly available, proposed section 30.5 broadly prohibits EPA from relying on the study in support of "significant regulatory actions."

Moreover, while proposed section 30.5's prohibition would apply to "pivotal regulatory science" used for "significant regulatory actions," the proposed rule says nothing to prohibit EPA's reliance on these studies for other agency purposes, such as in permitting, enforcement, or regulatory actions that do not qualify as "significant." Thus, EPA clearly does not believe that a study cannot be "best available science" based solely on the fact that underlying data and models are not publicly available.

In sum, if finalized, EPA's proposed rule would restrict EPA's ability to consider "best available science" when undertaking significant rulemakings, contrary to the numerous statutory directives discussed in detail below.

3. By prohibiting EPA from considering all valid and relevant studies when undertaking significant rulemakings, the proposed rule would prevent EPA from complying with an array of statutory provisions governing EPA's consideration of available science.

a) The Proposal Contravenes the Clean Air Act

[80] 320 F.3d 228, 247 (D.C. Cir. 2003).

Under Clean Air Act section 108(a),[81] EPA must establish air quality criteria for each air pollutant that serves as the basis for setting the national ambient air quality standards. Such criteria "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities."[82] As explained above, the scientific community, EPA, and the courts have all concluded that lack of public availability of underlying data does not render the study invalid. And, consideration of such studies can be essential for EPA to fulfill Clean Air Act section 108(a)'s directive that it consider "the latest scientific knowledge" in establishing air quality criteria, that it consider studies "useful" in indicating effects of pollutants on ambient air, and in providing an adequate margin of safety in the standard itself. [83] Thus, EPA's proposal to bar EPA from considering such studies would prevent EPA from complying with its statutory obligation under Clean Air Act section 108(a).

Section 108(a)(2) says nothing about excluding information—its evident purpose is to be inclusive as to information to be considered. EPA's historic practice reflects this broad directive: each NAAQS review evaluates virtually all studies in the area, excluding none, but assigning appropriate weight based on study-by-study evaluation. Since the NAAQS provisions were enacted in 1970, EPA has conducted many NAAQS rulemakings. The agency does not establish *per se, a priori* rules regarding study inclusion or exclusion, but rather evaluates each of the individual studies—and there are thousands typically evaluated for each NAAQS review—on their merits based on reasoned criteria. While details of the development and review of the criteria and standards have evolved over time, in practice, EPA has endeavored to include all relevant scientific studies in the process, even providing provisional assessments of relevant literature that appears after the formal scientific review has been completed. Over the years, tens of thousands of peer-reviewed studies of health effects, exposure, and atmospheric interactions, and monitoring have been included in reviews of criteria and standards. A requirement that they must be excluded from consideration unless the raw data and full methodologies are made available for all of them is inconsistent with the legislative mandate and EPA's practice over the last 40 years.

Thus, a science regulation that applies to the NAAQS is unlawful unless EPA can show that the new standard can be established and implemented consistent with the applicable statutory requirements. To do so, EPA must prove that public unavailability of data means that a study does not constitute "latest scientific knowledge useful" in indicating effects on human health or welfare.[84] EPA's Proposal neither acknowledges this requirement nor explains how the Proposal would not violate this statutory command.

[81] 42 U.S.C. § 7408(a).
[82] 42 U.S.C. § 7408(a)(2).
[83] *Id.*
[84] 42 U.S.C. § 7408(a)(2).

For example, in past NAAQS reviews, EPA has considered the Harvard Six Cities study[85] and American Cancer Society studies[86], despite the fact that the data underlying these studies is not publicly available. These studies, however, are plainly "useful in indicating the kind and extent of all identifiable effects on public health or welfare."[87] These seminal studies have been part of the air quality criteria since the mid-1990s—they have thus been accepted as "useful" by separate panels of CASAC, and by EPA, in three separate NAAQS reviews. Their use has been upheld by the D.C. Circuit.[88] Both studies have been reanalyzed and validated by highly competent third-party reviewers (the Health Effects Institute) with access to the underlying data.[89] The study results have been reproduced many times over. [90] Extended follow-up analyses of the ACS and Harvard Six Cities studies provide consistent and stronger evidence of an association with PM 2.5 and mortality at even lower air quality distributions than had previously been observed.[91] This type of cumulative weight of evidence is highly probative in assessing both causality and in establishing the level of the NAAQS.[92] The proposal says almost nothing about any of these other attributes that not only make these studies "useful," but indeed make them particularly high quality and reliable.

The primary ozone NAAQS provides further examples of the pernicious effects the proposal would have. Among the key controlled human exposure studies demonstrating that exposure to ozone causes adverse health effects in even healthy subjects at levels below the level of the then-current NAAQS are Adams (2006) and Schelegle (2009).[93] These studies were sponsored by the American Petroleum Institute, which controls access to the underlying data. The American Petroleum Institute refused an EPA researcher access to the data of a related

[85] Dockery, D.W., Pope, C.A., Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris Jr, B.G. and Speizer, F.E., *An association between air pollution and mortality in six US cities*, 329(24) New England Journal of Medicine 1753-1759 (1993).
[86] Pope, C.A., Thun, M.J., Namboodiri, M.M., Dockery, D.W., Evans, J.S., Speizer, F.E. and Heath, C.W., *Particulate air pollution as a predictor of mortality in a prospective study of US adults*, 151(3) American Journal of Respiratory and Critical Care Medicine 669-674 (1995); Krewski, D., Jerrett, M., Burnett, R.T., Ma, R., Hughes, E., Shi, Y., Turner, M.C., Pope, C.A. III, Thurston, G., Calle, E.E., Thun, M.J., *Extended Follow-up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality*, 140 Health Effects Institute, Boston, MA (2009).
[87] CAA section 108 (a)(2), 42 U.S.C. §7408(a)(2).
[88] *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d at 623.
[89] Krewski, Daniel, et al., *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality*, Health Effects Institute, Cambridge, MA (2000).
[90] *See* EPA, NCEA, *Integrated Science Assessment for Particulate Matter* (EPA/600/R-08/139F), 7-86 (2009).
[91] *See* EPA, *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standard* (EPA 452/R-11-003), 2-31 to 33 (Apr. 2011). *See also* Memorandum by Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science at 4 (May 12, 2018) (noting that "additional studies have confirmed the basic findings" of the Six Cities and American Cancer Society studies and that "the rigorous form of peer review and independent reanalysis" applied "has accomplished a measure of confidence in findings without public access to data and analytic methods.").
[92] *State of Mississippi v. EPA*, 744 F.3d 1334, 1344 (D.C. Cir. 2013) (endorsing EPA's weight of evidence approach, and stating that "incremental (and arguably duplicative) studies are valuable precisely because they confirm or quality previous findings or otherwise decrease uncertainty").
[93] *See* EPA, *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards* (EPA -452/R-14-006, 3-27, 4-10 (Aug. 2014).

Adams study it sponsored (Adams (1998)).[94] So not only would these evidently "useful" (under CAA section 108(a)(1)) studies be barred from consideration under the Proposal, but the Proposal creates a perverse incentive for industry to refuse access to study data. The published studies— peer reviewed—would obviously be providing information "useful" in indicating effects of air pollution, but the Proposal would not only bar their consideration but create an incentive for industry never to provide underlying data for any industry-sponsored study with a result not to industry's liking.

The most recent premiere long-term cohort study for PM is Domenici (2017) which found even greater effects of fine particles at levels below EPA's current standards.[95] This study used a Medicare database available to any research group that can guarantee confidentiality of personal data.[96] Yet the proposal could evidently bar consideration of this powerful study.[97]

NAAQS must be requisite to protect the public health, and to provide an "adequate margin of safety" in doing so.[98] The proposal violates this central statutory requirement. NAAQS are required to provide this margin of safety "to build a buffer to protect against uncertain and unknown dangers to human health."[99] EPA's Proposal would build a buffer against using the very studies necessary to guard against these dangers.[100]

b) EPA's Proposal contravenes the Toxic Substances Control Act (TSCA).

i. TSCA expressly requires that EPA consider reasonably available information and EPA's proposal would preclude EPA from considering some reasonably available information.

When Congress amended TSCA through passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), Congress provided a number of detailed instructions on how EPA should consider scientific information with respect to chemical substances; EPA's proposal contradicts Congress's carefully crafted scheme. In particular, Congress included a provision specifically requiring that EPA consider all "reasonably available

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[94] *See* EPA, *First External Review Draft Integrated Science Assessment for Ozone and Related Photochemical Oxidants* (EPA/600/R-10/076A), 6-7 n. 1 (Feb. 2011).
[95] Qian Di et. al., *Air Pollution and Mortality in the Medicare Population*, 376 New England Journal of Medicine 2513 (2017), https://www.nejm.org/doi/pdf/10.1056/NEJMoa1702747.
[96] *See* CMS, *Limited Data Set (LDS) Files*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html (last accessed Aug. 9, 2018) (noting data requires a signed data use agreement and data cannot be disclosed).
[97] *See* 83 Fed. Reg. 18768, 18773, Proposed section 30.5 final sentence ("where data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section"). There appears to be some interaction required before third party studies are considered to be publicly available.
[98] CAA section 109(b); 42 U.S.C. § 7409(b).
[99] *State of Mississippi*, 744 F.3d at 1353.
[100] *See American Farm Bureau v. EPA*, 559 F.3d 512, 525-26 (D.C. Cir. 2009) (remanding primary Particulate Matter NAAQS because inadequate consideration of certain epidemiologic studies resulted in a standard lacking an adequate margin of safety).

information."[101] When making decisions about testing or the risk evaluation or regulation of new or existing chemicals, "the Administrator shall take into consideration *information* relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, *that is reasonably available to the Administrator*." 15 U.S.C. § 2625(k) (emphases added). But under EPA's proposed rule, EPA would often be precluded from considering such reasonably available information if all the underlying data and models were not publicly available. *See* 83 Fed. Reg. at 18,769 n.3 (stating that proposal "would preclude [EPA] from using [non-public] data in future regulatory actions"). EPA's proposal violates the plain language of TSCA § 26(k), as well as Congress's clear purpose of ensuring that EPA consider all reasonably available information relating to a chemical when making a decision about the chemical.

Under its plain language, "available" means "able to be used or obtained; at someone's disposal."[102] Congress chose this standard to ensure that EPA would make decisions based on all reasonably available information. S. Rep. No. 114-67 at 9 (June 18, 2015) ("The section … requires EPA to consider reasonably available information about potential hazards and exposures of a chemical substance under the conditions of use when making decisions under TSCA…. The Committee intends that EPA systematically search for and identify relevant information that is available to inform safety assessments and determinations."); Oversight of the Environmental Protection Agency's Progress in Implementing Inspector General and Government Accountability Office Recommendations: Hearing before the Subcomm. on Superfund, Waste Management, and Regulatory Oversight of the S. Comm. on Environment and Public Works, 114th Cong. at 63 (June 14, 2016) ("[F]or the EPA to properly evaluate and regulate toxic substances, it is essential that they have the most up-to-date chemical and toxicity data available."). Congress also selected this standard to avoid paralysis by analysis—Congress wanted EPA to act on available information and not to postpone action waiting for new or perfect information to become available. *See, e.g.*, 162 Cong. Rec. S3511, S3517 (daily ed. June 7, 2016) (referring to "information reasonably available to EPA" as "ensur[ing] that such considerations do not require additional information to be collected or developed"). "Congress recognized the need to use available studies, reports and recommendations for purposes of chemical assessments rather than creating them from whole cloth." *Id.* at S3522. And Congress intended for EPA to consider studies even when they had not undergone all possible forms of vetting. "[I]n instances where there were other studies and reports unavailable at the time of the [National Academy of Sciences] recommendations, EPA should take advantage of those studies and reports in order to ensure that the science used for chemical assessments is the best available and most current science." *Id.* at S3522. Congress intended for EPA to consider all reasonably available information, and EPA's proposal would thwart that clear purpose.

Notably, this Administration has adopted two regulations under the amended TSCA defining reasonably available information. These regulations generally provide that:

> Reasonably available information means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA [for action]. Information that meets the terms of the

[101] Pub. L. No. 114-182, § 17(k), 130 Stat. 448, 502 (June 22, 2016) (codified at 15 U.S.C. § 2625(k)).
[102] *Oxford American Dictionary* 111 (3d ed. 2010).

> preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14.

40 C.F.R. § 702.33; *see also* 40 C.F.R. § 702.3 (similar definition for prioritization decisions). This bears no resemblance to the limitations put forward in the Proposal. Indeed, EPA has defined "reasonably available information" to include information EPA withholds as Confidential Business Information (CBI) under TSCA § 14. 15 U.S.C. § 2613. If the proposed rule forecloses EPA from considering information that cannot be fully disclosed, as it appears to do, then EPA cannot comply with both these regulations and the proposed rule.

EPA's proposal also violates other provisions of TSCA that expressly require EPA to act on "available information." For example, in preparing risk evaluations for existing chemicals, EPA "shall integrate and assess *available information* on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator."[103] Under the proposed rule, EPA would not be able to integrate and assess available information where all underlying data has not been disclosed. Similarly, when developing regulations for existing chemicals, EPA "shall consider and publish a statement based on *reasonably available information* with respect to" a number of factors, including the effects of the chemical on health and the environment.[104] But under the proposed rule, EPA cannot consider all reasonably available information when assessing those health and environmental effects.

Indeed, TSCA § 4(f) imposes a duty upon EPA to initiate regulation in response to any available information that meets certain substantive standards. However, if all the underlying information were not available, EPA's proposed rule would then foreclose EPA from considering that information during the resulting rulemaking. Congress would not have created a scheme where EPA *must* act in response to certain information but then cannot consider that information in taking action. Specifically, under TSCA § 4(f):

> Upon the receipt of—(1) *any information* required to be submitted under this Act, or (2) *any other information available* to the Administrator—which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings, the Administrator shall, … initiate applicable action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding, made without consideration of costs or other nonrisk factors, that such risk is not unreasonable.[105]

Thus if "any … information available" to EPA provides a reasonable basis to conclude that a chemical "presents a significant risk of serious or widespread harm to human beings," then EPA must initiate action to regulate the chemical. But under EPA's proposed rule, EPA would then be

[103] 15 U.S.C. § 2605(b)(4)(F)(i) (emphasis added).
[104] *Id.* § 2605(c)(2)(A) (emphasis added).
[105] 15 U.S.C. § 2603(f) (emphases added).

required to ignore the information triggering this duty when crafting the final regulation unless the source of the information fully disclosed all underlying data. That result clearly contradicts Congress's intent, which was to create a duty for EPA to react to any available information meeting the substantive standard of TSCA § 4(f).

In sum, Congress repeatedly directed EPA to consider all reasonably available information when making decisions under TSCA. The proposed rule would illegally preclude EPA from considering available information. The two cannot be reconciled, and the rule is unlawful.

ii. TSCA requires an agency to act on the "best available science," meaning that EPA must consider all available science and assess the quality of the science based on a variety of factors.

EPA's proposed blanket prohibition against basing a rulemaking on science for which underlying data or models are not publicly available would be particularly hard to reconcile with the "best available science" standard as articulated in TSCA, which clearly contemplates a case-by-case analysis in which EPA weighs a variety of factors when identifying the best available science. The relevant provision of TSCA requires that:

> (h) Scientific standards. In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the *best available science*, and shall consider *as applicable*—
> (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
> (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
> (3) *the degree of clarity and completeness* with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information *are documented*;
> (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
> (5) *the extent of independent verification or peer review* of the information or of the procedures, measures, methods, protocols, methodologies, or models.[106]

Thus, Congress provided EPA with factors to guide its consideration of the "best available science," and Congress did not make the public disclosure of all underlying data a requirement for material to be the "best available science." Quite the opposite; Congress included aspects of disclosure and independent review as parts of factors to be considered when weighing scientific information. But these are just aspects of five different factors to be weighed "as applicable," and

[106] 15 U.S.C. § 2625(h) (emphases added).

Congress clearly contemplated that EPA would sometimes rely on science that does not meet the proposed rule's requirement of full disclosure of all underlying data.

First, Congress directed EPA to consider these factors when weighing particular information; Congress specifically did not develop (or direct EPA to develop) bright-line criteria for eliminating information from consideration entirely. Thus, each factor includes the phrase "degree of" or "extent to which," without identifying any threshold that would be disqualifying.[107] This shows that Congress intended these factors to help EPA assess the weight information should be given based on its relative scientific reliability, not to create minimum thresholds of reliability below which information must be ignored by EPA altogether. For EPA to insert a screen on top of these factors—excluding information where the underlying data and models are not publicly available as required by the proposed rule—contradicts Congress's unambiguous intent about how EPA should approach its assessment of the best available science.

Second, Congress made the "degree of clarity and completeness" with which the underlying data is documented to be part of one factor for EPA to consider in evaluating whether a particular study is the "best available science."[108] But EPA must also consider "the degree of clarity and completeness" with which "assumptions, methods, quality assurance, and analyses" are documented as well.[109] Thus, Congress contemplated that EPA would still rely on some studies that did *not* document completely all the underlying data, much less disclose all of that information.

Third, Congress made "the extent of independent verification *or* peer review of the information *or* of the procedures, measures, methods, protocols, methodologies, or models" another factor to be weighed when considering whether information is the "best available."[110] Notably, Congress's choice of the disjunctive "or" reflects that "peer review" can be an adequate alternative to "independent verification," and Congress did not require that either "independent verification *or* peer review" be accomplished through public availability of data as required in the proposed rule. Moreover, Congress contemplated scenarios where EPA would give more weight to evidence even if the "information" had not undergone "independent verification or peer review" based on the extent to which the "procedures, measures, methods, protocols, methodologies, or models" had done so.

Fourth and most importantly, EPA cannot rationally elevate the interest in public disclosure of all underlying data above all the other factors that Congress expressly required EPA to consider in evaluating science. Congress required EPA to consider these five factors "as applicable" when weighing information, and Congress did not make full public availability of underlying data one of the factors, much less a decisive or absolute one.

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[107] *See, e.g.* 15 U.S.C. § 2625(h)(1) ("*the extent to which* the scientific information…[are] consistent with the intended use of the information") (emphasis added).
[108] 15 U.S.C. § 2625(h)(3).
[109] *Id*.
[110] 15 U.S.C. § 2625(h)(5).

This administration recently adopted a regulatory definition of "best available science" for purposes of TSCA which expressly incorporated consideration of these five factors and was otherwise inspired by use of the term in the Safe Drinking Water Act (SDWA).[111] EPA defined the phrase:

> Best available science means science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable:
>
> [TSCA § 26(h)(1)(5) factors][112]

According to EPA in selecting this definition, "the Agency is remaining consistent with the current approach already used Agency-wide, while also acknowledging the specific standards under TSCA."[113] Notably, this definition does not require public disclosure of all underlying data for science to be the "best available science," yet many studies that meet this definition of "best available science" would be excluded under EPA's proposed rule.

EPA's Proposal cannot be reconciled with EPA's existing definition of best available science, with decades of court and agency precedent, or with text of the statute. When a statute requires the agency to make a decision based on the "best available science," it would be unlawful to follow EPA's proposed rule.

iii. EPA's proposed rule also contradicts TSCA's requirement that decisions be made based on the weight of the scientific evidence.

TSCA § 26(*i*) requires EPA to make decisions regarding testing and regulating new and existing chemicals "based on the weight of the scientific evidence."[114] If EPA excludes certain information, as proposed, then EPA will not be able to weigh the evidence as a whole.

Indeed, this administration recently adopted a regulation defining "weight of scientific evidence" to mean "a systematic review method … that uses a pre-established protocol to *comprehensively*, objectively, transparently, and consistently, identify and evaluate *each stream of evidence*, including strengths, limitations, and relevance of *each* study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."[115] Systematic reviews consider the entire body of scientific evidence, but EPA's proposed rule would prevent EPA from conducting true systematic review because it would prohibit the Agency from considering studies where the data were not publicly available and it would

[111] *See* 82 Fed. Reg. 33,726, 33,731 (July 20, 2017), 42 U.S.C. § 300g-1(b)(3)(A).
[112] 40 C.F.R. § 702.33.
[113] 82 Fed. Reg. at 33,731.
[114] 15 U.S.C. § 2625(*i*).
[115] 40 C.F.R. § 702.33 (emphases added).

eliminate studies based on criteria other than their "strengths, limitations, and relevance."[116] If the proposed rule forecloses EPA from considering information that cannot be fully disclosed, as it appears to do, then EPA cannot comply with this regulation and the proposed rule.

In sum, EPA's proposed rule is inconsistent with TSCA's plain text. EPA should not adopt the proposed rule because it cannot be reconciled with the agency's duties under TSCA.

iv. Section 10 of TSCA does not authorize this proposal.

Nothing in Toxic Substances Control Act (TSCA) § 10 authorizes EPA to exclude scientific information during rulemakings on any basis. Section 10 authorizes EPA to research and develop information for purposes of carrying out TSCA.[117] Section 10 also authorizes EPA to develop systems to collect and disseminate information about chemical substances.[118] But TSCA § 10 is silent regarding rulemaking or EPA's use of scientific information in rulemaking. It does not authorize EPA to exclude scientific information on *any* basis; if anything, TSCA § 10 reflects a congressional judgment that EPA should be prepared to use any and all "toxicological and other scientific information which could be useful to the Administrator in carrying out the purposes of this [Act]."[119]

c) EPA's Proposal contravenes the Safe Drinking Water Act.

The Safe Drinking Water Act requires EPA to issue national drinking water regulations setting required purity levels for water from public water supply systems.[120] Before regulating, the Administrator must conclude that the contaminant at issue "may have" an adverse effect on the health of persons.[121] In regulating, the Administrator must consider "the best available public health information"[122] The section adds that in setting regulations, the Administrator "shall use ...the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" and in addition "data collected by accepted methods or best available methods."[123] When Congress promulgated these statutory requirements in 1996, the Senate Committee on Environment and Public Works[124] explained that the "Administrator has a *duty* to seek and rely upon the best available science and information to support…. [m]any

[116] *Id*.
[117] *See* 15 U.S.C. § 2609(a) ("The Administrator shall … conduct such research, development, and monitoring as is necessary to carry out the purposes of this [Act]."); *see also* 15 U.S.C. § 2609(c), (d), (e).
[118] *See* 15 U.S.C. § 2609(b), (c), (g).
[119] 15 U.S.C. § 2609(b)(2)(A).
[120] 42 U.S.C. § 300g-1.
[121] *Id*. at (b)(1)(A)(i).
[122] *Id.* at (b)(1)(B)(ii)(II).
[123] 42 U.S.C. § 300g-1(b)(3)(A). *See City of Waukesha v. EPA*, 320 F.3d at 247-48 (D.C. Cir. 2003) (holding that agency peer review satisfies requirement to use best, peer-reviewed science and supporting studies); *City of Portland v. EPA*, 507 F 3d 706, 716 (D.C. Cir. 2002) (same).
[124] The Report of the Senate Committee on Environment and Public Works is authoritative on these provisions, as the language adopted in the Committee bill (S.1316) on the use of science was adopted verbatim in Pub. L. 104-182. *See* S. Rep. 104-169 at p. 121 and Pub. L. 104-182 at §103.

of the most important activities including selecting contaminants for regulation, setting standards, designing analytical methods and structuring waivers, variances and exemptions."[125]

By restricting EPA to considering only those scientific studies for which underlying data, models, and other information is publicly available, EPA's proposal prevents EPA from complying with the SDWA directive that it consider the "best available" public health information and science when setting SDWA standards. Specifically, as explained above, the public will not necessarily have access to the underlying information used to produce the "best available, peer-reviewed science and supporting studies."[126] Nowhere does the SDWA authorize EPA to ignore such studies based on the public unavailability of underlying information. Thus, regardless of the merits of the core objective of EPA's proposal—"to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation" (proposed § 30.1 "What is the purpose of this subpart?"), EPA's attempt to elevate this objective above the agency's statutory obligation to consider the "best available" science when promulgating SDWA standards is unlawful.[127]

4. EPA's proposed exemption provision does not remedy the unlawfulness of prohibiting EPA from considering valid and relevant studies due to the public unavailability of underlying data and methods.

Though the proposed exemption provision in section 30.9 would grant the EPA Administrator discretion to authorize the agency to consider studies for which underlying data or models are not publicly available, this provision is insufficient to remedy the proposed rule's unlawfulness and detrimental impacts. It is well established that existence of a waiver or exemption mechanism cannot be used to justify a provision otherwise beyond an agency's legal authority. *Dimension Financial Corp. v. Board of Governors of Federal Reserve System,* 744 F.2d 1402, 1410 (10th Cir. 1984) ("The possible exception to the initial impact of Regulation Y (Part 225.21(B)(4)) contains requirements with no objective standard and thus unbounded agency discretion. This as a device to meet objections to the new regulation cannot cure the exercise of powers denied by Congress or not provided for by Congress. *Public Utilities Comm. of Calif. v. United States,* 355 U.S. 534 (1958); *In re Surface Mining Regulation Litigation,* 627 F.2d 1346 (D.C. Cir. 1980); *ALLTEL Corp. v. FCC,* 838 F.2d 551, 561 (D.C. Cir. 1988) ("The FCC cannot save an irrational rule by tacking on a waiver procedure. 'The very essence of waiver is the assumed validity of the general rule . . . .')(citing *WAIT Radio v. FCC*, 418 F.2d 1153, 1158 (D.C. Cir. 1969)); *United States Telecom Ass'n v. FCC,* 359 F.3d 554, 571 (D.C. Cir. 2004) ("Moreover, even if the FCC had adopted some lawful mechanism for making exemptions from its general national rule, it could not necessarily rely on the existence of that mechanism as the sole justification for not adopting a more narrowly tailored rule. . . . [T]he mere existence of a safety valve does not cure an irrational rule.")

[125] S. Rep. 104-169 at 28 (emphasis added).
[126] 42 U.S.C. § 300g-1(b)(3)(A).
[127] 83 Fed. Reg. at 18773.

First, while the statutory provisions described above *require* EPA to consider best available science and other relevant information when making regulatory decisions, *see, e.g.*, Safe Drinking Water Act, 42 U.S.C Section 300g-1(b)(3)(A)(i) ("The Administrator *shall* use the best available, peer reviewed science."), the Administrator has discretion over whether to grant an exception. *See* Proposed § 30.9 ("The Administrator *may* grant an exemption to this subpart on a case-by-case basis…")(emphasis added).[128] Where a statute requires that the agency consider certain information in reaching a decision, EPA cannot promulgate a rule that gives the Administrator discretion over whether to allow such consideration.

Second, the only basis on which the Administrator may grant an exemption under Proposed § 30.9 is that it "is not feasible" to "ensure that all dose response data and models underlying pivotal regulatory science is publicly available" as the rule requires.[129] However, the Proposal does not explain how "feasibility" is to be determined in this context—or even whether the term encompasses practical feasibility, cost-effectiveness, or other considerations. Moreover, there can easily be situations where it is theoretically "feasible" to make underlying data publicly available, but this information is nonetheless not publicly available. For example, a scientist who intends to rely on the same data to publish multiple papers may be disinclined to make that data available to competitors.[130] Yet, because it is technically "feasible" to make the underlying data publicly available, the proposed rule would not even provide the Administrator with authority to grant an exemption authorizing such consideration, thus forcing the Administrator to violate the law.

Third, even if it were lawful for EPA to ignore relevant science, the exemption provision is arbitrary, as it does not define sufficient criteria or process steps by which the Administrator may decide to exempt a study. The provision instructs the Administrator to rely on a handful of broad (and highly manipulable) policy considerations in determining whether it would be infeasible to make data and methods publicly available.[131] These factors could be applied broadly to give the Administrator nearly absolute discretion. From the face of the Proposal, it is not even clear that the Administrator would be required to provide a public, written explanation of his decision to grant (or deny) a waiver. This lack of accountability could lead to the arbitrary exclusion of studies the Administrator unilaterally chooses to not exempt.

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[128] 83 Fed. Reg. at 18774.

[129] 83 Fed. Reg. at 18774.

[130] Or in cases where companies jointly funded research it may be unclear who owns the data and has the right to share it, and companies may be reluctant to share it with competitors. *See, e.g.*, National Academies of Sciences, Engineering, and Medicine, *Principles and obstacles for sharing data from environmental health research: Workshop summary*, 45 The National Academies Press (2016), https://www.nap.edu/catalog/21703/principles-and-obstacles-for-sharing-data-from-environmental-health-research. ("As you can imagine. . . not all competitors play nicely together. Some even resort to gamesmanship to try to exclude competitors from the market. Things can get nasty and messy in a hurry in these discussions.").

[131] *See* 83 Fed. Reg. at 18774. Under §30.9(a), the Administrator should consider whether it is infeasible "in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." §30.9(b) references 70 Fed. Reg. 2664, which exempts peer review in situations of "disseminations of sensitive information related to certain national security, foreign affairs, or negotiations involving international treaties and trade where compliance with this Bulletin would interfere with the need for secrecy or promptness."

Finally, the exemption provision is impractical and likely could not be implemented effectively. According to the Congressional Budget Office, EPA "relies on about 50,000 scientific studies annually to perform its mission," and at times, relies on thousands of studies for one action.[132] Many of the studies that would be affected by this rule are complex and include large datasets that would lead to an extensive decision-making process under the exemption provision. EPA does not include any rationale in the proposal justifying how the Administrator could reasonably decide to exempt studies on a case-by-case basis given the tens of thousands of studies EPA considers each year. This provision could create a large backlog, which would result in important studies being effectively removed from EPA consideration because of the need to finalize a regulation before an exemption for every relevant study is granted. Accordingly, the exemption provision fails to safeguard against the unlawful exclusion of valid science from EPA's regulatory process.

C. EPA's Proposed Rule Would Violate the Information Quality Act.

EPA's proposed rule is also unlawful because it exceeds EPA's authority under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 16-554; H.R. 5658), commonly referred to as the Information Quality Act.[133] Specifically, the Information Quality Act requires EPA promulgate data quality guidelines that are consistent with those promulgated by the Office of Management and Budget. Contrary to EPA's assertion in the preamble to the proposal, the Proposed Rule is not consistent with OMB's data quality regulations.

The OMB Guidelines recognize that data availability is not necessary to high quality science, but is one among many factors. While imposing high standards of quality, objectivity, utility, and integrity of information disseminated by Federal Agencies, the Guidelines recognize the need to implement controls "flexibly, and in a manner appropriate to the nature . . . of the information to be disseminated."[134] As part of ensuring "objectivity" these guidelines encourage agencies that disseminate influential scientific, financial, or statistical information, "to include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."[135] However, they emphasize the need to treat certain data differently, due to privacy and confidentiality concerns.[136] In fact, the OMB Regulations specifically declare that "[w]ith regard to original and supporting data related thereto, *agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement*."[137] Rather, the OMB Guidelines instruct that agencies "identify, in consultation with the relevant scientific and technical communities, those particular types of data that can

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[132] Congressional Budget Office, *Cost Estimate: H.R. 1430* 2-3 (March 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.
[133] Codified at 44 U.S.C. 3504(d)(1) and 3516.
[134] OMB's *Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information*, 67 Fed. Reg. 8,452, 8,453 (Feb. 22, 2002).
[135] 67 Fed. Reg. at 8460.
[136] *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information*, 67 Fed. Reg. 8, 452, 8,460 (Feb. 22, 2002) (interest in making data publicly available "does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections").
[137] 67 Fed. Reg. at 8460 (emphasis added).

practicable [sic] be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints."[138] The OMB Regulations further explain that while "[m]aking the data and methods publicly available will assist in determining whether analytic results are reproducible…*the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.*[139] OMB explains that "where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken."[140]

By outright prohibiting EPA from relying on a study to support a significant rulemaking if that study's underlying data and models are not publicly available, EPA's proposed rule departs from OMB's unambiguous language instructing agencies that they "shall not" require that all data and models be subject to the reproducibility requirement, and that "the objectivity standard does not override other compelling interests."[141] The fact that EPA's proposed rule includes a discretionary "exemption" provision does not correct this problem, as that provision would not require the Administrator even to consider whether an exemption is warranted, let alone grant such an exemption under appropriate circumstances.

Because Congress expressly granted OMB the authority to set guidelines for data quality and instructed agencies like EPA to follow OMB's lead, EPA lacks statutory authority to adopt a regulation that is contrary to OMB's guidelines. Accordingly, EPA's proposed regulation violates the Information Quality Act and must be withdrawn.[142]

II. EPA's Proposed Rule is Unreasonable and Arbitrary and Capricious.

In addition to violating the requirements of the various statutes that EPA administers or is subject to, the Proposal suffers from a total failure to consider important dimensions of the profound shift in policy that it implements. In the Proposal, EPA neglects to consider the many legitimate reasons why a study's underlying data may not be publicly available—reasons that have nothing to do with the quality of the study—and fails to offer solutions consistent with these legitimate limitations. EPA makes vague gestures to various guidelines and practices issued by other agencies and scientific organizations, none of which actually support the Proposal's radical position that EPA should exclude consideration of studies that rely upon confidential data. EPA does not even establish that there is a real problem that the Proposal would actually address: nowhere in the Proposal does EPA identify any prior agency action that has been called into serious question due to a failure to release study data. EPA's utter failure "to consider an important aspect of the problem" and to provide an explanation for the Proposal

[138] 67 Fed. Reg. at 8460. There is no indication that EPA consulted with the scientific and technical community—or even its own Science Advisory Board—before proposing to require that the underlying data and models be made publicly available for all pivotal regulatory science regardless of ethical, feasibility, or confidentiality constraints.
[139] 67 Fed. Reg. at 8460 (emphasis added).
[140] 67 Fed. Reg. at 8460.
[141] *See* 67 Fed. Reg. at 8460.
[142] *Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010) ("[B]ecause Congress delegated to OMB authority to develop binding guidelines implementing the IQA, we defer to OMB's reasonable construction of the statute.")

that is consistent with the evidence before the agency renders the Proposal wholly arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Likewise, EPA's failure to explain its 180-degree change in position from its former belief that the lack of publicly-available data does not render a study inappropriate for consideration in regulating is a hallmark of arbitrary and capricious decision-making. *FCC v. Fox Telev. Stations, Inc.*, 556 U.S. 502, 515-16 (2009).

A. EPA Failed to Consider the Legitimate Reasons That Underlying Data May Not be Made Publicly Available, or to Propose Solutions to Remedy These Actual Limitations.

1. There are multiple reasons why underlying data are not publicly available for all studies.

There are legal and ethical requirements that restrict making public the data underlying studies, including rules to shield private personal information, requirements to maintain confidential business information, situations where obtaining the necessary permissions to release data are logistically difficult or impossible, and situations in which researchers have made significant investments in developing datasets that they intend to continue to work with for future studies. Not all of these barriers can be overcome, nor can they be overcome in every case. While there are ways potentially to address some of them, they can be extremely costly and burdensome, and/or may harm the prospects for further research. Accordingly, while the scientific community has made efforts to make more data publicly available, to the best of our knowledge all of the policies adopted by government and academic journals recognize that data is not, and need not be, publicly available to evaluate their quality.

a) Strong legal and ethical requirements limit the release of data in human subjects studies.

Particularly with respect to human subjects, there are strong legal and ethical privacy and confidentiality protections, which researchers are bound to respect.[143] In some cases, researchers would be subject to civil or criminal penalties for violations.[144]

The environmental health dose response studies targeted by EPA's proposal are likely to include human population studies (or epidemiological studies). Often the best available epidemiological studies contain extensive and sensitive data on individuals, such as environmental exposures, medical history (such as infant reproductive developmental abnormalities, children's behavioral and development problems, heart attacks or dementia among the elderly), dates of birth, residential address, drug use, race, socio-economic status (income,

[143] *See, e.g.*, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report* (Apr. 18, 1979), https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf; *Federal Policy for the Protection of Human Subjects; Final Rule*, 82 Fed. Reg. 7,149 (Jan. 19, 2017); HIPAA Privacy Rule, 45 C.F.R. §§ 160, 164.102-06, 164.500-534.

[144] *See*, The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191 (enacted Aug. 21, 1996) (providing for criminal and civil penalties for violations).

education), status of subjects' marriages, employment history, etc. For example, air pollution studies commonly use residential address information to assign air pollution exposures and link them to health effects.[145] Other studies focused on genetically susceptible populations may also be linked to genetic databases or contain information on key genetic mutations that are strongly predictive of serious health risks, such as risk of Alzheimer's disease, and are thus very sensitive.[146]

To conduct these studies, investigators must obtain informed consent from the study participants to collect protected health information, and investigators must sign documents promising to protect the privacy of this individually identifiable health information. Absent complex, difficult and costly de-identification and redaction techniques, these data simply cannot be released publicly. As discussed below in section II.A.2.b), in some cases such techniques are simply not applicable or still leave significant risk of breach of privacy.

Additional protections apply to specific types of human subject information. For example, medical records are subject to strict requirements governing the use and disclosure of such information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[147] HIPAA requires researchers to protect identifiable information, and it provides that such information may only be disclosed for research purposes with the written consent of the person providing the information.[148]

Another limitation on public availability of data is the requirement under the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) that for all federally funded studies involving human research subjects, researchers must first obtain Institutional Review Board (IRB) approval and informed consent from study participants.[149]

An IRB reviews each human subjects research project to ensure that the specific research protocol protects individual rights. Participants must be notified about the degree to which the confidentiality of their records will be maintained, and must receive appropriate notification and

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[145] *See, e.g.*, Kaufman, Joel D., et al., *Association between air pollution and coronary artery calcification within six metropolitan areas in the USA (the Multi-Ethnic Study of Atherosclerosis and Air Pollution): a longitudinal cohort study*, 388.10045 The Lancet 696-704 (2016).

[146] *See, e.g.*, Richardson JR, Roy A, Shalat SL, von Stein RT, Hossain MM, Buckley B, Gearing M, Levey AI, German DC, *Elevated serum pesticide levels and risk for Alzheimer disease*, 71(3) JAMA Neurology 284-90 (Mar. 1, 2014).

[147] Public Law 104 – 191.

[148] National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, The National Academies Press (2005).

[149] 45 C.F.R. §§ 46.101-124 is the U.S. Department of Health and Human Services ("HHS") citation for the Common Rule. A total of 18 federal agencies have adopted it; each agency has its own separate entry in the Code of Federal Regulations. This federal rule governs ethical constraints that federally funded studies must follow, including academic research, responding to earlier concerns of ethical lapses in medical research. *See, e.g.*, Jerry Menikoff, *Could Tuskegee happen Today?*, 1 St. Louis U. J. Health L. & Pol'y 311, 312-16 (2008) (describing the Congressional response to public outcry when the details of the Tuskegee experiment were brought to light). The thrust of the Common Rule is to address such matters of research ethics as informed consent, informational risk, and institutional oversight when research involves human subjects.

give consent if study data is to be shared outside the research team.[150] The IRB also considers risks to the participants and how use of the information obtained may adversely impact the rights and welfare of the subjects.[151] Most institutions have committed to comply with the Common Rule for all of their research, even when it is not federally-funded.[152]

For studies that had received IRB approval prior to finalization of this proposed rule, there may be no practical opportunity to make the data publicly available. Even for new studies going forward, it may be extremely difficult, require additional (often unavailable) funding for elaborate protective measures, or simply impossible to obtain IRB approval for protocols that would allow the data to be made publicly available.

EPA's own Science Advisory Board voiced these concerns that EPA was discounting the challenges to making even limited releases of data, saying:

> The proposed rule oversimplifies the argument that "concerns about access to confidential or private information can, in many case, be addressed through the application of solutions commonly in use across some parts of the Federal government." For studies already completed or underway, the participation of human subjects is undertaken according to terms approved by the cognizant IRB. These terms can vary from study to study. In some cases, the data cannot be released simply by redacting portions of it. For example, data may have been collected with an assurance to the participating individuals that their data would be kept confidential.[153]

Some researchers might respond by choosing to work only on public administrative datasets, but this would harm rather than strengthen science quality by curtailing scientific inquiry. Thus, the effects of EPA's proposed approach would cause some researchers to choose not to pursue research with human subjects, stifling scientific discovery, while others would forgo compliance with EPA's regulatory requirements and have their research ignored by EPA. As a result, EPA's proposal would both discourage the development of best available science as well as EPA's use of it.

> b) There are especially significant barriers to public release of underlying data and models from studies that have already been completed.

With respect to studies that have already been completed, there are additional formidable barriers to public release of underlying data and models. Particularly, with older studies, simply finding the data sets and determining ownership may be expensive or impossible. For older studies with human subjects, obtaining consent to release of data may be practically impossible,

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[150] *See*, 82 Fed. Reg. 7,149-7,274.
[151] *Id.*
[152] HHS, *Federalwide Assurance (FWA) for the Protection of Human Subjects*, https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html (last accessed Aug. 13, 2018).
[153] Memorandum by Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science (May 12, 2018).

and the data may have been collected in ways that would make protecting privacy with release difficult or impossible.[154]

For some studies, administrative issues related to the data could be the most difficult barrier to overcome in providing for public release. Larger and more costly studies are often performed by groups of researchers within a university, across multiple institutions, or across multiple individual companies. Over time, the data itself may become lost or misplaced, or it may become unclear who actually owns and controls access to the data. Academics move among institutions, companies merge and spin off, and the initial agreements were not always clear in the first instance. Obtaining consent from multiple institutional players takes extensive time and resources, at minimum, and simply may no longer be possible in some instances.[155]

These problems are exacerbated with respect to human subject studies. Researchers are legally and ethically obliged either to protect the privacy of the individual study subjects or attain each subject's consent to share data.[156] This can be impractical for older studies and virtually impossible for larger studies, and extremely burdensome. For example, the Harvard Six cities study was started in 1975 and had 8,111 participants.[157] The ACS CPSII extended analysis by Krewski in 2009, which is central to $PM_{2.5}$ NAAQS standards, was initiated in 1979 and encompassed data from 500,000 study participants who lived in 116 metropolitan areas.[158] For these types of situations, tracking down participants (or where the participants have passed away, their family members) to get consent is simply not realistically possible.

Even in situations where investigators might theoretically be able to attain consent, it would require extensive financial and human resources, which are usually simply not available, especially to academic researchers or to EPA. EPA ignores this prohibitive constraint and makes no attempt to address it.

c) There are additional significant barriers to public release of data in some situations, even for prospective studies.

Even with respect to prospective application of EPA's proposal, providing for public release of underlying data and models is costly and resource intensive, creating a serious disincentive for researchers to meet EPA's proposed requirements. Investigators willing to make their study underlying data publicly available would still face the logistical hurdle of making the data and models available in a manner sufficient for independent validation by the public. In

[154] *See, e.g.*, National Academies of Sciences, Engineering, and Medicine, *Principles and obstacles for sharing data from environmental health research: Workshop summary*, 61-63 The National Academies Press (2016), https://www.nap.edu/catalog/21703/principles-and-obstacles-for-sharing-data-from-environmental-health-research.
[155] *Id.* at 45.
[156] *Federal Policy for the Protection of Human Subjects; Final Rule*, 82 Fed. Reg. 7,149 (Jan. 19, 2017); HIPAA Privacy Rule, 45 C.F.R. §§ 160, 164.102-106, 164.500-534.
[157] Dockery, D.W., Pope, C.A., Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris Jr, B.G. and Speizer, F.E., *An association between air pollution and mortality in six US cities*, 329(24) New England Journal of Medicine, 1753-1759 (1993).
[158] Krewski D, Jerrett M, Burnett RT, et al., *Extended Follow-Up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality*, 140 Health Effects Institute, Boston MA (2009).

addition to the cost of thoughtful and effective deidentification or redaction of sensitive information, the proposed text would likely require researchers to prepare annotated manuals including precise detail as to what variables were collected, how information was collected, and the rationale for each step taken. Some manuals alone run into hundreds of pages. One press account noted the example of publicly available datasets from the National Center for Health Statistics, which can come with 100-page manuals; researchers would need to hire additional staff to meet such requirements.[159] Yet EPA fails even to recognize (much less propose any means to address) the cost to researchers in time and money, on top of the constraints on academic research already imposed by the very limited funding available for this type of work.

In addition, there are other barriers to public release of underlying data. Studies conducted on behalf of industry or with industry cooperation may contain confidential business information, the release of which could jeopardize a company's competitiveness.

Also, in some instances, researchers cannot make their data sets public without losing much of the value to the researcher of these laboriously and meticulously collected sets of information. Research, especially those studies that include large numbers of human subjects, are incredibly human and capital intensive endeavors. Moreover researchers may base years of work and multiple papers on unique datasets they developed and hold, and many scientists build their careers on carefully harvesting information from single large studies for years to come. It is not only unreasonable, but also unfair, to expect academic scientists to turn over their intellectual property and research investments, forgoing potential earnings and career advancements. Moreover, EPA's myopic and inflexible approach to data access gives no consideration to data sharing arrangements between researchers and the agency that could be developed to support EPA's consideration and integration of research.

If scientists are forced to choose between giving away their hard-earned data or forgoing any regulatory impact, it will discourage scientists from engaging in critical science that is targeted to help prevent disease and disability in our population. It appears that in many cases, scientists will choose to retain their datasets, with a worst-of-both-worlds result—EPA will be deprived of valid scientific information and the scientific community will be discouraged from contributing their critical expertise to policy-making. EPA's Proposal does not consider the real-world implications of forcing such choices on researchers.

The agency's failure to consider or examine any of these legitimate reasons for not making data publicly available is arbitrary and capricious.

2. The Proposal fails to propose any actual solutions to remedy the legitimate reasons for why data may not be made publicly available.

In the proposal EPA blithely and irrationally ignores or assumes away the real and significant issues raised above, suggesting that existing mechanisms and techniques can be used

[159] Alessandra Potenza and Rachel Becker, *Scott Pruitt's new 'secret science' proposal is the wrong way to increase transparency. Here's what scientists think a science transparency rule should include*, The Verge (May 1, 2018, 8:30am EDT), https://www.theverge.com/2018/5/1/17304298/epa-science-transparency-rule-scott-pruitt-data-sharing.

to protect privacy and confidentiality while making underlying research data publicly available. In fact, the evidence (including several of the sources that EPA cites) indicates that the potential mechanisms alluded to by EPA would only have the potential to address some of the barriers cited above, have serious limitations even for those, and are actually becoming less effective as it becomes easier to combine and manipulate public data sets.

a) EPA vaguely references a range of possible approaches to protecting privacy and confidentiality, but provides no evidence that any of these are sufficient to address the legitimate concerns raised above.

EPA vaguely claims "concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government."[160] EPA claims that there are examples from the Department of Health and Human Services, the National Institute of Standards and Technology, the Department of Education, and the Census Bureau. Unfortunately, apart from a reference to HHS guidance on data de-identification (discussed below), EPA does not actually identify or cite to any specific examples from these agencies in the proposed rule itself, making it impossible to discern what examples EPA believes exist or to meaningfully comment upon the degree to which such examples, if they exist, might suggest that these issues are manageable. The additional hyperlinks added to the docket on May 25, 2018, weeks into the comment period, also link to examples that provide no further assurance that this proposal can be implemented without implicating privacy concerns, and as discussed in detail below, the vaguely referenced other agencies' "solutions" are unlikely to be of much help.

The "solutions" EPA might have in mind do not address the issues raised by the Proposal because no other agency has tried to implement a requirement such as the one EPA proposes. Other agencies provide guidance and techniques to protect privacy during data collection and disclosure to allow more use of data collected by the *government*, not to mandate that data collected by academic or industry researchers be publicly available for purposes of replicating analyses. The Department of Education, for example, has shared techniques for institutions to provide data on students and schools to meet reporting requirements without compromising privacy.[161] They recognize that each technique "requires some loss of information."[162] While de-identified information may still be useful, e.g., to show overall school progress, in the context of the Education Department, it is not clear these techniques are transferable to other contexts.

EPA links to a document of the Privacy Technical Assistance Center, *Data De-identification: An Overview of Basic Terms*, which provides a high-level overview of key terms and practices to help educational agencies and institutions comply with the Family Educational Rights and Privacy Act (FERPA).[163] This document is concerned with data disclosure that occurs

[160] 83 Fed. Reg. 18,770.
[161] National Center for Education Statistics, *SLDS Technical Brief: Statistical Methods for Protecting Personally Identifiable Information in Aggregate Reporting* (Dec. 2010), https://nces.ed.gov/pubs2011/2011603.pdf.
[162] *Id.* at 27.
[163] Privacy Technical Assistance Center, *Data De-identification: An Overview of Basic Terms* (2001), https://studentprivacy.ed.gov/sites/default/files/resourcedocument/file/datadeidentificationterms.pdf.

"when schools, districts, or states publish reports on student achievement or share students' data with external researchers" not to make underlying data publicly available for independent validation.[164] Thus, it is unclear that methods used to de-identify but preserve data for those purposes would be adequate in this context. For example, one of the methods that the U.S. Department of Education uses for disclosure avoidance for tabular data is to not release information for any cell that has a size below some minimum, which essentially means not disclosing information where there are small numbers in a certain cell.[165] Thus, it is quite possible that techniques that result in a loss of information would prevent researchers from repeating the experiment. Yet EPA fails to acknowledge the nuances and limitations of these policies.

EPA links to a NIST document entitled *De-Identification of Personal Information* by Simson L. Garfinkel (NISTIR 8053), which discusses de-identification, but not in the context of making research data publicly available for independently validating scientific studies. The document instead notes that "that there is a trade-off between the amount of de-identification and the utility of the resulting data" and that "[i]t is thus the role of the data controller, standards bodies, regulators, lawmakers and courts to determine the appropriate level of security, and thereby the acceptable trade-off between de-identification and utility."[166] It further notes that "de-identification approaches based on suppressing or generalizing specific fields in a database cannot provide absolute privacy guarantees, because there is always a chance that the remaining data can be re-identified using an auxiliary dataset."[167]

EPA's reference to the U.S. Census Bureau is similarly unhelpful. Here EPA provides a link to a website titled *Data Ingest and Linkage* that details the U.S. Census Bureau's approach to linking data across many records they hold.[168] The Website links to a working paper that describes the method by which the Census assigns a unique person identifier to records it holds that enables it to link records together to create the final file.[169] It is totally unclear how this process on linking together records is a solution that EPA could implement to protect privacy of individuals when disclosing data as it concerns how to identify data with specific people—not protecting privacy.

While other agencies are clearly grappling with the issue of how to make government-collected data available, they have also highlighted the many challenges in protecting privacy and confidentiality while doing so—such as the ability for de-identified data to be re-identified—and these agencies accept that there is more work to be done before these concerns are fully

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[164] *Id*. at 1.
[165] *Id*. at 4.
[166] Simson L. Garfinkel, *De-Identification of Personal Information* (NISTIR 8053), 11-12 NIST (Oct. 2015), https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf.
[167] *Id*. at 5.
[168] U.S. Census Bureau, *Data Ingest and Linkage*, https://www.census.gov/about/adrm/linkage/technical-documentation/processing-de-identification.html (last accessed Aug. 13, 2015).
[169] Deborah Wagner & Mary Layne, *The Person Identification Validation System (PVS): Applying the Center for Administrative Records Research and Applications' (CARRA) Record Linkage Software*, CARRA Working Paper Series, Working Paper # 2014-01, U.S. Census Bureau (July 1, 2014).

addressed.[170] The letter filed in this docket by the Presidents of the National Academies of Science, Engineering and Medicine underscores these difficulties, specifically noting the National Academies' previous work finding that "statistical analyses of data sets that generate highly precise results—such as geographic specificity or other characteristics that identify respondents—may result in privacy breaches . . . This presents a new challenge that federal statistical agencies are just beginning to address."[171] EPA does not even acknowledge, much less try to address, these gaps in agencies' abilities to protect sensitive data.

EPA cursorily mentions a range of options for facilitating secure access to confidential data, including: "[r]equiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements."[172] EPA does not indicate whether it would deem providing access with these types of controls in place sufficient to meet EPA's proposed requirement "publicly available in a manner sufficient for independent validation." EPA also fails to recognize the significant costs associated with implementing most of these options or the risks to privacy that remain even if these methods are employed.

b) EPA cites to one example—the technique of deidentification—but fails to acknowledge, let alone address, the significant costs and limitations of this approach.

As already discussed, it is legally and ethically necessary to ensure the privacy of the individuals whose data have been collected, as some of these data, such as medical history or employment data, can be quite sensitive. EPA suggests deidentification and redaction of sensitive information can be used to protect privacy when study data is made public. EPA fails to recognize that these techniques are generally burdensome and costly, and may lose too much information for replication purposes. EPA also ignores the real concerns, based in empirical evidence, about reidentification of individuals through cross linking with existing public datasets and the ensuing breach of privacy.[173]

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[170] *See, e.g.,* Simson L. Garfinkel, *De-Identification of Personal Information* (NISTIR 8053), NIST (Oct. 2015) (detailing methods of re-identification and challenges to de-identifying information, concluding "there is comparatively little known about the underlying science of de-identification" and "there is a clear need for standards and assessment techniques that can measurably address the breadth of data and risks described in this paper.").

[171] Letter to Acting Administrator Wheeler 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 at 4 (July 16, 2018) (citations removed).

[172] 83 Fed. Reg. 18,771.

[173] "Recently, a peer reviewed study examined the identifiability of records from an environmental health study in Northern California. Using data considered by HIPAA to be sufficiently de-identified to be made public, which involved far fewer variables than would be required to make public in the cohort studies, they were able to correctly identify over 25% of the participants. Another study searched the Lexis-Nexis database for stories that mentioned hospitalization, and by matching that with age, race, sex and Zip code from a supposedly anonymized hospital admissions data base was able to match 43% of the people named in the news stories to their medical records." Comments of the International Society for Environmental Epidemiology on EPA's proposed rule on Strengthening Transparency in Regulatory Science (EPA-HQ-OA2018-0259-0001), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1973 (citing Sweeney L, Yoo JS, Perovich L, Boronow KE, Brown P and JG B., *Re-identification Risks in HIPAA Safe Harbor Data: A study of data from one*

Indeed, experts have observed that even the disclosure of redacted or "de-identified" data sets has become more fraught as public health studies have become more rigorous, because these studies are relying upon greater quantities of ever more granular personal information.[174]

i. Deidentification is complicated and costly.

EPA states that "[o]ther federal agencies have developed tools and methods to deidentify private information," but then cites to only one source, which does not address the concerns raised here.[175] EPA cites to the U.S. Department of Health and Human Services' *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*.[176] This guidance provides two methods for de-identifying data: (1) expert determination method, where an expert determines that, after application of statistical and scientific principals and methods, the risk is very small that the information alone or with other available information could be used to identify the subject; and (2) the safe harbor method, requiring that a number of identifiers are removed.[177] The first method requires case-by-case work, and EPA has provided no information regarding how EPA or others could potentially implement it or how much it might cost. In addition, there is no indication of how broadly this technique might be applicable to adequately de-identify data. *I.e.*, EPA must provide its views on whether this technique is likely to be applicable to the majority of studies relevant to EPA with non-public data, some studies, or only a handful. The second method requires removal of much information that may be necessary to be able to reanalyze or reproduce the research results, so it is unclear whether it would satisfy EPA's requirements in the Proposal. The second method is also costly, which EPA also completely disregards. Furthermore, even the safe harbor method has been shown to provide potentially insufficient privacy protections due to the mosaic effect, discussed more below.

EPA further states: "The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century. . . ," seemingly suggesting that data can easily be modified to address privacy concerns.[178] This is incorrect. The National Academies in fact recognizes that complex, evolving, and yet undeveloped techniques are needed to resolve these concerns: "Initially, relatively simple data masking techniques, such as top coding income amounts. . .were used to generate restricted data

environmental health study, Technology Science (2017) and Sweeney L., *Only You, Your Doctor, and Many Others May Know*, Technology Science (2015)).

[174] *See* Letter from Daniel S. Greenbaum, Health Effects Institute, to Lek Kadeli, Environmental Protection Agency 3 (Aug. 27, 2013) (describing the use of increasingly fine-grained community-level and zip code-level data in public health studies, and noting that "these characteristics – which have in general enhanced the quality and the sensitivity of the studies – increase the difficulty of providing a fully "de-identified" data set while also enabling a different investigator to conduct a full replication and sensitivity analysis of the original study results.").

[175] 83 Fed. Reg. at 18,771.

[176] 83 Fed. Reg. at 18,771 n. 17.

[177] HHS, *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*, https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

[178] 83 Fed. Reg. at 18,771.

products [,] [d]uring the last decade the increasing risks of confidentiality breaches have led researchers to develop increasingly sophisticated methodologies for restricted data products."[179] They state, "more research is clearly needed to assess the relative ability of different masking methods, and of synthetic data, to reduce the risk of disclosure while preserving data utility."[180] They recognize the current limitations of producing restricted data that sufficiently limits identifiability to allow it to be made publicly available in a useful form. They note that "well-informed policy making" requires "[r]esearch using detailed confidential data" that cannot be made public—which the Proposal fails to acknowledge to the detriment of the quality of EPA's policy decisions.[181] In the meantime, the National Academies state that more work is needed to allow "[h]igh-quality public-use files" that still assure "the inferential validity of the data while safeguarding their confidentiality."[182]

ii. Ongoing developments in data analytics make data deidentification more difficult to conduct and less likely to adequately protect privacy and confidentiality.

In pointing to the option of deidentification and redaction techniques, EPA also fails even to mention, let alone address, the increasing risk of re-identification through data analysis using multiple data sets. The so-called "mosaic effect" makes even very limited, redacted releases of data to the public a threat to the privacy of study subjects. OMB has recognized the threat to privacy from the mosaic effect, which it describes as "when the information in an individual dataset, in isolation, may not pose a risk of identifying an individual (or threatening some other important interest such as security), but when combined with other available information, could pose such risk."[183] OMB specifically highlighted the complicated nature of this threat and the need for agencies to address it carefully, particularly as they may not possess the needed expertise.[184]

Studies show the reality and scope of the re-identification threat. For example, Dr. Latanya Sweeney, professor of government and technology in residence at Harvard University, has examined deidentified datasets and combined them with other public data sets to test this concern. She was able to use information in medical information and a voter list, such as birth date, gender, and zip code, to identify individuals in the deidentified Massachusetts Group Health Insurance Commission dataset in 1997, including the then Massachusetts Governor,

[179] National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, 27 The National Academies Press (2005).
[180] *Id.* at 28.
[181] *Id.* at 2.
[182] *Id.*
[183] OMB Memorandum M-13-13, Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset 4-5 (May 9, 2013).
[184] *Id.* at 9-10 ("Agencies should note that the mosaic effect demands a risk-based analysis, often utilizing statistical methods whose parameters can change over time, depending on the nature of the information, the availability of other information, and the technology in place that could facilitate the process of identification. Because of the complexity of this analysis and the scope of data involved, agencies may choose to take advantage of entities in the Executive Branch that may have relevant expertise, including the staff of Data.gov.")

William Weld.[185] Studies have indicated that between 63% and 87% of the population of the United States could be uniquely identified by using only gender, ZIP code, and date of birth.[186] Dr. Sweeney was also able to link data in the Personal Genome Project to names and contact information, identifying between 84 to 97% of profiles.[187] In 2011 she was able to identify 43% of individuals in a department of health in Washington state hospital discharge database using newspaper stories.[188] Another study[189] showed how "data on air and dust samples from 50 homes in two communities in California could be combined with data released under the Safe Harbor provisions of the Health Insurance Portability and Accountability Act (HIPAA) to 'uniquely and correctly identify [in one community] 8 of 32 (25 percent) by name and 9 of 32 (28 percent) by address.'"[190]

The Commission on Evidence-Based Policymaking, which EPA also cites in the Proposal[191], also stresses the dangers of re-identification of data that has been stripped of direct identifiers. They note: "No existing statistical disclosure limitation method. . . is able to completely eliminate the risk of re-identification," despite increasingly complex techniques that have been developed since the 1970s.[192] They also note the threat posed by the "cumulative amount of information available about individuals and businesses that could be used for re-identification,"[193] with the threat increasing as available information grows and technology to allow re-identification improves.[194]

Further, the National Academies note, "data that are most useful to legitimate researchers typically have characteristics that pose substantial risk of disclosure."[195] This includes information such as:

- detailed geographic information;
- repeated data collection from the same subjects;
- outliers, such as people with very high incomes;
- many attribute variables; and

[185] Rothstein, Mark A., *Is deidentification sufficient to protect health privacy in research?*, 10.9 The American Journal of Bioethics 3-11, 6 (2010).
[186] *Id.* at 5.
[187] Sweeney, Latanya and Abu, Akua and Winn, Julia, *Identifying Participants in the Personal Genome Project by Name* (April 29, 2013), https://ssrn.com/abstract=2257732 or http://dx.doi.org/10.2139/ssrn.2257732.
[188] Sweeney L., *Matching known patients to health records in Washington State data*, Harvard University, Data Privacy Lab (2013), https://dataprivacylab.org/projects/wa/1089-1.pdf.
[189] Latanya Sweeney, Ji Su Yon, Laura Perovich, Katherine E Boronow, Phil Brown, and Julia Green Brody, *Re-identification Risks in HIPAA Safe Harbor Data: A Study of Data From One Environmental Health Study*, Technology Science (Aug. 28, 2017), https://techscience.org/a/2017082801/.
[190] Commission on Evidence-Based Policymaking, *The Promise of Evidence-Based Policymaking*, 54 (2017), https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf.
[191] 83 Fed. Reg. at 18771, n. 19.
[192] Commission on Evidence-Based Policymaking, *The Promise of Evidence-Based Policymaking* 53 (2017).
[193] *Id.* at 54.
[194] *Id.* at 55.
[195] National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, 21 The National Academies Press (2005).

- complete census data rather than a survey of a small sample of the population.[196]

There is increased vulnerability in "[d]ata with geographic detail, such as census block data" and longitudinal data obtained in panel surveys, which is often salient in environmental research.[197]

iii. Deidentification may make data sets unusable for reanalysis purposes.

Work by other experts in this area suggests that deidentification can be carried out and help protect privacy, but it may produce datasets that have lost vital information needed for specific analyses.[198] Even the HIPPAA guidelines document states: "Of course, de-identification leads to information loss which may limit the usefulness of the resulting health information."[199] Such results limit the utility of deidentified data sets and would not meet the requirements of the proposed rule which state that "*EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis*."

Further, even if it may be technically possible to release some amount of data while preserving privacy in some cases, doing so imposes substantial additional costs.[200] The preamble of the proposed rule suggests that privacy concerns can be addressed through mechanisms such as data masking, coding, and de-identification techniques—all of which would impose additional costs on researchers. The preamble also indicates that requirements for dose response data and availability may differ and involve a range of mechanisms such as deposition in public data repositories, and controlled access in federal research data centers—which would require EPA funding to maintain the facilities.[201] As discussed further in Section V of these comments, the proposed rule fails to acknowledge these costs, let alone provide any information about them or suggest ways to provide for them. Nevertheless, the costs can be significant, and even smaller costs could be prohibitive for many researchers.

At a time when federal funding for research in environmental and public health-related fields has largely flat-lined, academic researchers, in particular, are likely to have few additional

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[196] *Id.* at 21-22.
[197] *Id.* at 22.
[198] Simson L. Garfinkel, *De-Identification of Personal Information* (NISTIR 8053), NIST (Oct. 2015) (saying the goals of allowing data to be used while providing privacy protections "are antagonistic, in that there is a trade-off between the amount of de-identification and the utility of the resulting data.").
[199] HHS, *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*, https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.
[200] National Academies of Sciences, Engineering, and Medicine, *Principles and obstacles for sharing data from environmental health research: Workshop summary*, 46-47 The National Academies Press (2016), https://www.nap.edu/catalog/21703/principles-and-obstacles-for-sharing-data-from-environmental-health-research.
[201] *See*, The National Academies, *Improving Access to and Confidentiality of Research Data: Report of a Workshop*, National Academies Press 48 (2000) (At present, [costs for federal research data centers] are being covered partly by federal agency budgets and partly by user fees. The Census Bureau's research data centers have been supported in part by grants from the National Science Foundation and NIA, but may eventually have to recover more of their costs from users.").

funds available to undertake these activities.[202] This raises additional concerns—if researchers funded by industry are generally able to support the additional costs of making data publicly available, while academic researchers are far less likely to be able to do so, EPA's proposed approach could institutionalize a dangerous bias in the source of studies that EPA is allowed to use for regulatory activity.

With respect to the potentially very large costs that would accrue to EPA, EPA's proposal provides no indication that any funding to support such activities would be available. EPA funding is at its lowest level since the 1980s.[203] Absent a significant change in Congressional priorities, any EPA expenditures for the purposes of supporting making data publicly available would necessarily require cutbacks in other critical areas of environmental protection, which might include supporting additional research, conducting inspections, issuing permits, setting standards, or many other activities. EPA's Proposal includes no discussion of whether funds would be made available, nor whether other activities would be sacrificed, whether these trade-offs would make any sense, and what the overall impacts might be on public health and the environment.

B. The Proposal Will Not Advance the Supposed Cause of "Transparency" Upon Which it is Based.

The Proposal does not present or support the case that public accessibility to underlying data is necessary to vet scientific research—which, as discussed above, it is not—but even if it was, as discussed above, the scientific community is already taking steps to make underlying data publicly available where feasible, with the widespread understanding that this is neither necessary nor appropriate in all cases.[204] The Proposal does not examine the policies and practices that are already working to make data publicly available where feasible, the extent to which existing policies may already be sufficient to meet EPA's alleged transparency goals, or the reasons why some data is still not released publicly. Still less does EPA question whether this proposal would add anything to the current efforts, or whether it would have any effect whatsoever in increasing public accessibility of data.

1. Where there are lower hurdles to making data publicly available, this is already commonly occurring, with support from various initiatives.

[202] *See*, American Association for the Advancement of Science, *Trends in Federal Research by Discipline FY 1970-2017*, chart, (last updated July 2018), http://mcmprodaaas.s3.amazonaws.com/s3fs-public/Disc-1_0.jpg?RrBDGaSpG5edeDsiBRyoQyApdamjOs4O.

[203] *Compare* FY 2018 budget of $5.655 billion (EPA, *FY 2018 Budget in Brief* (May 2017)) and projected FY 2019 EPA budget of $6.146 billion (EPA News Release, *EPA FY 2019 Budget Proposal Released* (Feb. 12, 2018), https://www.epa.gov/newsreleases/epa-fy-2019-budget-proposal-released) with fiscal year 2017's budget of $8.058 billion and historical budgets (*EPA's Budget and Spending*, https://www.epa.gov/planandbudget/budget (last accessed July 26, 2018)).

[204] *See* National Academies of Sciences, Engineering, and Medicine, *Principles and obstacles for sharing data from environmental health research: Workshop summary*, The National Academies Press (2016), https://www.nap.edu/catalog/21703/principles-and-obstacles-for-sharing-data-from-environmental-health-research.

There are already various ongoing initiatives to make scientific data and models more commonly publicly available, where appropriate, as discussed more below. For example, EPA cites the ongoing implementation of the 2016 *Plan to Increase Access to Results of EPA-Funded Scientific Research*.[205] This Plan aims to maximize access to "research data underlying a publication" resulting from EPA-funded research.[206] It is worth emphasizing the Plan also exempts "research data [that] cannot be released due to one or more of constraints, such as requirements to protect confidentiality, personal privacy, proprietary interest, or property rights."[207] There is also a 12-month embargo period before publications are made publicly available.[208] The Plan also explicitly indicates that

> [i]t is important to recognize that some research data cannot be made fully available to the public but instead may need to be made available in more limited ways, e.g., establishing data use agreements with researchers that respect necessary protections. *Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications*.[209]

EPA also mentions the data availability policies or requirements of many scientific journals (although EPA does not specifically discuss any of these policies or indicate how or why they are not sufficient to address EPA's concerns).[210] Thus, where there are not significant barriers due to costs, or confidentiality or other concerns, there are increasing mechanisms to encourage scientists to make their data meaningfully and responsibly publicly available, and in response to these mechanisms, scientists frequently do so already.[211]

2. EPA's proposed approach does not require researchers to make underlying data publicly available.

There are multiple real and significant barriers to the public release of underlying data from some studies, and the Proposal cites no reason to believe that, in the majority of cases where data is not already released, one or more of those barriers are not present. Because those barriers are significant, this is not a situation where creating an incentive to private action is likely to be sufficient to drive such action where it is not already occurring.

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[205] 83 Fed. Reg. at 18770.
[206] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* 11 (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.
[207] *Id.* at 11.
[208] *Id.*
[209] *Id.* at 4-5 (emphasis added).
[210] 83 Fed. Reg. at 18,770 (stating that the policies and recommendations EPA considered were "informed by the policies recently adopted by some major scientific journals and cites to "related policies from the Proceedings of the National Academy of Sciences, PLOS ONE, Science, and Nature."); 83 Fed. Reg. at 18,771 n. 20 (claiming the "policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature" support the Proposal because they require authors to deposit the data underlying their studies in public data repositories).
[211] Jeremy Berg, *Obfuscating with transparency*, 360 Science 133 (Apr. 13, 2018), http://science.sciencemag.org/content/360/6385/133/tab-pdf ("Increasingly, many publications, including those from the Science family of journals, are linked to underlying data in accessible forms in repositories where they are readily available to interested parties, particularly those who seek to reproduce results or extend the analysis.").

Yet, with respect to release of data, the Proposal would only create an incentive for private action, not an actual requirement that data be released. First, this Proposal addresses data produced and held by external scientists, not data held by EPA itself or that EPA has authority to gain access to. Where EPA holds data, it is already governed by the Information Quality Act, OMB Circular A-110, and the Freedom of Information Act.[212] The Shelby Amendment required OMB to amend Circular A-110 to require that federal agencies provide "research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law" to the public through the Freedom of Information Act.[213] Importantly, the term "research data" excludes "[t]rade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law" as well as "[p]ersonnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study."[214] Many voiced concerns that even this provision could compromise scientific research and personal privacy.[215] This Proposal presumably is also not directed at studies funded by EPA, where the researchers must generally make data publicly available as a condition of receiving funding.[216] There are already mechanisms by which EPA is making research data publicly available where it has the authority and access to do so, and only after carefully ensuring that doing so will not compromise privacy interests.

Second, EPA has no authority to regulate the authors of studies or the scientific journals in which the studies are published, and EPA makes no attempt to regulate them directly. The preamble to the proposed rule states: "EPA should ensure that the data and models underlying scientific studies that are pivotal to the regulatory action are available to the public."[217] It further states that the proposed regulation is "designed to provide a mechanism to increase access to dose response data and models underlying pivotal regulatory science…."[218] The proposed regulations then state that for significant regulatory actions EPA "shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner

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[212] OMB Circular A-110 Revised 11/19/93 As Further Amended 9/30/99 36(d)(1) ("In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA."); *See also*, Lynn R. Goldman & Ellen K Silbergeld, *Assuring Access to Data for Chemical Evaluation*, 121 Environmental Health Perspectives 149 (Feb. 2013), https://ehp.niehs.nih.gov/wp-content/uploads/121/2/ehp.1206101.pdf (noting the numerous feasibility concerns that would arise were EPA to be required to make raw underlying data available for studies not governed by these mechanisms , given the large number of studies it usually relies on and that fact that EPA is usually not in possession of the raw data, in addition to funding and ethical limitations).

[213] OMB Circular A-110 (36)(d)(1).

[214] OMB Circular A-110 (36)(d)(2)(i).

[215] *See* Eric A. Fischer, *Public Access to Data from Federally Funded Research: Provisions in OMB Circular A-110*, Congressional Research Service, 13 (Mar. 1, 2013), https://fas.org/sgp/crs/secrecy/R42983.pdf.

[216] U.S. EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.

[217] 83 Fed. Reg. at 18769.

[218] 83 Fed. Reg. at 18770.

sufficient for independent validation."[219] But (apart from studies that EPA funds) EPA has no authority to require those data and models to be made public.

Hence, this proposal would regulate not the scientists, but EPA itself. EPA would "ensure" that data and models underlying scientific studies "pivotal" to regulatory action are publicly available *simply by barring EPA's own use in regulatory actions of any studies for which the authors do not make the data and models publicly available.* The "mechanism" mentioned in the preamble is not technical assistance or funding to encourage greater availability of data; it is simply the pressure generated by EPA's refusal to consider the results of a study if the authors do not release publicly the underlying data and models. The obvious question that EPA has neither asked nor attempted to answer in the Proposal is whether such a ban would be sufficient to incentivize study authors to make their data and models publicly available, where they have not already done so, or whether the ban will largely result in just limiting the studies available to EPA. Most of the significant barriers to release detailed above are not a matter of the researcher's preference, but rather take the form of legal and ethical constraints, significant costs, large time investments, or the loss of proprietary data critical to a researcher's future career prospects. While it seems plausible that having their research applied in a regulatory context would be viewed as an incentive by some, or perhaps many, researchers, there is no reason to believe that such an incentive would be sufficient to overcome the significant barriers to public release of data where those barriers exist. Indeed, the party most likely to be incentivized by EPA's proposed requirements is the regulated community which has vested financial interests in regulatory actions the agency may take—a situation that almost certainly will lead to significant bias and conflicts of interests in the scientific evidence that the agency considers.

Yet EPA barely acknowledges the nature of the "mechanism" it is proposing, and EPA certainly does not explore in any way how the mechanism would operate or whether it would be effective in driving release of data. Still less does EPA admit that the primary effect of this approach is very likely to be the exclusion of critical valid scientific studies from EPA's consideration. Finally, EPA utterly fails to contemplate what the effect of such exclusion would be on EPA's ability to adopt regulatory standards that protect public health and the environment.

C. The Proposal does not Acknowledge, Much Less Examine, its Likely Actual Effect—Reducing the Quality and Quantity of Studies upon which Regulatory Decisions are Based.

1. EPA fails to recognize that forcing the disclosure of all data and models would have harmful effects on the quality and quantity of scientific research used by EPA.

Although it appears highly unlikely that this proposal would drive additional data to be released, EPA presumes otherwise, and fails to recognize the harms that would likely result if EPA actually were successful in finalizing the rule. One reason researchers are particularly cautious about releasing human subjects data is that they understand that public willingness to

[219] 83 Fed. Reg. 18773.

participate in research studies depends upon protecting the privacy of the participants. Risks of privacy breaches and researchers' inability to control use of subject data will undermine potential participants' confidence in scientists' ability to protect their information.[220] This will likely reduce participation in studies or even lead to biases in responses from participants.[221] It could also result in attrition of participation by select subpopulations, particularly those who may be most vulnerable, such as children or people with disabilities or disease, or those with the most to protect, such as high socioeconomic populations. Reduced participation and particularly reduced participation among select subpopulations will reduce scientists' ability to draw meaningful inferences from their results to broader populations, the whole of which EPA is charged with protecting.

In addition, the prospect that their research would not be used if researchers were unable to make their data public is likely to deter researchers from even engaging in environmental health research, particularly research involving human subjects.[222] Lynn Goldman and Ellen Silbergeld conclude that a requirement by EPA that researchers release raw data underlying studies reviewed for rulemakings on pesticides and chemicals "would not be tenable" and would in fact "have a chilling effect on the engagement of the global scientific community in research relevant to the protection of human health and the environment."[223] Overall, the result will be to diminish and undermine the strength of the scientific information available to EPA.

2. Because EPA will be barred from using many valid scientific studies with nonpublic data, the net effect of this proposal will be to harm, not strengthen, EPA's use of science in the regulatory process.

The most damaging aspect of EPA's proposal is that it will bar EPA from using many valid scientific studies that provide critically important information supporting regulatory standards and requirements. This will significantly harm, not strengthen, EPA's use of science in the regulatory process—especially since the public availability of data is neither necessary nor sufficient to ensure the validity of the studies EPA relies upon. It is clearly arbitrary and

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[220] *See* Eugenia Economos, Farmworker Association of Florida, Testimony at EPA Public Hearing on Proposed Rule "Strengthening Transparency in Regulatory Science" (July 17, 2018); Leila Jamal et. al, *Research Participants' Attitudes Towards the Confidentiality of Genomic Sequence Information*, 22 Eur. J. Hum. Genetics 964 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4350593/.

[221] Christine Lothen-Kline et al., *Truth and Consequences: Ethics, Confidentiality, and Disclosure in Adolescent Longitudinal Prevention Research*, 33 Journal of Adolescent Health 385-394 (2003).

[222] *See* Augusta Wilson, Climate Sci. Legal Def. Fund, Testimony at EPA Public Hearing on Proposed Rule "Strengthening Transparency in Regulatory Science" (July 17, 2018), https://www.csldf.org/2018/07/16/why-we-oppose-to-the-epas-proposed-transparency-rule/ ("This could have a deeply concerning chilling effect on the conduct of important human health studies. Privacy concerns could influence what science gets done and what does not. Lines of scientific inquiry that would have been pursued may not be. The quality of data may be poorer than it otherwise would have been."); Augusta Wilson, *Big Tobacco's Smoke and Mirrors Revived by Pruitt's Science Transparency Policy*, The Hill (June 4, 2018, 5:00 PM), http://thehill.com/opinion/energy-environment/390638-big-tobaccos-smoke-and-mirrors-revived-by-pruitts-science ("Good scientists may understandably hesitate to pursue important lines of scientific inquiry if doing so will make them targets for regulators, interest groups and legislators who seek to impugn their credibility and troll through their emails looking for ways to publicly embarrass them.").

[223] Lynn R. Goldman & Ellen K Silbergeld, *Assuring Access to Data for Chemical Evaluation*, 121 Environmental Health Perspectives 149, 150 (Feb. 2013), https://ehp.niehs.nih.gov/wp-content/uploads/121/2/ehp.1206101.pdf.

capricious for EPA to sacrifice the agency's use of the best available science under these circumstances.

a) The prohibition on using studies with underlying nonpublic data will operate to exclude quality research results from EPA's regulatory process.

The next subsection provides an extensive discussion of some of the types of studies and specific studies that EPA would be unable to use under the Proposal.[224] Prior analyses by the Congressional Budget Office of related legislative proposals have also concluded that public availability requirements would significantly reduce the number of studies EPA relies upon—perhaps by as much as one-half.[225] Bizarrely, however, EPA does not even mention this probable effect of the Proposal, let alone provide information on which particular studies or types of studies would be excluded (absent a case-by-case exemption). Further, EPA utterly fails to consider what the effects of such exclusions could be on EPA's ability to develop and support standards to protect public health and the environment. There are many areas where these effects might be extremely damaging, as the examples below detail.

Not only would this proposal exclude valid studies, but it may well disproportionately exclude high quality studies. Some of the most robust and informative environmental health studies are human subjects studies with a large number of geographically distributed participants who are tracked over very long periods of time. These attributes make the results of these studies especially useful in regulatory decision making, since they are more representative of the population being addressed and provide information on exposure and health effects over a period of time. But these are also the attributes that make public release of the underlying data most difficult, and frequently impossible, as discussed above in Section II.A.1. Excluding these studies is highly likely to distort and undermine regulatory decision making by removing support for standards that are actually health protective. EPA has not identified any harms it is aiming to address through this Proposal, but whatever they are perceived to be, it is hard to see how they could outweigh the harm from barring EPA from considering the best available scientific information.

This Proposal also could be particularly harmful to EPA's ability to act in areas where the science is less developed, such as emerging threats. If there are a relatively small number of studies, the inability to consider some or all of them could cripple EPA's ability to act. This is

[224] Note that EPA has proposed to allow the Administrator to grant exemptions to the prohibition on a case-by-case basis, but the hurdle of requiring case-by-case determinations is so high (EPA relies on roughly 50,000 studies per year according to the CBO) and the criteria are sufficiently stringent (public availability must be "not feasible," which may well exclude, e.g., cost concerns) that it appears most plausible to assume that many studies will not be granted an exemption. *See* Section I.B.4 for further discussion.

[225] *See* Susanne S. Mehlman, Jon Sperl & Amy Petz, Cong. Budget Office, H.R. 1030: Secret Science Reform Act of 2015 at 2-3 (2015) ("CBO expects that EPA . . . would base its future work on fewer scientific studies . . . . CBO expects that the agency would probably cut the number of studies it relies on by about one-half . . . ."); Jon Sperl & Amy Petz, Cong. Budget Office, H.R. 1430: Honest and Open New EPA Science Treatment (HONEST) Act of 2017 at 1-2 (2017) ("EPA officials have explained to CBO that the agency would implement H.R. 1430 with minimal funding . . . . That approach to implementing the legislation would significantly reduce the number of studies that the agency relies on . . . .").

precisely the type of situation where a proactive early response could avoid extensive contamination (which is expensive to address) and multiple exposures (which are impossible to reverse), and the resulting adverse outcomes. Yet, apart from a question about how to apply the proposed rule to existing administrative records such as for the NAAQS, the closest EPA comes to hinting at the possibility of the regulatory and public health effects of excluding valid studies is when EPA asks the public to comment "on the effects of this proposed rule on individual EPA programs." None of these extremely consequential impacts of the Proposal are acknowledged or explored in any depth in the Proposal.

b) Examples of scientific studies that would be excluded

The proposed rule seeks to "ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation."[226] The proposal indicates that "[i]nformation is considered 'publicly available in a manner sufficient for independent validation' when it includes the information necessary for the public to understand, assess, and replicate findings."[227] Further, footnote three of the proposal states:

> Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use [sic] non-public data in support of its regulatory actions. *See Coalition of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 623 (D.C. Cir. 2010); American Trucking Ass'ns v. EPA, 283 F.3d 355, 372 (D.C. Cir. 2002).* EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.[228]

Taken together, EPA is proposing to prohibit the use of studies involving dose response data and models in significant regulatory decisions where the underlying data are not publicly available. Such a prohibition would affect virtually all pending and future regulatory actions and, if applied retrospectively, past regulatory actions. Regulatory actions would not reflect the best available science, leading to inadequate or absent critical public health and environmental protections.

Eight examples of pending, past, and future regulatory actions that are themselves put at risk from the proposed regulation, or cite to studies that under the Proposal may not be able to be utilized in future actions, explained in more detail below, include:

- **proposed bans of trichloroethylene (TCE) for use in vapor degreasing, aerosol degreasing, and spot cleaning in dry cleaning facilities under TSCA section 6(a);[229]**

[226] 83 Fed. Reg. at 18773 (emphasis omitted).
[227] *Id.* at 18773–74.
[228] *Id.* at 18769 n.3.
[229] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a), 82 Fed. Reg. 7432 (Jan. 19, 2017); Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a), 81 Fed. Reg. 91,592 (Dec. 16, 2016).

- **proposed ban of methylene chloride for use in paint and coating removal under TSCA section 6(a);[230]**
- **final rule setting formaldehyde emission standards for composite wood products under TSCA Title VI;[231]**
- **National Primary Drinking Water Regulation for arsenic under the SDWA;[232]**
- **NAAQS for oxides of nitrogen under the CAA;[233]**
- **NAAQS for ozone under the CAA;[234]**
- **forthcoming proposed National Primary Drinking Water Regulation for perchlorate in development under the SDWA;[235] and**
- **future regulatory action on the perfluoroalkyl substances (PFASs) perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) under SDWA and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).[236]**

Explanations of the likely effect of EPA's Proposal on these regulatory activities are described below.

Proposed bans of TCE for use in vapor degreasing, aerosol degreasing, and spot cleaning in dry cleaning facilities under TSCA section 6(a)

EPA has proposed two regulations under TSCA section 6(a) to ban the use of TCE in vapor degreasing, aerosol degreasing and spot cleaning in dry cleaning facilities.[237] Exposure to TCE is linked to several adverse health outcomes, including liver and kidney issues, developmental effects, and several forms of cancer.[238] The scientific basis for these proposed regulations is provided in the agency's 2014 risk assessment: *TSCA Work Plan Chemical Risk Assessment, Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses*[239] which

[230] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(e), 82 Fed. Reg. 7464 (Jan. 19, 2017).
[231] Formaldehyde Emission Standards for Composite Wood Products, 81 Fed. Reg. 89,674 (Dec. 12, 2016).
[232] National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6976 (Jan. 22, 2001).
[233] Review of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen, 83 Fed. Reg. 17,226 (Apr. 18, 2018).
[234] National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. 65,292 (Oct. 26, 2015).
[235] Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7762 (Feb. 11, 2011).
[236] Press Release, EPA, In Case You Missed It: "EPA Chief Vows that Clean Drinking Water is National Priority" (May 22, 2018), https://www.epa.gov/newsreleases/case-you-missed-it-epa-chief-vows-clean-drinking-water-national-priority.
[237] 82 Fed. Reg. at 7432; 81 Fed. Reg. at 91,592
[238] 82 Fed. Reg. at 7435–36.
[239] EPA, Office of Chem. Safety & Pollution Prevention, EPA Doc. No. 740-R1-4002, "TSCA Work Plan Chemical Risk Assessment: Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses" (2014) [hereinafter TCE Work Plan Risk Assessment], https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

drew heavily from the 2011 EPA Integrated Risk Information System (IRIS) Toxicological Review of TCE.[240] As noted in the 2014 work plan risk assessment,

> EPA/OPPT's work plan risk assessment for TCE is based on the hazard and dose-response information published in the toxicological review that the U.S. EPA's [IRIS] published in 2011. EPA/OPPT used the TCE IRIS assessment as the preferred data source for toxicity information. . . . The TCE IRIS assessment used a weight-of-evidence approach, the latest scientific information and physiologically-based pharmacokinetic (PBPK) modeling to develop hazard and dose-response assessments for TCE's carcinogenic and non-carcinogenic health effects. . .. Development of TCE's hazard and dose-response assessments considered the principles set forth by the various risk assessment guidelines issued by the National Research Council and the U.S. EPA.[241]

EPA clearly found the TCE IRIS assessment to be scientifically rigorous. EPA made this determination without the data underlying the key, peer-reviewed studies[242] used in the assessment being publicly available. EPA's proposed science rule would preclude the use of these studies, severely jeopardizing the fate of the proposed TCE bans and allowing high-risk uses of TCE to continue.

Proposed ban of methylene chloride for use in paint and coating removal under TSCA section 6(a)

EPA has proposed a ban on the use of methylene chloride in paint and coating removers.[243] Methylene chloride is associated with a number of hazardous health effects, including impaired visual and motor functions, respiratory irritation, headaches, nausea, and death.[244] The scientific basis for this proposed regulation is provided in the agency's 2014 risk assessment, *TSCA Work Plan Chemical Risk Assessment: Methylene Chloride: Paint Stripping Use*.[245] The work plan risk assessment for methylene chloride identified both cancer and non-cancer risks resulting from exposure to the use of methylene chloride in paint and coating

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[240] EPA, EPA/635/R-09/011F,"Toxicological Review of Trichloroethylene" (2011), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0199tr/0199tr.pdf.

[241] TCE Work Plan Risk Assessment at 65.

[242] The key studies used by EPA to derive the noncancer toxicity values for TCE are Deborah E. Keil et al., *Assessment of Trichloroethylene (TCE) Exposure in Murine Strains Genetically-Prone and Non-Prone to Develop Autoimmune Disease*, 44 J. Envtl. Sci. & Health, Part A 443 (2009); Margie M., Peden-Adams et al., *Developmental Immunotoxicity of Trichloroethylene (TCE): Studies in B6C3F1 Mice*, 41 J. Envtl. Sci. & Health, Part A 249 (2006), and Paula D. Johnson et al., *Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat*, 111 Envtl. Health Persp. 289 (2003). The key studies used by EPA to derive the cancer toxicity values for TCE are B. Charbotel et al., *Case-control Study on Renal Cell Cancer and Occupational Trichloroethylene Exposure in the Arve Valley (France)* (2006); and Ole Raaschou-Nielsen et al., *Cancer Risk Among Workers at Danish Companies Using Trichloroethylene: A Cohort Study*, 158 Am. J. Epidemiology 1182 (2003).

[243] 82 Fed. Reg. at 7464.

[244] *Id*. at 7468.

[245] EPA, Office of Chem. Safety & Pollution Prevention, EPA Doc. No. 740-R1-4003, TSCA Work Plan Chemical Risk Assessment: Methylene Chloride: Paint Stripping Use (2014) [hereinafter Methylene Chloride Work Plan Risk Assessment], https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf.

removers. As detailed in the work plan assessment, the proposed ban notes that liver toxicity and central nervous system effects are the most sensitive non-cancer endpoints for chronic and acute exposure, respectively.[246] Accordingly, these endpoints were used to evaluate the extent of risk resulting from exposure to methylene chloride using a margin of exposure (MOE) approach. The raw data underlying key studies used to derive the benchmark MOE for chronic exposure[247] and acute[248] exposures to methylene chloride are not publicly available. As with TCE, EPA's proposed regulation would preclude the agency from using these key studies to support the proposed rule to ban methylene chloride in paint and coating removers. The effect would be to severely jeopardize the finalization of this life-saving ban.

Final rule setting formaldehyde emission standards for composite wood products under TSCA title VI

In 2016, EPA issued a final rule establishing federal formaldehyde emission standards for composite wood products.[249] Formaldehyde exposure is associated with several adverse health impacts, including respiratory issues, eye and nose irritation, and lung and nasopharyngeal cancers.[250] As part of the rulemaking process, EPA conducted an economic analysis to determine which of several prospective regulatory actions would result in the largest net benefit after weighing the compliance costs that firms would incur and the public health benefits that would result from reduced formaldehyde exposure. [251] The monetary benefit that would result from the alleviation of adverse health outcomes associated with formaldehyde exposure was a core component of the economic analysis. Specifically, EPA calculated the annual estimated monetary benefits of avoided cases of eye irritation and nasopharyngeal cancer.

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[246] *Id.* at 115.

[247] K.D. Nitschke et al., *Methylene Chloride: A 2-Year Inhalation Toxicity and Oncogenicity Study in Rats* 11 Fundamental & Applied Toxicology 48 (1988).

[248] As discussed in the work plan chemical assessment for methylene chloride, EPA considered two different benchmark MOEs in its assessment of acute exposure risks—one derived from a 1-hour Spacecraft Maximum Allowable Concentration (SMAC) and the other from a California acute reference exposure level (REL). Methylene Chloride Work Plan Risk Assessment at 23. EPA preferred the SMAC-derived approach for reasons articulated in the work plan assessment. Raw data underlying many of the key studies used to derive the SMAC are not publicly available (Melvin E. Andersen et al., *Physiologically Based Pharmacokinetic Modeling with Dichloromethane, its Metabolite, Carbon Monoxide, and Blood Carboxyhemoglobin in Rats and Humans*, 108 Toxicology & Applied Pharmacology 14 (1991); Irma, Åstrand et al., *Exposure to Methylene Chloride: I. Its Concentration in Alveolar Air and Blood During Rest and Exercise and Its Metabolism*, 1 Scandinavian J. of Work, Env't & Health 78 (1975); G.D. DiVincenzo and & C.J. Kaplan, *Uptake, Metabolism, and Elimination of Methylene Chloride Vapor by Humans*, 59 Toxicology & Applied Pharmacology 130 (1981); Jack E. Peterson, *Modeling the Uptake, Metabolism and Excretion of Dichloromethane by Man*, 39 Am. Indus. Hygiene Ass'n J. 41 (1978); V.R. Putz et al., *A Comparative Study of the Effects of Carbon Monoxide and Methylene Chloride on Human Performance*, 2 J. Envtl. Pathology & Toxicology 97 (1979); Ronald S. Ratney et al., *In Vivo Conversion of Methylene Chloride to Carbon Monoxide*, 28 Archives of Envtl. Health: An Int'l J. 223 (1974); Richard D. Stewart et al., *Experimental Human Exposure to Methylene Chloride*, 25 Archives of Envtl. Health: An Int'l J. 342 (1972).

[249] 81 Fed. Reg. at 89,674.

[250] *Id.* at 89,677–78.

[251] EPA, Economic Analysis of the Formaldehyde Standards for Composite Wood Products Act Final Rule (2016) [hereinafter Formaldehyde Standards Econ. Analysis], Docket ID: EPA-HQ-OPPT-2016-0461-0037.

EPA relied on several robust, peer-reviewed studies to demonstrate the relationship between exposure to formaldehyde and these endpoints. For nasopharyngeal cancer, EPA referenced the highly regarded U.S. National Toxicology Program (NTP) Report on Carcinogens (RoC).[252] The U.S. NTP concluded that chronic exposure to formaldehyde increases risk of nasopharyngeal cancer as evidenced by several key human epidemiological studies.[253] For eye irritation, EPA relied on two epidemiological studies that examined residential exposure to formaldehyde.[254] Both these studies showed that the prevalence of eye irritation increases with heightened exposure to formaldehyde. The data underlying key, peer-reviewed studies that identify nasopharyngeal cancer and eye irritation resulting from formaldehyde exposure are not publicly available. EPA would have been forced ignore these studies were the proposed rule in place at the time the formaldehyde rule was developed. If the proposed rule is applied retrospectively, the formaldehyde rule will be at significant risk.

National Primary Drinking Water Regulation (NPDWR) for arsenic under the Safe Drinking Water Act (SDWA)

In 2001, EPA published a final rule, pursuant to its obligations under the Safe Drinking Water Act, establishing a new maximum contaminant level (MCL) for arsenic.[255] Ingestion of high levels of arsenic can result in death, and even low-level ingestion can lead to severe health impacts, including skin diseases.[256] As part of the rulemaking process, EPA requested that the National Research Council (NRC) review the agency's prior standards and risk assessments for arsenic as well as the available scientific data regarding the risks of arsenic exposure and ingestion.[257] Among the critical studies that the NRC analyzed were two epidemiological studies performed in the 1960s and 1970s that documented the relationship between arsenic in well water and skin diseases of an affected community in Taiwan.[258] The studies found that ingestion of high levels of arsenic through well water correlated to a higher likelihood of developing skin

[252] Nat'l Toxicology Program, Formaldehyde, in Report on Carcinogens (RoC), 14th ed. 2016), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf; Nat'l Toxicology Program, *Final Report on Carcinogens Background Document for Formaldehyde* (Jan. 22, 2010) (used to develop the 2011 RoC review for formaldehyde).

[253] *Id.* at 1–2 (citing M. Hauptmann et al., *Mortality from Solid Cancers Among Workers in Formaldehyde Industries*, 159 Am. J. Epidemiology 1117 (2004); Allan Hildesheim et al., *Occupational Exposure to Wood, Formaldehyde, and Solvents and Risk of Nasopharyngeal Carcinoma*, 10 Cancer Epidemiology, Biomarkers & Prevention 1145 (2001); Thomas L. Vaughan et al., *Occupational Exposure to Formaldehyde and Wood Dust and Nasopharyngeal Carcinoma*, 57 Occupational & Envtl. Med. 376 (2000); Sheila West et al., *Non-viral Risk Factors for Nasopharyngeal Carcinoma in the Philippines: Results from a Case-Control Study*, 55 Int'l J. Cancer 722 (1993)).

[254] Formaldehyde Standards Econ. Analysis at 4-24 to -25 (citing Lawrence P. Hanrahan et al., *Formaldehyde Vapor in Mobile Homes: A Cross-Sectional Survey of Concentrations and Irritant Effects*, 74 Am. J. Pub. Health 1026 (1984); Kai-Shen Liu et al., *Irritant Effects of Formaldehyde Exposure in Mobile Homes*, 94 Envtl. Health Persp. 91 (1991)).

[255] 66 Fed. Reg. at 6976.

[256] CDC Fact Sheet, Arsenic – ToxFAQs (2007), https://www.atsdr.cdc.gov/toxfaqs/tfacts2.pdf.

[257] *See* Nat'l Research Council, *Arsenic in Drinking Water* (1999).

[258] *See generally id.* (citing Wen-Ping Tseng, *Effects and Dose-response Relationships of Skin Cancer and Blackfoot Disease with Arsenic*, 19 Envt'l Health Persp. 109 (1977); Wen-Ping Tseng et al., *Prevalence of Skin Cancer in an Endemic Area of Chronic Arsenicism in Taiwan*, 40 J. Nat'l Cancer Inst. 453 (1968)).

cancer and other skin diseases. NRC's report concluded that based on the available evidence, EPA's previous standard for arsenic was inadequate for protecting the public health.[259]

Following the NRC report, EPA finalized a MCL of 10 ppb for arsenic, which was based on the two epidemiological studies from Taiwan.[260] Both studies were peer reviewed, published in prestigious health and environmental journals, and have been cited numerous times by other researchers. Yet it is unlikely the data from these studies could be made publicly available, as the data are four to five decades old and include confidential individual health information. If applied retroactively, or if EPA re-evaluates the MCL for arsenic, the proposed rule would likely mean that EPA could not rely on these studies.

National Ambient Air Quality Standards (NAAQS) for oxides of nitrogen under the Clean Air Act (CAA)

In 2004, EPA awarded a grant to the University of Washington to study the effects of long-term air pollution on the development of cardiovascular disease. More than 6,000 patients across the nation participated in the 10-year study, called the Multi-Ethnic Study of Atherosclerosis Air Pollution Study ("MESA Air").[261] Results from the initial study showed that long-term exposure to oxides of nitrogen (NO_x) and fine particulate matter contributes to cardiovascular disease.[262] MESA Air was the first study to show the negative health effects of long-term exposure to air pollution. Through funding from EPA, the National Institutes of Health, and the Health Effects Institute, MESA Air research is ongoing.[263]

On April 18, 2018, EPA published a final rule maintaining the current NAAQS for NO_x.[264] As part of the rulemaking process, EPA published the *Integrated Science Assessment for Oxides of Nitrogen – Health Criteria*.[265] This assessment incorporated research from MESA Air, including research related to modeling and statistical techniques, and was relied on by EPA in maintaining the NAAQS for NO_x in 2018. Yet because confidential health data comprises most of the research's data, as well as other identifying data such as ages and addresses, it is extremely unlikely the underlying data can be made publicly available. Researchers seeking to use the study's data must formally request and be granted access to de-identified datasets and are prohibited from further distributing data received.[266] Despite initially funding the research, under the proposed rule, EPA would be restricted from relying on this research in future rulemakings.

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[259] *See* Nat'l Research Council, *Arsenic in Drinking Water* 8-9 (1999).
[260] EPA, Six-Year Review 2 Health Effects Assessment: Summary Report 34 (2009) (citing Tseng (1977); Tseng et al. (1968)), https://www.epa.gov/sites/production/files/2014-12/documents/822r09006.pdf.
[261] *Multi-Ethnic Study of Atherosclerosis (MESA) Air Study*, EPA (last visited Aug. 13, 2018), https://www.epa.gov/air-research/multi-ethnic-study-atherosclerosis-mesa-air-study.
[262] Dr. Wayne Cascio, *EPA's MESA Air Study Confirms that Air Pollution Contributes to the #1 Cause of Death in the U.S.*, The EPA Blog (May 25, 2016), https://blog.epa.gov/blog/2016/05/epa-mesa-air-study/.
[263] MESA AIR HOME, Univ. of Wash. Sch. of Pub. Health, Dep't of Envtl. & Occupational Health Servs. (last visited Aug. 13, 2018), http://deohs.washington.edu/mesaair/home.
[264] 83 Fed. Reg. at 17226.
[265] EPA, EPA/600/R-15/-68, Integrated Science Assessment for Oxides of Nitrogen—Health Criteria (2016).
[266] Memorandum from W. Craig Johnson, MESA Coordinating Ctr., on MESA Deidentified Dataset Distribution Policy Statement (Apr. 12, 2016), https://www.mesa-nhlbi.org/PublicDocs/MESA_DeidentifiedDataDistribution_PolicyStatement_04122016.pdf.

NAAQS for ozone under the CAA

In October of 2015, EPA strengthened the NAAQS for ozone,[267] which is the main component of smog. Ozone pollution is linked to asthma and other respiratory health problems, and it is particularly dangerous for children and the elderly. As part of the rulemaking process, EPA published the *Integrated Science Assessment for Ozone and Related Photochemical Oxidants* in 2013, which reviewed the available science to build the scientific basis for the NAAQS.[268] In the Integrated Science Assessment, EPA relied on recent epidemiological studies demonstrating the causal relationship between ozone and childhood asthma as well as other developmental effects.[269] These studies were peer-reviewed and are invaluable to ensuring that all people, and especially children and older adults, are protected from the dangerous impacts of smog. However, the studies include individual demographic and genetic data. It is unlikely the data could be made publicly available. Under the proposed rule, when EPA reviews the ozone NAAQS, the agency would likely be unable to rely on these studies.

Forthcoming proposed NPDWR for perchlorate in development under the SDWA

In 2011, EPA made a regulatory determination to develop a national primary drinking water regulation for perchlorate under the SDWA, based on the conclusion that "there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern."[270] Underlying this conclusion is a body of literature detailing the health risks associated with perchlorate, namely the chemical's interference with normal thyroid function by inhibiting uptake of iodide into the thyroid gland. Iodide is essential to making thyroid hormones that regulate the body's metabolism and orchestrate fetal and infant brain development. In its determination, EPA cited a study by Michael Zimmermann, which reviews the adverse effects that iodine deficiency has on children's health.[271]

Currently EPA is using peer-reviewed studies[272] to develop the dose-response model central to deriving the maximum contaminant level goal (MCLG) for perchlorate in drinking water. These studies demonstrate that perchlorate exposure during pregnancy results in low

[267] 80 Fed. Reg. at 65292.
[268] EPA, EPA/600/R-10/076F, Integrated Science Assessment for Ozone and Related Photochemical Oxidants (2013), https://www.momscleanairforce.org/wp-content/uploads/2015/05/Ozone-2013-ISA-Executive-Summary.pdf.
[269] *See, e.g.*, Muhammad T. Salam et al., *Roles of Arginase Variants, Atopy, and Ozone in Childhood Asthma*, 123 J. of Allergy & Clinical Immunology 596 (2009); Talat Islam et al., Glutathione-S-transferase (GST) P1, GSTM1, *Exercise, Ozone, and Asthma Incidence in School Children*, 64 Thorax 197 (2009).
[270] 77 Fed. Reg. at 7762.
[271] *Id.* at 7763 (citing Michael Zimmerman, *Iodine Deficiency*, 30 Endocrine Reviews 376 (2009)).
[272] EPA, Post-Meeting Peer Review Summary Report: External Peer Review for EPA's *Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water* (Mar. 2018), https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0439-0012, Docket ID: EPA-HQ-OW-2016-0439-0012.

maternal level of the thyroid hormone T4 leading to neurodevelopmental problems in children.[273] As with the Zimmermann study, the data underlying these studies are not publicly available. Under EPA's Proposal, the agency would be unlikely to rely on these studies putting at risk both the 2011 regulatory determination itself and EPA's ongoing work to develop the perchlorate NPDWR.

Future regulatory action on PFOA and PFOS under the SDWA and CERCLA

In May 2018, EPA announced that the agency will begin the process of developing, under the SDWA, maximum contaminant levels (MCLs) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), in addition to designating these chemicals as "hazardous substances," possibly under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).[274]

EPA developed health advisories for PFOA and PFOS in 2016. The supplementary documents[275] provided with these advisories detail the various sources of evidence that EPA considered in its characterization of the health impacts of PFOA and PFOS. Among the sources of health effect information was the C8 Health Project,[276] a community-wide assessment of approximately 69,000 individuals living in or near Parkersburg, West Virginia, that was mandated as part of a lawsuit following a major release of PFOA from the DuPont Washington Works production plant into the area's drinking water. Based on this data set and other relevant studies, the researchers leading the C8 Health Project concluded that there was a probable link between PFOA exposure and several harmful health effects, including thyroid disease, ulcerative colitis, kidney cancer, and testicular cancer.[277]

The presiding judge sealed the data from the C8 Health Project to protect participant privacy. [278] Under EPA's proposed rule, when the Agency is developing regulations for PFOA—as it intends to do in the near future—it would not consider publications from the C8 Health

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[273] Martjin Finken, et al., *Maternal Hypothyroxinemia in Early Pregnancy Predicts Reduced Performance in Reaction Time Tests in 5- to 6-Year-Old Offspring*, 98 J Clin Endocinol Metab, 1417 (2013). ; Korevaar et al., *Association of Maternal Thyroid Function During Early Pregnancy with Offspring IQ and Brain Morphology in Childhood: A Population-Based Prospective Cohort Study* 4 Lancet Diabetes & Endocrinology 35 (2016); Victor J. Pop et al., *Low maternal free thyroxine concentrations during early pregnancy are associated with impaired psychomotor development in infancy*, 50 Clinical Endocrinology 149 (1999); Victor J. Pop et al., *Maternal hypothyroxinaemia during early pregnancy and subsequent child development: a 3-year follow-up study* 59 Clinical Endocrinology 282 (2003); F. Vermiglio et al., *Attention deficit and hyperactivity disorders in the offspring of mothers exposed to mild-moderate iodine deficiency: a possible novel iodine deficiency disorder in developed countries*, 89 J. Clinical Endocrinology & Metabolism 6054 (2004).

[274] Press Release, EPA, In Case You Missed It: "EPA Chief Vows that Clean Drinking Water is National Priority" (May 22, 2018), https://www.epa.gov/newsreleases/case-you-missed-it-epa-chief-vows-clean-drinking-water-national-priority.

[275] EPA, EPA-822-R16-003, Health Effects Support Document for Perfluorooctanoic Acid (PFOA) (2016); EPA, EPA-822-R16-002, Health Effects Support Document for Perfluorooctane Sulfonate (PFOS) (2016).

[276] Frisbee, et al., *The C8 Health Project: Design, Methods, and Participants*, 117 Envtl. Health Persp. 1873 (2009), https://ehp.niehs.nih.gov/wp-content/uploads/117/12/ehp.0800379.pdf.

[277] C8 Science Panel, *The Science Panel Website*, http://www.c8sciencepanel.org/index.html (last updated Jan. 4, 2017).

[278] Frisbee et al., at 1876.

Project because the raw underlying data are not publicly available. In failing to consider such crucial case studies, EPA would be ignoring best available science, thereby undermining its own attempt to protect Americans from emerging health threats such as PFOA and PFOS.

c) Prominent scientists and leaders in public health agree that this Proposal would harm science-based public health protections.

Leading experts in public health, science, and environmental policy agree that the proposed rule would have far-reaching, detrimental impacts on public health and would constrain EPA's decision-making capabilities. By limiting the scientific studies that EPA may consider, the proposed rule would lead to less effective environmental policies and weaker public health protections. Experts have said the following:

- "[The proposed rule] will threaten the lives of real people." – Commissioners of the Minnesota Pollution Control Agency and Department of Health[279]
- "If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim." – John P. A. Ioannidis, C.F. Rehnborg Chair in Disease Prevention at Stanford University[280]
- "It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them. . . . Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes." – Editors of *Science* family of journals, *Nature*, *Public Library of Science* journals, *Proceedings of the National Academic of Sciences*, and *Cell*.[281]
- "Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits. . . . [the proposed rule] could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts." – Members of the Science Advisory Board[282]
- "[The proposed rule] would prevent the best science from informing policy decisions and result in weaker health safeguards." – Harold P. Wimmer, National President and CEO of the American Lung Association[283]

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[279] Letter from John Linc Stine, Comm'r, Minn. Pollution Control Agency, & Jan Malcolm, Comm'r, Minn. Dep't of Health, to E. Scott Pruitt, Adm'r, EPA (May 15, 2018), http://www.documentcloud.org/documents/4465265-MPCA-MDH-Joint-Letter-to-EPA-Science.html#document/p1.

[280] John P.A. Ioannidis, *All Science Should Inform Policy and Regulation*, 15 PLoS Med. 5 (2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576.

[281] Jeremy Berg et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data*, 360 Science (2018), http://science.sciencemag.org/content/360/6388/eaau0116?utm_campaign=toc_sci-mag_2018-05-03&et_rid=296581013&et_cid=2008556.

[282] Memorandum from Alison Cullen, Chair of SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to the Members of the Chartered SAB and SAB Liaisons (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[283] Press Release, Am. Lung Ass'n, American Lung Association Strongly Opposes EPA's Proposed Rule to Limit Critical Health Science (Apr. 24, 2018), http://www.lung.org/about-us/media/press-releases/epa-propose-limit-health-science.html.

- "If [the proposed rule] had been in effect 20 years ago, the nation might have forgone programs that are preventing over 50,000 premature deaths each year." – Environmental Protection Network[284]
- "[The proposed rule] would greatly weaken EPA's ability to comprehensively consider the scientific evidence across the full array of health effects studies. This would negatively impact EPA public protections that reduce levels of lead, harmful chemicals, and fine particle pollution, among others." – 985 scientists in a joint letter to Administrator Pruitt[285]
- "[The proposed rule] would severely hamstring the agency when it comes to developing and enforcing public health rules by limiting the kinds of research the EPA can use in crafting rules." – Union of Concerned Scientists[286]
- "[Administrator] Pruitt is moving to rid the EPA of the science needed for effective regulation. . . . Its potential impact goes well beyond the EPA's regulatory effectiveness to the underlying role of science in American society." – Dr. Bernard Goldstein, Professor Emeritus of Environmental and Occupational Health at the University of Pittsburgh and former EPA Assistant Administrator for Research and Development.[287]

Additionally, when the U.S. House of Representatives passed similar legislation in 2017, H.R. 1430, numerous professional organizations raised concerns about the implications of the proposed legislation.[288] The Environmental Data & Governance Institute (EDGI) found that:

> A bill that provided genuine provisions for public data access and usability, and did not focus on mandating the reproducibility of studies and on prohibiting the use of any data that could not be divulged to the general public in its entirety, would not be expected to hamper the EPA in a significant way. EDGI's analysis of H.R. 1430 shows that it does not achieve its stated goals. Instead, our research shows that H.R. 1430 would not promote transparency and that its passage would instead block the EPA from using the data it needs to fulfill its mission of protecting public health and the environment.[289]

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[284] Memorandum from Envtl. Prot. Network on Preliminary Assessment of Pruitt's Proposed Regulation to Restrict EPA's Use of Sound Science 2 (Apr. 26, 2018), https://docs.wixstatic.com/ugd/4868e0_8bbc47f8b66848e4a60503d4dd3a9e72.pdf.

[285] Letter from 985 Scientists to E. Scott Pruitt, Adm'r, EPA (Apr. 23, 2018), https://s3.amazonaws.com/ucs-documents/science-and-democracy/secret-science-letter-4-23-2018.pdf.

[285] Press Release, Union of Concerned Scientists, Scientists Oppose Pruitt's Research Restrictions (Apr. 23, 2018), https://www.ucsusa.org/news/press-release/scientists-oppose-new-pruitt-restrictions#.WwM1Mu4vyUl.

[286] Press Release, Union of Concerned Scientists, Scientists Oppose Pruitt's Research Restrictions (Apr. 23, 2018), https://www.ucsusa.org/news/press-release/scientists-oppose-new-pruitt-restrictions#.WwM1Mu4vyUl.

[287] Bernard Goldstein, *Why the EPA's 'Secret Science' Proposal Alarms Public Health Experts*, The Conversation (May 18, 2018, 6:40 AM), https://theconversation.com/why-the-epas-secret-science-proposal-alarms-public-health-experts-96000.

[288] *See* Vivian Underhill et al., Envtl. Data & Governance Initiative, Public Protections Under Threat at the EPA: Examining Safeguards and Programs that Would Have Been Blocked by H.R. 1430 (2017), https://envirodatagov.org/wp-content/uploads/2017/03/Public-Protections-under-Threat-at-the-EPA.pdf; Jon Sperl & Amy Petz, Cong. Budget Office, H.R. 1430: Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (2017).

[289] *See* Vivian Underhill et al., Envtl. Data & Governance Initiative, Public Protections Under Threat at the EPA: Examining Safeguards and Programs that Would Have Been Blocked by H.R. 1430 18 (2017), https://envirodatagov.org/wp-content/uploads/2017/03/Public-Protections-under-Threat-at-the-EPA.pdf.

D. EPA's Policy Rationales for its Proposal are Arbitrary and Capricious

1. EPA arbitrarily fails to provide a reasoned explanation for why the proposed rule is needed.

In essence, EPA's proposed regulation is a solution in search of a problem—a problem that does not exist. The administrative record for the Proposal fails to show that the Agency's past regulatory decisions inappropriately relied on scientific information of questionable value. In fact, EPA fails to point to a single example of a case in which, in developing regulations, EPA relied upon a study or studies later found to be questionable or invalid. Having failed to address this foundational question, EPA also misses the questions that would build on that—even if EPA actually had used invalid science in some instance, EPA would still have to ask whether the underlying data for that study had been made publicly available, and if not, if the problems with the study could have been avoided through having made the data publicly available.

The Proposal neither acknowledges the mechanisms EPA already uses to ensure the integrity of science in decision-making nor establishes that there is a problem that the Proposal is needed to solve. The reality is that both Congress and EPA have established an array of mechanisms and safeguards over the last five decades to ensure that the Agency's decisions are grounded in best available science. These mechanisms include review of agency science and decisions by EPA's scientific advisory boards, including the Science Advisory Board (SAB), the Clean Air Scientific Advisory Committee, Board of Scientific Counselors, the Science Advisory Committee on Chemicals, and the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel[290]—a process that a work group of the SAB recently described as a "rigorous review process that goes beyond the typical journal peer review procedures,"[291] and that the National Research Council recognized as playing an "important role in helping EPA to ensure the credibility and quality of . . . science-based decisions."[292] The Proposal also ignores EPA's use of independent peer review processes to evaluate certain studies used in regulatory decisions;[293] the use of transparent literature surveys that are themselves subject to peer review

[290] *See* 42 U.S.C. § 4365 (establishing the Science Advisory Board and requiring that EPA seek its review of, among other things, certain rulemakings under the Clean Air Act, Federal Water Pollution Control Act, Resource Conservation and Recovery Act, Noise Control Act, Toxic Substances Control Act, and Safe Drinking Water Act); 42 U.S.C. § 7409 (requiring the Clean Air Scientific Advisory Committee to advise EPA on matters relating to the National Ambient Air Quality Standards); 7 U.S.C. § 136w (requiring EPA to seek comments from the FIFRA Science Advisory Panel on certain rulemakings under FIFRA, and to seek advice on operating guidelines for scientific analyses by EPA that lead to actions carrying out FIFRA);

[291] Memorandum by Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science 4 (May 12, 2018) (observing that the Proposal "fails to mention that EPA has mechanisms for vetting science through several expert panels," including the SAB and others).

[292] Nat'l Research Council, Science for Environmental Protection: The Road Ahead 181 (2012) ("External advisory groups—including SAB, BOSC, and NACEPT—play an important role in helping EPA to ensure the credibility and quality of its scientific studies and science-based decisions.").

[293] *See, e.g.*, EPA Sci. and Tech. Policy Council, *Peer Review Handbook* xiii, 15 (4th ed. 2015) (noting that EPA has a "long-standing history of peer review" and providing for peer review of internally generated studies designated as "Influential Scientific Information" or "Highly Influential Scientific Assessments"); Nat'l Research Council,

and public comment, such as the Integrated Science Assessments (ISA) that inform the National Ambient Air Quality Standards;[294] and independent review of EPA science programs and risk assessment practices by authorities such as the National Research Council.[295] Major regulatory decisions—and the underlying scientific bases for those decisions—are also subject to public comment and judicial review, which serves as an important check on agency decisions that fail to properly account for the best available science.

Thanks to these multiple and overlapping safeguards, the quality of the science underlying EPA decisions is robust.[296] More to the point, there is no indication that EPA science suffers from the so-called "replication crisis" that the Proposal identifies as the principal reason for requiring the public disclosure of underlying data or models for studies used in EPA decisions.[297] It is telling that the sources EPA cites in support of its claims of a "replication crisis"[298] call into question its existence[299] and in many instances promote solutions that do not involve access to underlying data[300]—such as looking at cumulative evidence using a variety of methods instead of over-emphasizing the results of a single study.[301] It is even more telling that

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Science for Environmental Protection: The Road Ahead 180 (2012) ("In rule-making processes that rely on extensive reviews of scientific information, EPA generally imposes a strong preference for reliance on published, peer-reviewed studies. The agency's peer review policy states that 'peer review of all scientific and technical information that is intended to inform or support Agency decisions is encouraged and expected.'").

[294] *See* EPA, EPA/600/R-15/067, *Preamble to the Integrated Science Assessments* 5-25 (2015) (describing the steps EPA undertakes in preparing an Integrated Science Assessment, including extensive and transparent compilation and screening of relevant literature; public comment and independent review by the CASAC; and EPA's application of recognized frameworks in evaluating public health causation relationships).

[295] *See*, e.g., Nat'l Research Council, *Review of EPA's Integrated Risk Information System (IRIS) Process* 3 (2014) (describing the charge of the authoring committee as encompassing a review of recent changes to EPA's IRIS program as well as to "review current methods for evidence-based reviews and recommend approaches for weighing scientific evidence for chemical hazard and dose-response assessments."); Nat'l Research Council, Science for Environmental Protection: The Road Ahead at x (explaining that EPA asked authoring committee "to assess independently the overall capabilities of the agency to develop, obtain, and use the best available scientific and technologic information and tools to meet persistent, emerging, and future mission challenges and opportunities").

[296] *See* Nat'l Research Council, Science for Environmental Protection: The Road Ahead at 13 ("For over 40 years, EPA has been a national and world leader in addressing the scientific and engineering challenges of protecting the environment and human health."); Wendy Wagner, *Science in Regulation: A Study of Agency Decisionmaking Approaches* 29 (2013) (describing EPA's NAAQS review process as "exemplary" and a "five-star process for incorporating science into regulatory policy").

[297] 83 Fed. Reg. at 18770.

[298] It is additionally unclear what EPA means by "replication crisis," and EPA appears to be misusing the term, as the source it cites to describes a "reproducibility crisis," Marcus R. Munafò et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1 (2017), and another source details how "[a]s the movement to examine and enhance the reliability of research expands, it is important to note that some of its basic terms—reproducibility, replicability, reliability, robustness, and generalizability—are not standardized," Steven N. Goodman et al., *What Does Research Reproducibility Mean?*, 8 Sci. Translation Med. 1 (2016).

[299] Munafò et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1 (2017) ("Whether 'crisis' is the appropriate term to describe the current state or trajectory of science is debatable. . . . ")

[300] *See, e.g.*, Marcia McNutt, *Reproducibility*, 343 Science 229 (2014) ("[J]ournals can only do so much to assure readers of the validity of the studies they publish. The ultimate responsibility lies with authors to be completely open with their methods, all of their findings, and the possible pitfalls that could invalidate their conclusions.").

[301] John P.A. Ioannidis, *Why Most Published Research Findings Are False*, 2 PLoS Med. 0696, 0700–01 (2005) ("Second, most research questions are addressed by many teams, and it is misleading to emphasize the statistically significant findings of any single team. What matters is the totality of the evidence.").

the Proposal identifies *no* EPA actions that have been called into question because the science underlying those actions cannot be validated or replicated. In any event, the Proposal does not require replication of studies and only limits the cumulative evidence and context in which to interpret any given study—only hampering EPA's reliance on more robust scientific findings even if such a crisis were to exist.[302]

In addition, numerous independent reviews of EPA's science-based actions by the courts, as well as the consistency with which the Agency has solicited and relied on the advice and approval of its external Science Advisory Board committees have added to the credibility of EPA's decisions. The Proposal provides no information supporting the notion that the overarching processes of EPA assessment of relevant scientific studies and subsequent peer review of such assessments, as well risk and policy assessments that EPA has developed and improved over time, are in any way insufficient to address the concerns that are allegedly the main focus of the proposal.

EPA's failure to identify a problem or inadequacy that new regulations are needed to address is not only arbitrary—it is also contrary to the directive of E.O. 12866 which states that:

> [f]ederal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. [303]

E.O. 12866 further directs each agency to "identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." [304] Before proceeding any further with this proposal, EPA should clearly identify the problem it is trying to solve, provide evidence that there is, in fact, a problem, and allow for public comment on whether a problem exists that could be addressed through EPA regulation.

This is not to say that EPA's use of science cannot be improved or strengthened—of course continued improvement is always desirable. But to improve upon current practices it is necessary to identify what is deficient, why, how it can be corrected and the potential effects of such deficiency and any proposed changes to practice. EPA does none of these.

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[302] Marcus R. Munafò & George Davey Smith, *Repeating Experiments Is Not Enough*, 553 Nature 399, 399–400 (2018), https://www.nature.com/articles/d41586-018-01023-3#ref-CR3 (noting that "[i]f a study is skewed and replications recapitulate that approach, findings will be consistently incorrect or biased" and suggesting that instead, "an essential protection against flawed ideas is triangulation," or "the strategic use of multiple approaches to address one question").

[303] Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

[304] *Id.*

2. EPA arbitrarily fails to offer a reasoned explanation for its departure from existing policies that broadly require the agency to consider all available scientific information when undertaking rulemakings.

In addition to the statutes discussed in Section I.B.3 that require EPA to use the best available science when making regulatory decisions, a number of EPA's own policies embed this requirement as well. By arbitrarily limiting the science EPA considers when making regulatory decisions, the Proposal contravenes these policies, injuring the scientific integrity of EPA's actions. As discussed in more detail in Section II.E because EPA is changing course from established policy, EPA must fully acknowledge and justify its decision, which it has failed to do in the Proposal.

EPA's own existing Scientific Integrity Policy states:

> To support a culture of scientific integrity within the Agency, this policy. . . [r]ecognizes . . . policy makers within the Agency weigh the best available science, along with additional factors such as practicality, economics, and societal impact, when making policy decisions.[305]

The Proposal conflicts with this policy by restricting what may be the best available science on a given topic from EPA's consideration solely because the underlying data cannot be made public. As described above, public availability of data is neither necessary nor sufficient to ensure that studies constitute "best available science." The Proposal does not acknowledge this departure from the agency's Scientific Integrity Policy, much less explain why such a departure is reasonable.

Likewise, the Proposal is in tension with EPA's Information Quality Guidelines, developed in response to OMB guidelines issued under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, which require EPA to ensure the objectivity of influential scientific information it disseminates by using "the best available science and supporting studies conducted in accordance with sound and objective scientific practices."[306] EPA considers information to be disseminated when EPA prepares and distributes information to support an Agency decision or regulation or when EPA distributes information in a way that suggests EPA agrees with it, that it supports EPA's viewpoint, or if in the distribution EPA proposes to use it to support or formulate a regulation or agency decision.[307] Thus, the Proposal conflicts with the Guidelines by restricting scientific studies that EPA may use to support regulations, which may cause it to disseminate other information to support its regulations that is not based on the best available science.

[305] EPA, Scientific Integrity Policy 3-4.
[306] EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency 21-22 (2002), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf.
[307] *Id.* at 15-16.

EPA's Peer Review Handbook similarly acknowledges that "EPA strives to ensure that the scientific and technical bases of its decisions meet two important criteria: (1) they are based upon the best current knowledge from science, engineering, and other domains of technical expertise; and (2) they are credible."[308] EPA's Science Policy Council Handbook on Risk Characterization also requires reasonableness in the agency's risk assessments, which is achieved when "the characterization is based on the best available scientific information."[309] These policies clearly impact EPA's regulatory actions, and thus will be impacted by the Proposal. Yet EPA completely fails to analyze the impact the Proposal will have on its ability to comply with these policies and fails to explain why it is changing course or justify its decision to do so. Indeed, the Proposal fails to even acknowledge that the agency *is* changing positions.

3. EPA's Proposal arbitrarily fails to consider and deviates from best practices in scientific review, which support using a broad array of information, informed by a "weight of the evidence" approach, rather than arbitrarily excluding certain studies up front.

There is broad agreement in the scientific literature, reflected in EPA's own guidance, that a "weight of the evidence" approach is an optimal way to analyze and synthesize an array of scientific information in a decision-making context.[310] This approach, which is described in more detail below, calls for scientific assessments to be based on a broad array of studies—reflecting multiple lines of inquiry, where appropriate—each of which is carefully weighted based on various indicia of credibility. This careful and rigorous process is incompatible with the requirements of the Proposal, which would bar EPA from considering even highly credible, persuasive studies based solely on whether the underlying data is available. Yet the Proposal never acknowledges the conflict between its requirements and EPA's proven practices for scientific assessments, and never provides any good reasons for this change of course.

One prominent example of this "weight of the evidence" approach is contained in EPA's *Preamble to the Integrated Science Assessments*.[311] The ***Integrated Science Assessments*** are pollutant-specific reports that EPA produces as the scientific basis for establishing and updating

[308] EPA, EPA Peer Review Handbook 4th Edition A-4 (Oct. 2015), https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.
[309] EPA, Sci. Policy Council, Risk Characterization Handbook 18 (2000), https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.
[310] *See, e.g.*, Matthew E. Bates, Olivia C. Massey, & Matthew D. Wood, *Weight-of-Evidence Concepts: Introduction and Application to Sediment Management* 5-8 (US Army Corps of Engineers ERDC/EL SR-18-1, Mar. 2018), http://www.dtic.mil/dtic/tr/fulltext/u2/1048843.pdf (reviewing literature on development of and best practices in weight-of-evidence assessment, and observing that "Within the US, the USEPA and its partner agencies use and recommend the use of WOE extensively."); *Cf.* John P.A. Ioannidis, *All science should inform policy and regulation*, PLOS Med 15:5 (May 3, 2018) ("Even the strongest science may have imperfections. In using scientific information for decision-making, it is essential to examine evidence in its totality, recognize its relative strengths and weaknesses, and make the best judgment based on what is available."); U.S. EPA. Preamble to the Integrated Science Assessments (ISA). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-15/067, 2015. *See also* EPA Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* at 2 (June 2003) (describing EPA's guidance for carcinogen risk assessment and ecological risk assessment as additional examples of the agency's "weight-of-evidence" approach).
[311] EPA, Preamble to the Integrated Science Assessments (ISA) (EPA/600/R-15/067) (2015).

EPA's National Ambient Air Quality Standards (NAAQS), which establish health-based standards for critical air pollutants. The Integrated Science Assessments are intended to implement the Clean Air Act's directive to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health and welfare which may be expected from the presence of [a] pollutant in the ambient air."[312] These are some of the most consequential scientific evaluations that EPA performs, in terms of the health, environmental, and economic impacts of the resulting standards, and they must withstand the highest level of technical and legal scrutiny.[313] Thus, EPA uses the very best and most defensible scientific methods to produce them, which are described in the *Preamble to the Integrated Science Assessments*.

The *Preamble to the Integrated Science Assessments* is an "overview document outlining the basic steps and criteria used in developing the Integrated Science Assessments," which EPA references as a companion document to each Integrated Science Assessment.[314] As EPA explains, the "Preamble describes the process of searching the literature, selecting studies for consideration, evaluating study quality, synthesizing and integrating the evidence, and characterizing the evidence for public health and welfare impacts of criteria air pollutants."[315] It also "describes the five-level causal framework for evaluating weight of evidence and drawing scientific conclusions and causal judgments."[316] Central to this scientific assessment process is the understanding that evidence from all types of studies, such as animal studies, human observational studies (cohort, time series), controlled chamber studies, and exposure assessments, among others, must be evaluated and incorporated into final determinations of effects. No single study alone drives the final determinations of causality; rather, the weight of evidence from several lines of inquiry is critical.[317] This framework to evaluate all available science builds upon decades of accrued knowledge and thinking drawing from expertise across several disciplines, including evidence-based decision making.[318]

The Preamble states: "In its evaluation and integration of the scientific evidence on health or welfare effects of criteria pollutants, the U.S. EPA determines the weight of evidence in support of causation and characterizes the strength of any resulting causal classification."[319] The

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[312] *Learn About the ISAs*, EPA (quoting 42 U.S.C. § 7408(b)) (alteration in original), https://www.epa.gov/isa/learn-about-isas (last visited Aug. 14, 2018).
[313] *See Mississippi v. EPA*, 744 F.3d 1334, 1344-45 (D.C. Cir. 2013) (upholding EPA's use of the "weight of evidence" approach in setting NAAQS, saying EPA "evaluated the evidence as a whole through an 'integrative synthesis,' what it called a 'weight of evidence approach.' And appropriately so: one type of study might be useful for interpreting ambivalent results from another type, and though a new study does little besides confirm or quantify a previous finding, such incremental (and arguably duplicative) studies are valuable precisely because they confirm or quantify previous findings or otherwise decrease uncertainty") (citations omitted).
[314] EPA, Preamble to the Integrated Science Assessments. https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244 (last visited Aug. 14, 2018).
[315] *Id*.
[316] *Id*.
[317] *See* EPA, Preamble to the Integrated Science Assessments at 22.
[318] *See* Marcus R. Munafó & George Davey Smith, *Robust research needs many lines of evidence*, Nature (Jan. 23, 2018), https://www.nature.com/articles/d41586-018-01023-3#ref-CR3.
[319] EPA, Preamble to the Integrated Science Assessments at 18.

Preamble explains in further detail:

> In the ISA, the U.S. EPA assesses the body of relevant literature, building upon evidence available during previous NAAQS reviews, to draw conclusions on the causal relationships between relevant pollutant exposures and health or environmental effects. ISAs use a five-level hierarchy that classifies the weight of evidence for causation. This weight-of-evidence evaluation is based on the integration of findings from various lines of evidence from across health and environmental effect disciplines that are integrated into a qualitative statement about the overall weight of the evidence and causality.[320]

Similarly, section 26 of the Toxic Substances Control Act (TSCA) requires that decisions made under sections 4, 5, or 6 of the law must adhere to certain scientific standards including use of best available science and a weight of the scientific evidence approach.[321] In its final regulation, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, EPA defines weight of scientific evidence as:

> Weight of scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance. [322]

Systematic review in turn requires a full review of the body of scientific evidence available, where study quality is evaluated largely according to methodological design and not the degree to which underlying data are publicly available.[323] EPA's Proposal contravenes TSCA's requirements to apply a weight of the scientific evidence approach, as defined by the agency, by instating a process that, among other things, conflicts with applying a systematic review approach in the evaluation of chemicals under TSCA.

The Proposal's approach of preemptively barring studies based on the unavailability of data cannot be reconciled with EPA's detailed policies for scientific assessment.

> 4. EPA irrationally conflates scientific "validity" and "transparency" with data availability, incorrectly assuming that eliminating the use of studies without publicly available data will improve scientific validity and transparency.

In the preamble to the proposed rule, EPA states that the intent of the regulation is "to strengthen the transparency of EPA regulatory science." [324] Later in the preamble, EPA states: "[e]nhancing the transparency and validity of the scientific information relied upon by EPA

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[320] *Id.* at 22 (footnote omitted).
[321] 15 U.S.C. § 2625(h), (*i*).
[322] 40 C.F.R. § 702.33.
[323] Nat'l Research Council, Review of EPA's Integrated Risk Information System (IRIS) Process, https://www.nap.edu/catalog/18764/review-of-epas-integrated-risk-information-system-iris-process.
[324] 83 Fed. Reg. at 18,768.

strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions."[325] EPA then leaps to the unexplained conclusion that barring the use of studies without publicly available data will enhance transparency and validity. EPA's assumption that data availability (or "transparency" in the form of data availability) ensures the use of valid science or its equivalent to using the best available science is manifestly incorrect, and hence provides an irrational basis for the proposed rule. In fact, neither data availability in particular, nor transparency in general, is equivalent to or a guarantee of "validity" in scientific studies.

a) EPA arbitrarily fails to explain why EPA's existing mechanisms are inadequate to ensure the scientific integrity of its actions.

The Proposal ignores both the available approaches embraced by the scientific community and the record of past EPA assessments, which reveal alternative methods for ensuring the credibility of potentially useful scientific studies. These alternatives include, but are not limited to: confidential sharing of data with independent research teams that are in a position to validate results; comparisons of research findings with the results of other peer-reviewed research efforts, including through meta-analyses and literature reviews that are designed to shed light on consistent findings across studies; and strong peer-review processes led by scientific journals, by EPA, or by advisory bodies such as the SAB.[326] Indeed, the SAB workgroup that examined the Proposal expressly noted its failure to acknowledge any of these mechanisms:

> The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods. For example, the Health Effects Institute (HEI) conducted a re-analysis of the influential Harvard Six Cities and American Cancer Society (ACS) epidemiologic studies and was able to replicate its findings and to assess the robustness of the findings via sensitivity analysis . . . in this particular case, an unusually rigorous form of peer review and independent reanalysis, coupled with many follow-up studies, has accomplished a measure of confidence in findings without public access to data and analytic methods. . . . The proposed rule fails to mention that EPA has mechanisms for vetting science through several expert panels . . . . For example, the EPA CASAC routinely reviews and evaluates epidemiologic and toxicological studies that are the basis for dose-response relationships used in risk and exposure assessments for air pollutants regulated under the National Ambient Air Quality Standards. Although such mechanisms do not typically engage in reanalysis of original data using the same methods as the original investigators, they do entail a rigorous review process that goes beyond the typical journal peer review procedures.[327]

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[325] *Id.* at 18,769.

[326] *See, e.g.*, Letter to Acting Administrator Wheeler 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 2 (July 16, 2018) ("The National Academies have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data.").

[327] Memorandum from Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, Alison Cullen, to Members of the Chartered SAB and SAB Liaisons 4 (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf//E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

EPA scientific assessments typically begin with expert staff identifying and assessing peer reviewed studies and studies published in reputable scientific journals. This includes examining the strengths and weaknesses of individual studies, including factors such as design, the reputation and past work of the researchers, quality assurance, methods and analyses. This is followed by a broader look to examine the consistency and coherence of the study with respect to the findings of similar study types across multiple studies, as well as a more integrated assessment of the weight-of-evidence that considers multiple lines of scientific evidence. The assessments are in turn peer reviewed by EPA scientific advisory committees as well as the public.[328] In certain exceptional cases, reanalysis by EPA or competent third party investigators can provide some additional credibility.

As the SAB workgroup that examined the Proposal noted, the record of EPA's treatment of the evidence in the case of two landmark fine particle epidemiology studies shows how scientific researchers and EPA used all of these approaches in examining the association between long-term exposures to fine particles and mortality. This effort began with Harvard's "Six Cities" study, reported in (Dockery et al., 1993).[329] The researchers initially sought to reproduce their initial findings using a data base with a much larger number of subjects and cities and did indeed reproduce those findings (Pope et al., 1995) (see below).[330] By 2009 enough new evidence had accumulated for EPA's integrated assessment for particulate matter to conclude that the number of large U.S. cohort studies, together with supporting evidence from other epidemiology and toxicological studies were sufficient to infer a causal relationship between long-term PM2.5 exposures and mortality and cardiovascular effects. This conclusion regarding causality (the strongest finding possible under the causality classification methodology[331]) based on these studies was endorsed by the external Clean Air Scientific Advisory Committee (CASAC), which noted: "The five-level classification of strength of evidence for causal inference has been systematically applied; this approach has provided transparency and a clear statement of the level of confidence with regard to causation, and we recommend its continued use in future ISAs."[332] (Samet, 2009). Thus, the link between particulate matter exposure and mortality that was observed in the Six Cities study has been vetted through multiple mechanisms that have confirmed the validity of the findings *without* public access to the underlying data—including extensive reanalysis using larger datasets with longer duration of follow up and different statistical methods; reproduction and corroboration with independent studies using distinct populations and methodologies; and rigorous external review by independent scientists.

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[328] *See, e.g.*, EPA, Preamble to the Integrated Science Assessments 3, Figure II, (2015) https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244.

[329] Douglas W. Dockery et al., *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 New Eng. J. Med. 1753 (2003).

[330] C. Arden Pope, III et al., *Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults*, 151 Am. J. Respiratory & Critical Care Med. 669 (1995).

[331] The Preamble to the Integrated Science Assessments Sections describes the five-level hierarchy that classifies the weight of evidence for causation and methodology to make the determination, and "causal relationship" is the strongest finding.

[332] Letter from Dr. Jonathan M. Samet, Professor & Chair, Dep't of Preventive Med, Univ. of S. Cal., to Lisa P. Jackson, Adm'r, EPA (Nov. 2, 2009).

The Proposal says virtually nothing about the use of these existing mechanisms in EPA's current scientific assessment practices, or the level of confidence those mechanisms afford in EPA's regulatory science. Yet despite the proven track record of these mechanisms in assuring the validity of landmark studies such as the ACS and Six Cities studies, the Proposal would effectively reject their use and require EPA instead to exclude consideration of studies based on the sole criterion of public availability of underlying data. The Proposal's failure to explain this choice is arbitrary and capricious.

b) EPA arbitrarily equates data availability with valid science.

As discussed in detail in Section II.C.2, the absence of publicly available underlying data does not make the results of a study invalid or even suggest that the study is likely to be invalid. Nor has EPA presented evidence to suggest that studies with publicly available underlying data are more likely to represent strong science than studies without such data availability. As discussed in Section II.A.1, key reasons why researchers do not make data for some studies publicly available have nothing to do with scientific quality. Further, as discussed below and in the *Terminology* section, while reanalyzing study results using the same data is one way to help validate those results, it is neither the primary nor a sufficient way to do so. Hence, EPA's apparent conflation of data availability and best available science is not based on any evidence cited by EPA, is contrary to the evidence before EPA, and is simply arbitrary.

EPA's Preamble to the Integrated Science Assessments provides another discussion of how EPA evaluates study quality, and similarly, does not call out publicly available data:

> [T]he individual study quality is evaluated by considering the design, methods, conduct, and documentation of each study, but not the study results. This uniform approach aims to consider the strengths, limitations, and possible roles of chance, confounding, and other biases that may affect the interpretation of individual studies and the strength of inference from the results of the study.[333]

A statement by the American Statistical Association on p-Values: Context, Process, and Purpose further emphasizes the multiple considerations related to quality, stating "Researchers should bring many contextual factors into play to derive scientific inferences, including the design of a study, the quality of the measurements, the external evidence for the phenomenon under study, and the validity of assumptions that underlie the data analysis."[334] Similarly, the letter filed by the Presidents of the National Academies of Sciences, Engineering, and Medicine in this docket lists multiple reports conducted since 2007 that have examined EPA's scientific assessment processes and "that advise EPA on the scientific bases of regulatory decisions related to human health and the environment."[335] According to the NASEM Presidents,

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[333] EPA, Preamble to the Integrated Science Assessments at 7, https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244.

[334] Ronald L. Wasserstein & Nicole A. Lazar, *The ASA's Statement on p-Values: Context, Process and Purpose*, 70:2 The American Statistician 129, 131 (2016).

[335] Letter to Acting Administrator Wheeler 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 2 (July 16, 2018).

> These reports encourage EPA to consider *all available science in the rule-making process* and provide guidance about how the agency could be more transparent in describing how evidence is gathered and evaluated. . . . 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. Researchers may be contacted to answer questions about the conduct of the study or be asked to provide additional data. *If the study data are not available, their absence may affect how the study is rated and used in the analysis, but the study should not necessarily be eliminated from the assessment.*[336]

OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies* provide another important example of the distinction between information transparency and quality. Unlike the Proposal, which conflates transparency with quality, OMB's Guidelines encourage transparency as a means to obtain greater objectivity in data, but do not consider it an absolute requirement or the only means by which objectivity can be achieved. The Guidelines specifically provide that it is possible to verify the objectivity of information that cannot be made publicly available through other types of "robustness checks."[337]

As an example, the OMB Guidelines point to the Harvard Six Cities Study, where underlying data could not be made publicly available due to confidentiality concerns. In that case, the raw data was released only to researchers at the Health Effects Institute, who were bound to the same confidentiality requirements as the original researchers, and who were able to reanalyze and reproduce the study's results. [338]

c) Reanalyzing a study using publicly available data is not necessary to ensure valid science nor sufficient to ensure against invalid results.

To ensure the validity of scientific research, the scientific community relies most heavily upon peer review. In peer review, independent scientists with related expertise evaluate a study's quality using the types of factors discussed above. Studies used by EPA are often further evaluated by one of EPA's scientific advisory boards, such as the Clean Air Science Advisory Committee or the Science Advisory Board. These types of reviews do not depend on a study's data being made publicly available.

Making data available does allow independent researchers to try to reanalyze the same data and produce the same results. But reanalyzing a study is just one of many ways the scientific community ensures integrity, and it is not, in fact a widely used mechanism.[339]

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[336] *Id.* (emphasis added).
[337] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8,452, 8,460 (Feb. 22, 2002).
[338] *Id.* at 8,456.
[339] *See* John P.A. Ioannidis, *All science should inform policy and regulation*, 15 PLOS Med 1, 2 (May 3, 2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576 (However, we should recognize that

Reproducing study results using a different population or method is generally considered a stronger validation than simply reanalyzing the results using the same data, as it shows that the results hold across a different population.[340]

5. EPA arbitrarily attempts to bolster one element of scientific transparency, while ignoring significant other transparency-related concerns.

Another arbitrary aspect of this proposal is that EPA appears to assume that the only way to enhance transparency in regulatory science is to ensure that the underlying data and modeling for individual studies are publicly available. In fact, significant concerns have been raised about other non-public aspects of the modern scientific research and publication process that may undermine the accuracy of scientific results. For example, there are rising concerns about the increasing numbers of predatory pay-to-publish journals, which provide little-to-no guarantee of scientific integrity of their published studies.[341] Other areas of concern include undisclosed financial bias.[342] But rather than evaluating concerns related to transparency across the spectrum of peer-reviewed science, EPA has arbitrarily seized upon one narrow area. This area also happens to be a target of regulated industries, as discussed further in Section VII.

6. EPA's justification of the proposal is incoherent and lacks almost any evidentiary support.

Although as discussed above, EPA has not identified a problem with EPA's use of science, EPA may be assuming (without any basis of support) that it needs to strengthen the validity of the science EPA uses in rulemaking. If so, EPA then appears to leap to the conclusions (again without any supporting evidence) that the only way to strengthen the validity of the science is by enhancing transparency, that no other possible steps to enhancing integrity are worth considering, and that enhancing transparency means making underlying data and models publicly available. This is all before EPA even gets to its obviously illogical conclusion

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most of the raw data from past studies are not publicly available. In a random sample of the biomedical literature (2000–2014), none of 268 papers shared all of their raw data. Only one shared a full research protocol. The proportion of studies that have had all their raw data independently re-analyzed is probably less than one in a thousand. The number of studies that have been exactly replicated in new investigations is quite larger, but still a minority in most fields.") (citing Iqbal S, Wallach J, Khoury MJ, Schully S, Ioannidis JPA., *Reproducible research practices and transparency across the biomedical literature,* 14 PLoS Biol. 1 (2016) ("Replication studies were rare (n = 4), and only 16 studies had their data included in a subsequent systematic review or meta-analysis.")).

[340] *See, e.g.,* Comments of the International Society for Environmental Epidemiology on EPA's proposed rule on Strengthening Transparency in Regulatory Science Section 2 (EPA-HQ-OA2018-0259-0001), https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1973 ("However, although data reanalysis has a role to play, ultimately, the key determination of the consistency of scientific evidence comes from replication, not reanalysis.") (note that ISEE uses the term "replicate" to mean what we have defined in these comments as "reproduce").

[341] *See* Gina Kolata, *Many Academics are Eager to Publish in Worthless Journals*, N.Y. Times (Oct. 30, 2017), https://www.nytimes.com/2017/10/30/science/predatory-journals-academics.html; *Publish and Don't Be Damned*, The Economist (June 23, 2018), https://www.economist.com/science-and-technology/2018/06/23/some-science-journals-that-claim-to-peer-review-papers-do-not-do-so.

[342] EPA, *Scientific Integrity Policy*, https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf (seeking to protect agency reliance on science from political interference, personal motivations, conflicts of interest, bias, etc.).

that threatening exclusion of studies without publicly available data will "increase access to dose response data and models underlying pivotal regulatory science," [343] rather than simply bar EPA from considering a vast universe of useful and rigorously vetted studies. The evidence cited by EPA in support of the need to strengthen science through its proposed approach is so vague and perfunctory that it is largely impossible even to tell which conclusions various sources are supposed to support. EPA's rationale for its data availability requirements consists of a few conclusory statements by EPA itself, a reference to "the replication crisis," and citations to a handful of articles and guidance issued by EPA and OMB. None of these provide a rational basis of support for the Proposal.

EPA begins by stating that the "proposed rule is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions."[344] While EPA is correct that it must disclose the basis and provide an adequate explanation for rulemaking (principles EPA manifestly fails to follow in this Proposal), it does not follow that these principles either require or support the quite specific notion that dose response data and models must be publicly available. Nor does EPA attempt to explain how these broadest of rulemaking principles support EPA's specific proposed approach here.

Next, EPA states that the proposal is "consistent with" two recent executive orders and OMB guidelines on information quality and agency information management. [345] One of the executive orders says nothing more than that environmental regulations should be "developed through transparent processes that employ the best available peer-reviewed science . . . . "[346] The other is targeted at eliminating regulations including those that are "unnecessary" and "ineffective," which, as our comments detail, the Proposal clearly would be.[347] While the OMB guidelines on information quality generally support transparency in science, they call for a far more nuanced approach than EPA proposes here and do not call for agencies to exclude studies for which underlying data is not available, as discussed above in section I.C. In fact, as discussed above, EPA's proposal unlawfully contravenes these guidelines.

EPA then states that the Proposal "builds upon" prior EPA actions in response to government-wide data access and sharing policies. [348] In support of this claim, EPA cites generally to five prior EPA policy documents related to science. EPA fails to point to a single statement, provision or requirement in any of these documents, however, as support for the specific approach proposed here. This is not surprising, as EPA's proposal to exclude studies with non-public data is actually a significant change from the prior policies, which supported balancing the interest in access to data with interests in privacy and confidentiality, as discussed in more detail in Section II.E. In fact, one of the documents cited by EPA, the *Plan to Increase Access to Results of EPA-Funded Scientific Research*, directly contradicts an apparent premise of

[343] 83 Fed. Reg. at 18,770.
[344] 83 Fed. Reg. at 18,769.
[345] *Id*.
[346] Exec. Order No. 13,783, 82 Fed. Reg. 16,093, 16,093 (Mar. 31, 2017); s*ee also* discussion in Appendix A.
[347] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017); *see also* discussion in Appendix A.
[348] 83 Fed. Reg. at 18,770.

EPA's Proposal, stating: "Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications."[349] EPA ignores this contradiction altogether and provides no explanation whatsoever as to how the Proposal "applies concepts and lessons learned from [EPA's] ongoing implementation" of this plan, as EPA asserts.[350]

EPA also claims that the Proposal builds on the "experience of other federal agencies in this space."[351] In this case, EPA simply lists other federal agencies without referring to any policies, documents or actions by those agencies, except for one particular Census Bureau database that allows federal Census data to be shared securely. Obviously a bald uncited statement that other federal agencies have "experience in this space" is far too vague to allow meaningful comment by the public on EPA's rationale for its action, much less provide any support or rationale for the proposed policy. Further, the Census Bureau database cited is an example of how an agency can provide secure access to its own data, but it does nothing to explain or justify EPA's Proposal to exclude third party studies with nonpublic data from consideration in rulemaking. The U.S. Census Bureau operates the Federal Statistical Research Data Centers, which are secure facilities providing authorized access to restricted-use microdata for statistical purposes only. To gain access, researchers must obtain Census Bureau Special Sworn Status—passing a moderate risk background check and swearing to protect respondent confidentiality for life. This approach meets the U.S. Census Bureau's needs by allowing access to confidential information only to researchers whose proposals meet certain criteria, who go through a vetting process, and who agree to protect the information. Yet again, this is a structure designed to protect data collected by the government, not third parties, and there are substantial costs to this approach, which are borne by the Census Bureau. It is clearly not directly transferable to the context of the Proposal. [352] It is also unclear whether such a structure, even if it were practical (which it is not), would be sufficient to satisfy EPA's requirement to make data and models "publicly available."

Next, EPA vaguely refers to recommendations from third party advocates supporting "open science."[353] EPA does not specify, let alone discuss, those recommendations. EPA certainly does not explain how EPA's current use of science is inconsistent with any such recommendations or inadequate in light of them, or whether any of these third party organizations believe that studies with nonpublic data are insufficiently valid for use in rulemaking. Indeed, one of the organizations cited by EPA—the Bipartisan Policy Center

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[349] EPA, Plan to Increase Access to Results of EPA-Funded Scientific Research 4–5 (2016) (emphasis omitted), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.
[350] 83 Fed. Reg. at 18,770.
[351] *Id*.
[352] *See* Letter to Acting Administrator Wheeler 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 3 (July 16, 2018). ("There are several differences in the confidential microdata collected from individuals and businesses by federal statistical agencies through surveys, versus data and results from the kinds of studies that are within the scope of the EPA proposed rule. These differences have important implications about making data publicly accessible. What works well in the federal statistical environment may not translate effectively to EPA, where stakeholders might be strongly motivated to discount study results that run counter to their regulatory preferences.").
[353] 83 Fed. Reg. at 18770.

("BPC")—filed a letter in this docket stating emphatically that "the proposed rule is not consistent with the BPC report in substance or intent. While the Science for Policy Project panel encouraged greater transparency and access to data, the report never suggested excluding studies from consideration in developing regulation if data from those studies were not publicly available."[354] Again, the policy documents cited in the footnote accompanying this statement generally undercut rather than support EPA's Proposal, as discussed in detail in Appendix A.

EPA also suggests that "these policies" (which policies it is unclear) "are informed by the policies recently adopted by some major scientific journals."[355] EPA does not cite any specific policies adopted by the journals named in the footnote, but it does not appear that any of those journals has determined that studies with nonpublic data are invalid and should not be relied upon or used. To the contrary, the editors of these journals issued a strong public statement affirming that "in not every case can all data be fully shared," that "the merits of studies relying on data that cannot be made publicly available can still be judged," and that "[i]t does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them…Excluding relevant studies simply because they do not meet rigorous transparency standards will adversely affect decision-making processes."[356] Again, however, EPA's failure to provide any specific information or citations in support of its conclusory statements make it impossible to meaningfully comment on the support for EPA's Proposal.

Further, EPA mentions "the replication crisis,"[357] but provides no information on the reality, seriousness, scope, implications, or causes of such a crisis. EPA fails to explain what it understands the "replication crisis" to be, much less how EPA's proposal might ameliorate it. It is not even clear whether EPA understands the meaning of the term "replication," as the agency fails to distinguish between "replicability" and "reproducibility," and uses both terms apparently interchangeably.[358] *See* earlier discussion of key terminology at page 9.

The proposed regulatory text provides, "[i]nformation is considered 'publicly available in a manner sufficient for independent validation' when it include the information necessary for the public to understand, assess, and *replicate* findings" and then lists "data" as the first type of information that may be included.[359] Yet "replicating findings" is essentially limited to laboratory animal and randomized controlled trials and does not capture the vast majority of human epidemiological studies. More importantly, replicating studies does not require access to underlying study data, but rather details regarding the methodological design. Further "reproducing" studies is generally viewed as a more informative and resource efficient approach to validation of research.

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[354] Letter from Jason Grumet, President of BPC to Administrator Scott Pruitt (May 22, 2018).
[355] *Id.*
[356] Jeremy Berg et al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018).
[357] *Id.*
[358] *Compare, e.g.*, 83 Fed. Reg. at 18774 (proposed rule requires information to be available "for the public to understand, assess, and replicate findings"), *and* 83 Fed. Reg. at 18770 (alluding to "replication crisis" as a basis for the need for the proposed rule), *with* 83 Fed. Reg. at 18772 (discussing an analysis purporting net benefits from the proposal due to "greater reproducibility"), *and* 83 Fed. Reg. at 18769 ("EPA must. . . ensure that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility.").
[359] 83 Fed. Reg. at 18773-74 (emphasis added).

Finally, to the extent that specific circumstances justify actually replicating a study, EPA fails to explain why it is necessary to make a study's underlying data broadly available to the public rather than employing a more secure approach that protects personal privacy. For example, to quell concerns about the validity of the American Cancer Society Cancer Prevention Study II (ACS CPSII) and the Harvard Six Cities Study—both seminal air pollution studies that are described earlier in these comments—an independent panel of Canadian and American scientists independently audited and reanalyzed them. Due to personal privacy concerns, the data was not made publicly available but was instead held in a restricted access data warehouse at the Health Effects Institute, an organization funded by both the automotive industry and EPA. The independent audit and reanalysis took three years and roughly one million dollars. It evaluated the consistency and accuracy of the data and then undertook a series of comprehensive analyses to test the robustness of the original findings and interpretations to alternative analytic approaches. The results of the independent analysis found resoundingly similar results for both studies.[360]

The results of this reanalysis suggest that routine assessment of quality indicators such as methodology, confounding and bias routinely evaluated in the peer review process are generally sufficient to confirm a study's validity. Further, while it plainly would be infeasible to undertake such an expensive and time-consuming reanalysis for the vast majority of studies, this example demonstrates that it is possible to undertake a reanalysis without making underlying data broadly available to the entire public. Yet EPA's proposed rule apparently would bar regulators from relying on these high quality and extensively vetted studies due to the fact that the underlying data was never made publicly available. EPA does not—and cannot—explain how a rule that would prohibit the agency from considering these seminal, high quality scientific studies comports with its goal of strengthening the agency's use of science in regulatory actions.

7. EPA has failed to explain why it has singled out dose response studies to be excluded if their underlying data and models are not publicly available, but has not similarly targeted any other types of studies commonly used by EPA.

EPA also has proposed to target the requirements for public availability specifically to the data and modeling underlying one specific subset of scientific research—dose response studies. EPA has provided no explanation or justification for targeting dose response studies in particular or for not including other types of studies or scientific information. EPA has not suggested that these studies are inherently less reliable than other studies, that they more

[360] For the Harvard Six cities study, the reanalysis results were 1.28 hazard ratio for mortality per 18.6 microgram per meter cube of PM2.5, in comparison to a hazard ratio of 1.26 found in the original study. For the ACS CPSII study, the reanalysis showed that for every 25.4 microgram per meter cube change in PM2.5 there was an associated hazard ratio for mortality of 1.18 (results of the independent reanalysis), as compared to the hazard Ratio of 1.17 reported by the original investigators. Daniel Krewski, et al., *Overview of the reanalysis of the Harvard six cities study and American Cancer Society study of particulate air pollution and mortality*, 66 J. Toxicology & Envtl. Health Part A 1507 (2003); Health Effects Inst., Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality (2000).

commonly fail to publicly disclose data and modeling information, that replication is more necessary for these studies than others, or any other conceivable reason. Absent any explanation from the agency, it is impossible to comment on the factual predicates for EPA's proposed decision, or the reasonableness of EPA's justification, except to state that it appears completely arbitrary in the absence of any rationale. *See, e.g., Transactive Corp., v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996) ("A long line of precedent has established that an agency action is arbitrary when the agency offered insufficient reasons for treating similar situations differently.").

8. EPA arbitrarily failed to consider the implications of this proposal on interagency coordination.

Additionally, EPA arbitrarily failed to consider the far-reaching implications this Proposal could have on inter-agency coordination and consultation given that other agencies normally rely on research potentially excluded by the Proposal.[361] In the numerous environmental statutes that EPA cites, there are dozens of provisions that require EPA to coordinate or consult with other Federal entities—especially when implementing research programs and issuing information or guidelines.[362] The Proposal would almost certainly frustrate and impair this coordination and consultation, either by forcing EPA to ignore the science provided by other agencies or by severely restricting the science that EPA itself would be able to share with other agencies in these statutorily required processes. The Proposal arbitrarily ignores these potential impacts.

In addition to the many examples of statutorily required consultation that are identified in Appendix B, other federal agencies routinely incorporate and rely upon EPA science assessments in their own efforts to carry out their mandates to protect human health and safety. As with statutorily required consultations, the Proposal utterly fails to acknowledge or consider what impacts restricting EPA's own use of dose-response studies would have on the work of these other agencies. Indeed, there is no evidence that these other agencies were even permitted to comment on the Proposal as part of the usual process of interagency review.

Some selected examples of other federal agency programs that rely on EPA science include:

- The Food and Drug Administration (FDA) enforces tolerances established by EPA for pesticide chemical residues in human and animal foods under the Federal Insecticide,

[361] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem.").

[362] *See* 42 U.S.C. §§ 7403, 7408(a), 7408(c), 7408(f), 7412 (Clean Air Act §§ 103, 108, 112); 33 U.S.C. §§ 1314. 1317(a)(7), 1345(d)(1) (Clean Water Act §§ 304, 307(a)(7), 404(d)(1)); 42 U.S.C. §§ 6907(a), 6911, 6912(a)(2)-(6), 6942(b), 6981(a) (Resource Conservation and Recovery Act §§ 1008(a), 2001, 2002(a)(2)-(6), 4002(b), 8001(a)); 7 U.S.C. §§ 136w-3, 136w(d), 136a-1(n)(2)-(3), 136(ll)(2), 136t(b), 136i-2(c) (Federal Insecticide, Fungicide, and Rodenticide Act §§ 2, 4, 11, 22, 25, 28); 15 U.S.C. §§ 2608(d), 2604(f)(5), 2604(h)(2)(B)(ii) (Toxic Substances Control Act); 42 U.S.C. § 300g-1 (b)(1)(D), 300g-1(d), 300j-13(a)(5), 300j-3d, 300j-19(b)(2)(A) (Safe Water Drinking Act). *See also* Appendix B: Table of Consultation Requirements.

Fungicide, and Rodenticide Act, including through a comprehensive pesticide residue monitoring program that tests for approximately 700 pesticide residues in both imported and domestic commodities.[363] To the extent the Proposal affects EPA's tolerances, the nature and effectiveness of FDA's own work to monitor for violations of those tolerances would be impacted.

- FDA also regulates contaminants in bottled water under the Federal Food, Drug and Cosmetics Act. Section 410 of the Act requires that FDA regulations for bottled water be issued in coordination with the effective date of National Primary Drinking Water Regulations issued under the Safe Drinking Water Act, and be no less protective of public health than those standards. If the Proposal impedes EPA's work to establish drinking water standards, this may affect FDA's own ability to justify protective bottled water standards.[364]
- In certain circumstances, FDA also coordinates with EPA to provide the public with information and advice on environmental contaminants in foods. For example, in 2017 FDA and EPA released a joint advisory on mercury hazards associated with the consumption of fish and shellfish, which was based in part on EPA's assessment of the "reference dose" or level of exposure that a person can experience over a lifetime without a risk of harm.[365] The Proposal could radically alter the science EPA would be permitted to consider in future such initiatives, and frustrate the ability of FDA and other agencies to coordinate effectively with EPA to develop joint advice and information.
- The Department of Housing and Urban Development is required by statute to assist EPA in assessing the extent of radon contamination in the United States and developing measures to avoid and reduce radon contamination.[366] HUD has also developed policies to require radon testing at properties receiving federal financing, which incorporate EPA radon standards.[367] To the extent the Proposal affects future EPA assessments of radon risks, the scope, cost and effectiveness of HUD radon programs could be affected as well.

9. EPA's proposal irrationally excludes proceedings that tend to benefit industry interests, even though these proceedings are far less transparent than the rulemakings EPA has targeted.

EPA's claims that it values transparency are clearly a pretext for eliminating "inconvenient," life-saving science from rulemakings that increase public health protection. Among other things, by excluding adjudications, permit proceedings, and certain rulemakings, EPA has excluded proceedings where EPA and industry regularly rely on nondisclosed information and where agency action in general, and particularly expeditious action, tends to

[363] FDA, *Pesticide Residue Monitoring Program Questions and Answers, https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm583711.htm* (last visited Aug. 13, 2018).
[364] FDA, *Guidance for Industry: Bottled Water and Total Coliform and E. Coli; Small Entity Compliance Guide, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm206215.htm* (last visited Aug. 14, 2018).
[365] Advice About Eating Fish, From the Environmental Protection Agency and Food and Drug Administration; Revised Fish Advice; Availability, 82 Fed. Reg. 6572 (Jan. 19, 2017).
[366] *See* Pub. L. 100–628, title X, § 1091, Nov. 7, 1988, 102 Stat. 3283.
[367] *See* HUD, HUD Office of Multifamily Development Radon Policy, Notice H 2013-03 (Jan. 31, 2013), *available at https://www.hud.gov/sites/documents/13-03HSGN.PDF*.

favor industry. By limiting the proposal to "significant regulatory actions," the proposed rule would treat exactly the same study differently depending on whether it supports regulation or non-regulation in a particular context. The proposed rule will tend to exclude evidence when it supports a health-protective regulation that is costly to industry, but the proposed rule will then allow the use of the exact same evidence when the ultimate agency decision avoids regulation or deregulates industry activities or otherwise has low compliance costs. Thus, the Proposal is clearly shaped to favor industry interests, not to further transparency.

Specifically, EPA has chosen to limit the application of this Proposal to "significant regulatory actions" under E.O. 12866, and thus EPA does not extend this Proposal to adjudications, permit proceedings, or many less economically significant rulemakings.[368] In particular, EPA has effectively exempted the TSCA new chemicals program where industry seeks expeditious actions allowing market access and EPA regularly fails to disclose its own analyses and the studies and materials supporting those decisions, much less any underlying data. As explained below, in these proceedings industry seeks affirmative authorization from EPA to commercialize chemicals, so industry has a vested interest in expeditious government action.

EPA's decision to exempt these proceedings is particularly egregious because these proceedings are extraordinarily more opaque than the rulemakings EPA has targeted with this Proposal. In the TSCA new chemicals program, EPA often provides no meaningful opportunity for public review or comment before EPA takes action, and EPA regularly violates its existing statutory and regulatory obligations by disclosing almost none of its analyses or the information supporting its decisions to authorize the manufacture of new chemicals. Notably, much of the information at issue has never been peer-reviewed or subjected to nearly the level of public scrutiny as have the studies that EPA is trying to exclude from health-protective rulemakings under the proposed rule. EPA cannot credibly claim to pursue transparency with this Proposal while running certain programs as "black boxes" where little, if any, information is disclosed. To be clear, the problem is that EPA often does not disclose its own analyses or many of the underlying studies at all, much less underlying data; it is outrageous for EPA to then turn around and suggest that, in other contexts, disclosure of its analyses and the supporting peer-reviewed studies provides insufficient transparency.

As drafted, EPA's Proposal will not apply to EPA's New Chemicals Review Program under TSCA. TSCA § 5 governs EPA's review of "new chemical substance[s]," generally chemicals that have not previously been distributed in U.S. commerce.[369] By and large, no person may manufacture (defined to include import) a "new chemical substance" in the United States without providing EPA notice at least 90 days beforehand. [370] When a person submits a pre-manufacture notice (PMN), EPA must review the PMN and make one of three types of determinations under TSCA § 5(a)(3).[371] EPA then must take the actions required by the

[368] 83 Fed. Reg. at 18,771.
[369] *See* 15 U.S.C. §§ 2604, 2602(11).
[370] *Id.* § 2604(a)(1).
[371] *Id.* § 2604(a)(1)(B). Depending on the circumstances, instead of submitting a PMN, a person may seek to obtain one of several exemptions from the PMN process, such as the Test Marketing Exemption. The proceedings governing applications for these exemptions involve even less public disclosure than EPA's processing of PMNs. EPA's proposal will also not apply to the proceedings governing these exemptions.

relevant determination, and the person must comply with any applicable requirement imposed.[372] The person may not begin manufacturing the chemical substance until EPA has completed its review and made a determination. These proceedings do not qualify as significant regulatory actions under E.O. 12866, because EPA does not consider them rulemakings and because the regulation of chemicals that have not yet been introduced to the market generally will not be economically significant within the meaning of the E.O.

Because industry generally cannot manufacture a new chemical substance until EPA has completed its review, industry has a strong interest in expeditious action on PMNs. Nor is this idle speculation; industry commenters have repeatedly called for EPA to move more expeditiously.[373] Providing disclosure in these proceedings would likely, at a minimum, take additional time, and thus it seems likely that EPA has exempted these proceedings to serve industry's interest in hasty resolution.

Moreover, the New Chemicals Program is infinitely more opaque than the rulemakings EPA is currently targeting with its Proposal, often in direct violation of law. EPA does not make the public files for new chemicals electronically available, and when a person does obtain a copy of the public file from EPA, [374] the files generally reveal almost none of EPA's analyses supporting its decisions or the information submitted to support those decisions, with massive amounts of data redacted or concealed as Confidential Business Information (CBI). It's not a question of failing to disclose all the underlying data; EPA often fails to disclose the supporting studies or information at all.

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[372] *Id.*

[373] *See, e.g.,* Am. Coatings Ass'n Comment on New Chemicals Review Program 2 (Jan. 20,2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0068 ("We urge the Agency to expedite the process as much as possible, so that manufacturing is able to commence."), Docket ID: EPA-HQ-OPPT-2017-0585-0068; Am. Chemistry Council Comment on New Chemicals Review Program 7 (Jan. 19,2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0062 ("These delays underscore industry's continuing concerns that the section 5 program remains too slow . . . ."), Docket ID: EPA-HQ-OPPT-2017-0585-0062; U.S. Chamber of Commerce Comment on New Chemicals Review Program 3 (Jan. 19, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0057 ("[T]he Chamber believes that EPA should continue to strive to meet the 90-day goal in a timelier and more effective fashion . . . ."), Docket ID: EPA-HQ-OPPT-2017-0585-0057; Am. Petrol. Inst. Comment on New Chemicals Review Program 2 (Jan. 19, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0053 ("EPA should respond to a request for a Pre-Notice Consultation in a short timeframe—two to four days, rather than two to four weeks."), Docket ID: EPA-HQ-OPPT-2017-0585-0053; Int'l Fragrance Ass'n N. Am. Comment on New Chemicals Review Program 1 (Jan. 20, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0064 (identifying as a problem "review periods far exceeding 90 days – some exceeding a year"), Docket ID: EPA-HQ-OPPT-2017-0585-0064.

[374] As EDF has previously explained, EPA is already committing systematic procedural violations by failing to make the public files for new chemicals electronically available to the general public. Envtl. Def. Fund Comment on New Chemicals Review Program 23–26 (Jan. 20, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071, Docket ID: EPA-HQ-OPPT-2017-0585-0071. Under TSCA § 5(d), each Pre-manufacture Notice (PMN) "shall be made available, subject to section 14, for examination by interested persons." 15 U.S.C. § 2604(d)(1). EPA's implementing regulations provide that "[a]ll information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice," 40 C.F.R. § 720.95, and those public files are supposed to be "available in the electronic docket at http://www.regulations.gov." *Id.* § 700.17(b)(1). But EPA generally does not make the public files for PMNs electronically available.

As EDF detailed in prior comments and in various blog posts, EPA regularly conceals vast swathes of information in this program, including providing many blank documents identified as consisting of health and safety studies.[375] Notably, in this same context, industry commenters have urged EPA to take steps to accept data and information that will not be publicly disclosed or where EPA will only be provided with or make public industry-prepared summaries of the underlying data. *See, e.g.*, Comment submitted by Raleigh Davis, Assistant Direction, EHS, American Coatings Association (ACA), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0068 ("ACA strongly encourages EPA to develop as many of these [non-disclosure agreements] as possible."); Comment submitted by Jared Rothstein, Senior Manager, Regulatory Affairs, Society of Chemical Manufacturers & Affiliates (SOCMA), p.1 https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0049 ("EPA should accept the submission of robust summaries."). Thus, industry has expressed a desire for EPA to continue to operate the new chemicals program with limited disclosure, and thus far, EPA has acceded to that wish.

If EPA extended the rule articulated in proposed § 30.5 to the new chemicals program, it would seem that EPA would either have to make much of the information in the public files available *or* EPA would be precluded from using this information. 83 Fed. Reg. at 18.769 n.3 (stating that EPA is proposing to preclude itself from using such data in future regulatory actions). Without this information, EPA generally would not be able to find that the new chemical "is not likely to present an unreasonable risk of injury to health or the environment," the finding that allows unregulated manufacture of the chemical. *See* 15 U.S.C. § 2604(a)(3)(C). Notably, TSCA expressly provides a resolution when EPA has insufficient information, requiring that EPA regulate the chemical. *Id.* § 2604(a)(3)(B)(i), (e). When "the information available to [EPA] is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance; … [EPA] shall issue an order" regulating the chemical "to the extent necessary to protect against an unreasonable risk of injury to health or the environment." *Id.* 2604(e).Thus, excluding the information would require EPA to regulate the new chemicals before they could enter the market.

Thus, EPA's exclusion of the new chemicals program clearly favors industry, allowing industry to conceal information and evade regulation. In addition, EPA cannot rationally impose stringent new disclosure requirements that exclude extensive peer-reviewed, high-quality studies in some contexts while simultaneously authorizing the commercial distribution of new chemicals with almost no disclosure and no peer-review.

[375] Envtl. Def. Fund Comment on New Chemicals Review Program 24-25, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071. For more detail, see EDF's series of blog posts on its finding in its our review of public files for nearly 70 new chemicals for which EPA made "not likely to present an unreasonable risk" determinations, *E.g.*, Stephanie Schwartz & Richard Dennison, *EPA's Appalling Failure to Provide Public Access to Public Data on TSCA New Chemicals*, EDF Health Blog (Jan. 24,2018), http://blogs.edf.org/health/2018/01/24/epas-appalling-failure-to-provide-public-access-to-public-data-on-tsca-new-chemicals/.

E. EPA's Proposal is Arbitrary Because it is Inconsistent With Long-Standing EPA and Federal Government Policies and Ongoing Efforts to Strengthen Science Quality in a Measured and Balanced Way through EPA's Existing Science Policies.

EPA claims throughout the Proposal that it is consistent with EPA and other federal government policies and approaches to transparency. However, a closer look reveals that the documents that EPA itself cites do not support the over-simplified and drastic approach taken by the Proposal. Federal government policies to promote data transparency have instead advocated a careful approach that balances the benefits of data disclosure with the costs and risks associated with it. Nowhere do they suggest that confidential information that cannot be made public is no longer valid for agency use. Instead, they aim to maximize the integrity and usability of data through data sharing when possible and practical—to enhance rather than hinder the ability of government agencies to achieve their missions. The Proposal is based on unsubstantiated claims that lack evidence, deviates from existing EPA and broader federal government policy without acknowledgement or explanation, and conflicts with leading research and policy proposals in this area— rendering the Proposal arbitrary and capricious.

Agencies are required to justify reversals in policy by addressing the existing record and reasons for why a change in policy is appropriate.[376] They must acknowledge the change and "show that there are good reasons for the new policy."[377] The agency must supply a reasoned analysis beyond which would be required in the absence of the old policy.[378] An agency may not "disregard contrary or inconvenient factual determinations that it made in the past."[379] EPA in the past took the position that:

> [EPA] does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the Federal courts have made clear that the EPA is not required to obtain or analyze the raw data in order to rely on such studies. If the EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.[380]

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[376] *FCC v. Fox Television Stations, Inc*. 556 U.S. 502, 515 (2009).
[377] *Id*.
[378] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) ("[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").
[379] *FCC v. Fox Television Stations, Inc*. 556 U.S. 502, 537 (2009) (Kennedy, J. concurring).
[380] House of Representatives, Committee on Agriculture, *Hearing to Consider the Impacts of the Environmental Protection Agency's Actions on the Rural Economy* Serial No. 114-41, 82 (Feb. 11, 2016) (response to questions from Gina McCarthy, Administrator, EPA); *See also* Email from Nancy Beck to Justin Schwab and Richard Yamada (Mar. 5, 2018, 1:42:01 AM) (part of FOIA release to request by Union of Concerned Scientists citing EPA pesticide program documents from December 2016) (email flags language from EPA pesticide program documents: "To be clear, EPA continues to believe that the raw data should be made available for public inspection to ensure that EPA's assessments are as transparent as possible. While the EPA therefore strives to ensure that data underlying research it relies upon are accessible to the extent possible, it does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. The EPA frequently relies on peer reviewed studies in

Thus, EPA in the past set forth a view diametrically opposed to the one it is taking now—in the past relying heavily on studies it would now be excluded from using. EPA previously recognized that there are other ways to validate scientific studies, such as through peer review, that do not require release of underlying data and its prior view rightly saw the danger in adopting a policy that would require EPA to make public underlying data.

EPA's current policies set forth standards of scientific integrity that involve use of the best scientific information available (see II.D.2), which the Proposal also now re-writes. While previously EPA took the view that all valid science (with proper quality control and assessment measures in place) should be considered as it sets standards, EPA now takes the position that it is more important to use only those studies where the underlying data and models are made available to the public, even if this compromises EPA's ability to use the best available science. EPA's existing open data policies recognize with exceptions and exemptions that as much as the pursuit of making data public is a worthy goal, there are competing interests. EPA has always taken the view that not releasing certain kinds of data to uphold these competing interests does not in fact compromise its scientific integrity or commitment to transparency—and the balance it strikes is the one most suitable to help its achieve its greater mission. The Proposal is arbitrary because EPA does not even acknowledge that it is now changing its view drastically and does not address the valid reasons underlying its prior policies or explain why they now merit changing.

1. Instead of providing a reasoned explanation for its change in policy, EPA wrongfully claims the Proposal is consistent with existing EPA, federal government, and third-party practices and policies.

As discussed further below in Section VIII.D, the footnotes of EPA's Proposal in many cases provide only vague references to policies and reports that purportedly support the Proposal, leaving the public to guess as to what EPA is referring and embark on a treasure hunt for the relevant item. But even where EPA provides specific citations, examination quickly reveals that frequently they do not fully support the propositions they accompany, and, when viewed in full context, provide evidence against the Proposal. Because EPA makes a series of conclusory statements provided with no explanation or reasoning that would help the reader understand why EPA interpreted the cited record to support the Proposal, the Proposal appears to be completely unsupported by evidence and explanation—rendering it arbitrary and capricious. A full documentation of the misrepresentations made in the footnotes of the Proposal is available in Appendix A and demonstrates that EPA is not able to substantiate its claims that the Proposal has been informed by or is consistent with the policies of EPA, other agencies, or other organizations.

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the public literature across agency programs without possessing underlying data and the federal courts (see Coalition of Battery Recyclers Association v. EPA, 604 F.3d 613 (D.C. Cir. 2010); American Trucking Associations v. EPA, 203 F.3d 355 (D.C. Cir. 2002)) have made clear that EPA is not required to obtain or analyze the raw data in order to rely on such studies. If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.").

EPA claims: "The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science."[381] The sentence is accompanied by a footnote listing a number of organizations, for most of them not providing reference to any specific policies, recommendations, or statements.[382]

One of these vague references points to the Administrative Conference of the United States' Science in the Administrative Process Project, without providing further detail. Assuming that EPA is referring to the Administrative Conference of the United States' *Recommendation 2013-3: Science in the Administrative Process*, Wendy Wagner, sole author of ACUS's final report *Science in Regulation: A Study of Agency Decisionmaking Approaches* and who served on the panel that produced the Bipartisan Policy Center's recommendations also cited by the Proposal has stated: "They don't adopt any of our recommendations, and they go in a direction that's completely opposite, completely different. . . . They don't adopt any of the recommendations of *any* of the sources they cite. I'm not sure why they cited them."[383] While ACUS recommends agencies increase transparency of how they rely on scientific information and strive to make data underlying scientific information publicly available, nowhere does it suggest that agencies should not consider or rely on studies where underlying data and models cannot be made publicly available, or that these circumstances make scientific information less valid. ACUS instead suggests that information be made publicly available "to reproduce or assess the agency's technical or scientific conclusions" "[c]onsistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines"[384] Moreover, ACUS acknowledges valid limitations on public disclosure of data such as legal protections for privacy, trade secrets, and confidential business information.[385] Thus, ACUS recommends data be made public only "[t]o the extent practicable and permitted by law and applicable policies."[386] Unlike the Proposal, the recommendation acknowledges that agencies may still use information where underlying data cannot be publicly disclosed, and suggest agencies "note that fact and explain why they used the results if they chose to do so."[387] It thus provides a much more nuanced policy recommendation than that outlined in the Proposal—which suggests EPA either find a way to make underlying data and models public, despite the numerous potential obstacles and concerns in doing so, or completely disregard the research study.

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[381] 83 Fed. Reg. at 18,770.
[382] 83 Fed. Reg. at 18,770. n. 10 ("These include policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data*, *Expanding Access to Research Data*, and *Access to Research Data in the 21st Century;* the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project").
[383] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 25, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/.
[384] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process*, 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).
[385] 78 Fed. Reg. 41,352, 41,358 n.12 (July 10, 2013).
[386] 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).
[387] 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

EPA's claims that its Proposal is consistent with the policies of major science journals is similarly misleading. [388] EPA does not explain why the policies of scientific journals regarding the disclosure of data underlying their published studies *should* inform how an agency with a mission to protect human health and the environment uses research for regulatory actions. Additionally, these journals' policies provide exceptions for when privacy or other concerns do not allow for public sharing of data, and they never represent that this on its own weakens the validity of the research.[389] And, as discussed supra in Section I.B.2.a), the editors of these journals have specifically dismissed the Proposal.[390]

EPA wrongfully claims its policy is consistent with existing OMB and EPA policies, while failing to recognize that these polices—while advocating for more transparency—take a measured, nuanced approach to data disclosure.[391] EPA cannot finalize this policy without acknowledging and providing a reasoned explanation for its divergence from long-standing policy and without providing actual evidence that supports the Proposal, which it has not done. Prior policies recognize that government decision-making requires considering all scientific information, and legitimate limitations to data disclosure should not obstruct sound policy-making. EPA cannot rely on these documents to support the rule, leaving an inadequately thin record of evidence to support the Proposal, and must respond to policy rationales articulated in these documents as it now changes course.

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[388] 83 Fed. Reg. at 18,770 (EPA states that the policies and recommendations it considered were "informed by the policies recently adopted by some major scientific journals and cites to "related policies from the Proceedings of the National Academy of Sciences, PLOS ONE, Science, and Nature."); 83 Fed. Reg. at 18,771 n. 20 (citing "policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature" as potential mechanisms for compliance with Proposal).

[389] Taylor & Francis, *Data Sharing FAQs*, https://authorservices.taylorandfrancis.com/data-sharing-faqs/ (All our policies allow exceptions where data sharing violates protection of human subjects or other valid subject privacy concerns.) (last accessed Aug. 15, 2018); Elselvier, *Research Data Policy*, https://www.elsevier.com/about/our-business/policies/research-data (policy merely encourages when possible, rather than requires, data sharing: "Research data should be made available free of charge to all researchers wherever possible and with minimal reuse restrictions.") (last accessed Aug. 15, 2018); PLOS One, *Data Availability*, http://journals.plos.org/plosone/s/data-availability (allows exceptions to making data public "for ethical or legal reasons, e.g., public availability would compromise patient confidentiality or participant privacy" or present other threats) (last accessed Aug. 15, 2018); Springer Nature, *Research data policies FAQs*, https://group.springernature.com/gp/authors/research-data-policy/faqs/12327154 ("reasonable restrictions on data availability are permitted to protect human privacy, biosafety or respect reasonable terms of use for data obtained under license from third parties.") (last accessed Aug. 15, 2018). *See, also*, discussion in Appendix A.

[390] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

[391] EPA states: "This proposed rule is also consistent with . . . the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies* (the Guidelines) and OMB *Memorandum 13–13: Open Data Policy—Managing Information as an Asset*." 83 Fed. Reg. at 18,769-70. EPA says the Proposal "builds upon prior EPA actions in response to government wide data access and sharing policies," that it applies "concepts and lessons learned" from implementation of to the 2016 *Plan to Increase Access to Results of EPA-Funded Scientific Research*, 83 Fed. Reg. at 18,770, also citing to EPA *Open Government Plan 4.0*, *Open Data Implementation Plan*, *EPA's Scientific Integrity Policy*, and *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, 83 Fed. Reg. at 18,770 n. 8.

The *Plan to Increase Access to Results of EPA-Funded Scientific Research*, discussed supra at I.B.2.b), represents the view EPA has consistently espoused in the past, that when it can make data available without compromising other critical values, it does, but will not exclude information from its consideration when it cannot.[392]

EPA cites to its implementation of OMB's guidelines, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. These Guidelines note "[t]he mission of the EPA is to protect human health and safeguard the natural environment upon which life depends" and "[t]he collection, use, and dissemination of information of known and appropriate quality are integral to ensuring that EPA achieves its mission."[393] They thus highlight that the controls on data quality exist to allow EPA to meet its mission—unlike the Proposal, which changes EPA's existing view by placing transparency of data, apparently for its own sake even when unrelated to data quality, ahead of EPA's ability to achieve its mission. As explained above in Section I.C, the Proposal violates the Information Quality Act and these Guidelines.[394]

EPA disregards the careful approach to data disclosure outlined in OMB Memorandum M-13-13, *Open Data Policy-Managing Information as an Asset*, which requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities, and does not establish a policy of requiring agency data to be made public in order for the agency to be able to rely on it.[395] It recognizes that sharing agency data with the public can result in numerous benefits, but requires careful thought about privacy and confidentiality concerns. The memorandum establishes "a framework to help institutionalize the principles of effective information management at each stage of the information's life cycle to promote interoperability and openness," noting "[w]hether or not particular information can be made public, agencies can apply this framework to all information resources to promote efficiency and produce value."[396] It places consideration of privacy concerns at the forefront, saying "[a]gencies should exercise judgment before publicly distributing data residing in an existing system by weighing the value of openness against the cost of making those data public."[397] EPA has provided no indication that it has carefully weighed these costs and benefits.

Before agencies make data publicly available, OMB Memorandum M-13-13 requires that agencies "review the information collected or created for valid restrictions" such as legal, "privacy, confidentiality pledge, security, trade secret, contractual, or other valid restrictions to release."[398] OMB recognizes these restrictions "may affect the amount, type, form, and detail of

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[392] *See, also*, discussion in Appendix A.
[393] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA/260R-02-008)* 5 (Oct. 2002), https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.
[394] *See, also*, discussion in Appendix A.
[395] OMB Memorandum M-13-13, *Open Data Policy-Managing Information as an Asset* 1 (May. 9, 2013).
[396] *Id.*
[397] *Id.* at 6.
[398] *Id.* at 9.

data released by agencies."[399] It also requires agencies to consider the "'mosaic effect' of data aggregation," discussed at Section II.A.2.b)ii, which EPA does not acknowledge at all in the Proposal.[400]

EPA's *Open Government Plan 4.0* acknowledges that not all data is releasable to the public, even as it aims to "increase publicly accessible EPA data to support citizens' participation in government and promote transparency and accountability of Agency operations."[401] EPA states: "By providing *releasable* information in open and machine-readable formats, EPA enables the public and other organizations to better leverage the rich wealth of information available."[402] EPA's own *Open Data Policy* notes that it is important to develop "policies and processes to ensure that only appropriate data are released to the public and made available online."[403] To do so, EPA uses different "access levels" for different data sets, (public, restricted public and non-public) and notes that it may not be able to publicize data due to "law, regulation or policy, which address privacy, confidentiality, security or other valid restrictions."[404] EPA has not made clear that restricted access would satisfy the requirement of making information "publicly available." The Proposal seems to completely do-away with this multi-level, nuanced approach, imposing a blanket "publicly available" requirement for all studies EPA intends to rely on, despite obstacles to their release.

The Proposal turns away from EPA's *Scientific Integrity Policy*, which stresses "a firm commitment to evidence,"[405] endorses use of "the best available science"[406] and "[r]equire[s] reviews. . . regarding the content of a scientific product to be based only on scientific quality considerations."[407] The Proposal, on the other hand, inhibits use of sound scientific information and evidence by arbitrarily excluding science for reasons unrelated to its quality. While the policy "[r]ecognizes the value of independent validation of scientific methods"[408] and facilitating "the free flow of scientific information" by making information available "including access to data and non-proprietary models underlying Agency policy decisions,"[409] this is proposed as a flexible standard and an ideal to aspire to, not an absolute rule that takes priority over other competing interests—such as use of the best scientific information. As discussed more in Section VII.C this Administration has blatantly violated key aspects of the policy by silencing scientists and the dissemination of scientific information, which this Proposal seems aimed at continuing, directly undoing "EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information – uncompromised by political or other interference" and goal to communicate scientific findings openly and actively to the public.[410] By now placing

[399] *Id.* at 10.
[400] *Id.* at 9-10.
[401] EPA, *Open Government Plan 4.0* 4 (Sept. 2016).
[402] *Id.* (emphasis added).
[403] EPA, *Open Data Policy Implementation Plan* 4, https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf.
[404] *Id.*
[405] EPA, *Scientific Integrity Policy* 3.
[406] *Id.* at 3-4.
[407] *Id.* at 4.
[408] *Id.*
[409] *Id.*
[410] *Id.* at 5.

"transparency" ahead of use of the best available science, aside from violating statutory requirements, EPA is changing its own policies and priorities and must justify this new position.

In footnote 2, EPA dubiously claims the Proposal is consistent with the *Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity* (Mar. 9, 2009).[411] Notably, the Memorandum specifies, "Except for information that is *properly restricted from disclosure* under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions."[412] Not only does the Memorandum provide no support for the notion that agencies should be barred from relying on studies where the underlying data is properly restricted from disclosure it additionally discusses disclosure only of findings and conclusions, not underlying data.

Thus, despite EPA's claims to the contrary, the Proposal marks a shift in policy that EPA has up to this point followed EPA arbitrarily fails to acknowledge this shift, to identify good reasons for the change, or to explain why EPA believes the proposed rule would be an improvement over current mechanisms utilized by EPA to ensure the integrity of EPA's actions.

2. EPA's Proposal fails to consider important implementation problems that existing EPA and federal government policies place at the forefront.

An agency rule is arbitrary and capricious if it "entirely failed to consider an important aspect of the problem."[413] EPA's Proposal completely fails to consider the numerous barriers that currently exist to making underlying data public. As highlighted in OMB and EPA policies, there is an understanding that the worthy goal of ensuring greater transparency of scientific information is in tension with other compelling, competing interests such as privacy and confidentiality. When these two are in tension, existing policies have recognized that this will prevent certain data from being publicly released—and that agencies still need to be able to use scientific information in these circumstances. Transparency goals should not override the ability of the agency to rely on otherwise valid scientific information as it goes about achieving its core mission. While the Proposal purports to take into account privacy and confidentiality concerns, it appears to do so by either grossly oversimplifying EPA's ability to address these concerns or by deeming all such information unusable—essentially completely failing to consider the problems of this approach.

OMB Circular A-130 recognizes that the values of openness, transparency, and allowing the free flow of information between the federal government and the public are important values, they must be contextualized. Thus, it cautions: "Promoting openness and interoperability, *subject*

[411] 83 Fed. Reg. at 18,769 n. 2 ("If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking.")

[412] *Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity* (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009), https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09 (emphasis added).

[413] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

to applicable legal and policy requirements, increases operational efficiencies, reduces costs, improves services, supports mission needs, and increases public access to valuable Federal information."[414] Similarly it states: "The open and efficient exchange of scientific and technical Federal information, *subject to applicable security and privacy controls* and the proprietary rights of others, fosters excellence in scientific research and effective use of Federal research and development resources."[415] Circular A-130 makes clear that "[p]rotecting an individual's privacy is of utmost importance. The Federal Government shall consider and protect an individual's privacy throughout the information life cycle."[416] It requires that agencies recognize that "Federal information is managed by making information accessible, discoverable, and usable by the public to the extent permitted by law and *subject to privacy, security (which includes confidentiality), or other valid restrictions pertaining to access, use, dissemination, and disclosure. . . .*"[417]

Further, Circular A-130 requires agencies to "[l]imit the creation, collection, use, processing, storage, maintenance, dissemination, and disclosure of [personally identifiable information] to that which is legally authorized, relevant, and reasonably deemed necessary for the proper performance of agency functions" and "[t]o the extent reasonably practicable. . .reduce all [personally identifiable information] to the minimum necessary for the proper performance of authorized agency functions."[418]

The appendix to the Circular realizes that privacy protections require ongoing progress and:

> Emerging technologies and services may continue to shift the ways in which agencies acquire, develop, manage, and use information and technology. As technologies and services continue to change, so will the threat environment. Agency programs must have the capability to identify, respond to, and recover from current threats while protecting their information resources and the privacy of the individuals whose information they maintain.[419]

OMB Memorandum M-14-06 specifically lays out policies intended to help agencies make the most of "administrative data that cannot be made publicly available due to statutory, regulatory, or policy protections," for statistical purposes, including "activities typically characterized as research, evaluation, and analysis, as long as the focus of those activities is on reporting aggregate findings about a group."[420] It notes "[s]ome administrative data can be publicly released, whereas other administrative data cannot be released. . . [and] it is the case that both types of administrative data (public and nonpublic) can be useful for Federal statistical

[414] OMB Circular A-130 at 3 (emphasis added).
[415] *Id.* at 4 (emphasis added).
[416] *Id.*
[417] *Id.* at 14 (emphasis added).
[418] *Id.* at 17.
[419] *Id.* at Appendix 1-1.
[420] OMB Memorandum M-14-06 at 6.

purposes," suggesting agencies should not abandon reliance on data not able to be publicly released.[421]

OMB Memorandum M-11-02 "strongly encourages Federal agencies to engage in coordinated efforts to share high-value data" but notes that in certain cases sharing data will contravene other compelling concerns and that federal agencies need to think about applicable privacy laws, regulations, and policies to "fully protect[] individual privacy" and preserve public trust.[422] Unlike the Proposal, it takes a more nuanced approach recognizing that sharing data is not always appropriate and should only be done "responsibly and appropriately."[423]

OMB recognizes that even when just sharing information among agencies, privacy concerns must be weighed against those benefits that agencies can achieve with sharing data: "Agencies should work together to determine what data sharing opportunities are desirable, feasible, and appropriate. In general, data sharing should only be pursued if the benefits outweigh the costs."[424]

OMB Memorandum M-10-06 also encourages "a plan for timely publication of the underlying data. . . in an open format and as granular as possible, consistent with statutory responsibilities and subject to valid privacy, confidentiality, security, or other restrictions."[425] The memorandum aims to achieve "transparency, participation, and collaboration,"[426] recognizing that not making data available does not deter those goals when there are valid concerns and the legitimacy of the data is not otherwise questioned.

EPA's *Draft Strategic Data Action Plan Version 1.0* similarly aims to work towards a more open government, and to increase the public's access to high quality data. However, the agency recognizes barriers to this goal, not applying the plan to "data resources containing Confidential Business Information (CBI) or sensitive data that are not available for public access."[427] In similarly recognizes that "[i]n order to protect the privacy and security of the public, businesses, and US Government staff and operations, some types of data may be deemed sensitive and will not be made public or published on Data.gov."[428]

These all highlight instances where EPA and OMB have recognized that privacy and confidentiality present ongoing concerns that are not easily addressed and that conflict with other aims of federal government. Yet, they recognize that protecting information in these cases is a valid path, and not making data public does not compromise the validity of the findings or

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[421] *Id.* at 2.
[422] OMB Memorandum M-11-02.
[423] *Id.*
[424] Memoranda 01-05 -- Guidance on InterAgency Sharing of Personal Data - Protecting Personal Privacy (Dec. 20, 2000), https://www.whitehouse.gov/wp-content/uploads/2017/11/2001-M-01-05-Guidance-on-Inter-Agency-Sharing-of-Personal-Data-Protecting-Personal-Privacy.pdf.
[425] OMB Memorandum M-10-06 on Open Government Directive at 8.
[426] *Id.* at 1.
[427] EPA, *Draft Strategic Data Action Plan Version 1.0* 3 (Mar. 2011) https://www.epa.gov/sites/production/files/documents/epa_sdap_v1.0.pdf.
[428] *Id.* at 14.

conclusions upon which the data is based and should prevent agencies from using those findings, conclusions, and data to inform their work. The Proposal provides no explanation for why EPA is now changing its view to a conflicting one, making the Proposal arbitrary.

III. The Proposed Rule's Peer Review Provisions Raise Numerous Concerns.

Proposed section 30.7 provides that "EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions* consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 Fed. Reg. 2664) and the exemptions described therein." This proposed provision generally appears to be designed to enshrine OMB's existing peer review requirements for "influential scientific information."[429]

Remarkably, the preamble to the proposed rulemaking lacks any explanation whatsoever for why EPA is proposing this new peer review requirement or what its impact might be. EPA has additionally not provided any information to suggest that EPA is not already following OMB's Peer Review Bulletin. EPA's lack of any supporting rationale or analysis frustrates the public's ability to provide meaningful comment on this provision,[430] and is itself a sign that this requirement is fundamentally arbitrary. In addition, the discussion below outlines several specific concerns with this proposed regulatory requirement.

A. EPA Has Failed to Consider the Costs of Making OMB Peer Review Requirements Judicially Enforceable.

The most obvious change wrought by EPA's incorporation of OMB's Peer Review Bulletin into EPA's regulations is that it apparently would make the OMB Peer Review requirements judicially enforceable. At present, OMB Peer Review Bulletin requirements are not judicially enforceable.[431] Rather, the Bulletin "specifically disclaims that its contents create any enforceable rights, thereby preserving the agency's discretion to interpret and apply" the Bulletin.[432] If EPA finalizes its proposed peer review rules, EPA may find itself subject to countless legal challenges to its regulations based on compliance with OMB Peer Review requirements. These additional legal challenges would come at a cost, including the financial cost of increased litigation as well as the cost to public health and the environment when unwarranted legal challenges lead to lengthy delays in implementation of needed regulatory protections. Given that EPA is already subject to OMB Peer Review requirements, it is unclear

[429] OMB, *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664, 2677 (Jan. 14, 2005) [Hereinafter: OMB Peer Review Bulletin].
[430] *See Connecticut Light & Power Co. v. Nuclear Regulatory Com*., 673 F.2d 525, 530 (D.C. Cir. 1982) ("The purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rule-making process. If the notice of proposed rule-making fails to provide an accurate picture of the reasoning that has led the agency to the proposed rule, interested parties will not be able to comment meaningfully upon the agency's proposals."); *Honeywell Int'l, Inc. v. EPA*, 372 F.3d 441, 445, (D.C. Cir. 2004) ("Under the Administrative Procedure Act, a notice of proposed rulemaking must "provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.").
[431] OMB Peer Review Bulletin § XII, 70 Fed. Reg. at 2674 ("This Bulletin is intended to improve the internal management of the executive branch, and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.").
[432] *Family Farm Alliance v. Salazar*, 749 F.Supp. 2d 1083, 1095 (E.D. Ca. 2010).

whether the proposed regulation would provide any new benefits in terms of ensuring that EPA's regulations are based on valid and unbiased science. Yet the administrative record for this proposed rulemaking is devoid of any EPA analysis of the costs and benefits of making the existing peer review requirements judicially enforceable. EPA must carefully evaluate the anticipated costs and benefits from these proposed regulatory requirements and provide a reasoned explanation for why they are needed.

B. EPA Must Clarify that Studies that Have Already Been Adequately Peer-Reviewed by Third Parties Need Not be Re-Reviewed by EPA.

Because proposed section 30.7 expressly incorporates the OMB Peer Review Bulletin "and the exemptions described therein," it appears that EPA intends to incorporate the OMB Peer Review Bulletin provision providing that "agencies need not have further peer review conducted on information that has already been subjected to adequate peer review."[433] However, there is some ambiguity due to language in proposed section 30.7 instructing that EPA must "ask peer reviewers to articulate the strengths and weaknesses of EPA's justifications for the assumptions applied and the implications of those assumption for the results." Obviously, peer review conducted prior to EPA's reliance on a study would not have involved review of the strengths and weaknesses of EPA's justifications. If EPA were required to re-peer review all influential scientific information, this rulemaking would burden EPA with needless and significant costs that likely would bring many EPA rulemakings to a standstill, preventing EPA from fulfilling its statutory mission of protecting public health and the environment. To prevent this from happening, EPA must clarify that the proposed rule will not supplant EPA's existing authority under the OMB Peer Review Bulletin not to conduct further peer review where information has already been subject to adequate peer review—and that such prior peer review is not subject to the requirement in proposed section 30.7 that reviewers consider the strengths and weaknesses of EPA's justifications.

C. EPA Must Clarify the Intent of the Exemption Provision with Respect to Peer Review Requirements and Confirm that the OMB Peer Review Bulletin's Waiver Provision Would Remain in Effect for EPA.

EDF does not support the peer review provisions for the reasons detailed in this section, but if EPA moves ahead with these proposed provisions, EPA must revise the proposed regulatory language to clarify that the waiver authority provided by the OMB Peer Review Bulletin—which OMB itself has emphasized "ensure[s] needed flexibility"—would remain in effect for EPA even if EPA finalizes the proposed peer review regulations.[434]

Proposed section 30.9(b) provides that the Administrator may grant an exemption from the peer review requirements if he or she determines that "[it] is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality for Peer Review (70 FR 2664), Section IX." Oddly, however, only two of the seven enumerated exemptions in Section IX of the OMB Peer

[433] OMB Peer Review Bulletin, 70 Fed. Reg. at 2675.
[434] OMB Peer Review Bulletin, 70 Fed. Reg. at 2673.

Review Bulletin pertain to feasibility—Exemption 1 governing "national security, foreign affairs, or negotiations involving international trade or treaties" and Exemption 3 governing time-sensitive health or safety disseminations.[435] If EPA decides to finalize peer review requirements, EPA must amend its proposed regulation to clarify that all of the exemptions set forth in section IX of the OMB Peer Review Bulletin remain in effect regardless of whether they pertain to feasibility. Furthermore, EPA must clarify what, if any, additional effect is intended by the exemption provision in proposed section 30.9.

Additionally, EPA must amend the proposed rule to confirm that the "Deferral and Waiver" provision set forth in Section VIII of the OMB Peer Review Bulletin remains in effect for EPA. That provision provides: "The agency head may waive or defer some or all of the peer review requirements of Sections II and III of this Bulletin where warranted by a compelling rationale. If the agency head defers the peer review requirements prior to dissemination, peer review shall be conducted as soon as practicable." [436] OMB explained that this provision "ensure[s] needed flexibility in unusual and compelling situations not otherwise covered by the exemptions in the Bulletin before information is disseminated."[437] If EPA were to finalize the "exemption" language in proposed section 30.9(b) without clarification, it is possible that it could be read to encompass the entirety of the Administrator's ability to grant exemptions, supplanting Section VIII of the OMB Peer Review Bulletin.

D. EPA Must Clarify How the Proposed Rule Would Impact EPA's Existing Peer Review Handbook.

EPA's Peer Review Handbook incorporates the provisions of OMB's Peer Review Bulletin.[438] In the Handbook, EPA confirms that it "conducts peer review of its products in accordance with the guidance in the OMB Peer Review Bulletin."[439] However, the EPA Peer Review Handbook adds details and specific procedures that are not present in the OMB Peer Review Bulletin.

Surprisingly, EPA's proposed peer review regulations do not even mention EPA's Peer Review Handbook, let alone explain how the new proposed regulations would impact EPA's compliance with the Handbook. For example, EPA's Handbook specifies "exemption criteria" in Section 3.3.[440] EPA must clarify whether anything in the proposed peer review regulation would supplant instructions in the Peer Review Handbook, and if so, provide a reasoned explanation for the change. Likewise, EPA must explain the role of the Peer Review Handbook going forward in administering peer review requirements.

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[435] OMB Peer Review Bulletin, 70 Fed. Reg. at 2674.
[436] OMB Peer Review Bulletin, 70 Fed. Reg. at 2673.
[437] OMB Peer Review Bulletin, 70 Fed. Reg. at 2673.
[438] U.S. EPA, *Science and Technology Policy Council Peer Review Handbook*, 4th Ed. (2015), https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf. [Hereinafter: EPA Peer Review Handbook].
[439] EPA Peer Review Handbook at 26.
[440] EPA Peer Review Handbook at 44-45.

IV. The Proposal Would Impose Arbitrary and Inappropriate Methods for Assessing Health Risks

A. EPA's Proposal Seeks to Undermine Key Scientific and Public Health Tenets Relating to Dose-Response and the Use of Defaults.

The proposed rule asserts that a broad interest of the current Administration is to "ensure that the data and models underlying scientific studies that are pivotal to. . . regulatory action are available to the public"[441] and to "change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis."[442] However, the Proposal specifies a particular interest and initial focus on "dose response data and models" as evident throughout the preamble and proposed regulatory provisions.

Dose-response studies are a critical element of risk assessments for toxicants including air pollutants. Assessment of a toxicants risks typically proceeds through a four-step process: 1) hazard identification, 2) dose-response assessment, 3) exposure assessment, and 4) risk characterization.[443] Dose-response assessment describes the relationship between exposure to a toxicant and observed effect on human or ecological receptor. EPA provides the following description of dose-response on its website: "Dose-Response Assessment…characterizes the quantitative relationship between chemical exposure and each credible health hazard. These quantitative relationships are then used to derive toxicity values."[444] Dose-response plays a central role in the evaluation of chemical risks as it provides the characterization of the potency or effect size of the toxicant. In other words, dose-response assessment is used to determine the levels of exposure at which adverse effects will occur and thus informs what risk management actions should be taken to protect human and ecological health. Dose-response assessments are commonly used to derive chemial toxicity values. The lower a substance's toxicity value the greater its potency and the less exposure is necessary for an effect to occur.

EPA reveals the underlying motivation behind its interest in transparency of dose-response data and models on page eight of the Proposal, where it states:

> In addition, this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies

[441] Proposed Rule, 83 Fed. Reg. at 18769-70.
[442] Proposed Rule, 83 Fed. Reg. at 18770.
[443] EPA, *Conducting a Human Health Risk Assessment*, https://www.epa.gov/risk/conducting-human-health-risk-assessment (last accessed Aug. 16, 2018).
[444] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last accessed Aug, 16, 2018).

> that explore: A broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models.[445]

This excerpt raises several troubling and erroneous concepts that are contrary to core scientific tenets and best practices in chemical hazard and risk assessment as discussed extensively in a seminal 2009 report by the National Academies (Academies): *Science and Decisions: Advancing Risk Assessment (Science and Decisions)*.[446] The report was requested and sponsored by EPA's National Center for Environmental Assessment and was developed over a three-year period by a 15-member committee that included state environmental agencies, non-governmental organizations, industry, and academic institutions. The committee was specifically tasked with "developing scientific and technical recommendations for improving risk analysis approaches used by EPA, including providing practical improvements that EPA could make in the near term (2-5 years) and in the longer term (10-20 years)."[447] The report has been cited over 400 times in the scientific literature.

The Proposal fails to discuss these best practices for risk assessment, much less provide any persuasive reason for departing from them. The Proposal provides no support for its assertion that there is "growing empirical evidence" of nonlinearity in dose-response relationships; fails to acknowledge or contend with the National Academies' finding that non-threshold dose-response relationships are common for toxicants, and should be assumed as a default; fails to discuss the well-known rationales put forward by the National Academies for using default models; and irrationally prioritizes consideration of studies that employ a wide range of dose-response models, without any consideration for whether those alternative dose-response models are appropriate for risk assessment. Alarmingly, the Proposal offers no analysis of how the proposed requirements to consider threshold-response relationships and avoid default models would further the protection of human health and the environment—and gives no indication that the Agency has considered whether its proposed approach affords appropriate protection for the public in evaluating the risks of dangerous pollutants and toxicants. The proposed requirement is irretrievably arbitrary and unjustified, and must be withdrawn.

1. <u>The proposal arbitrarily dismisses linear (i.e., non-threshold) dose-response relationships.</u>

EPA makes a blanket assertion that "there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects" without any evidentiary basis.[448] In contrast, in *Science and Decisions*, the Academies discussed at length the

[445] Proposed Rule, 83 Fed. Reg. at 18770.
[446] National Academies, *Science and Decisions: Advancing Risk Assessment* (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.
[447] *Id*.
[448] Proposed Rule, 83 Fed. Reg. at 18770.

evidence for the opposite. Namely, non-linear dose-response relationships—that is the existence of thresholds of chemical exposure below which effects are not expected to be observed—is the exception rather than the rule when considering background exposures, co-exposures, variability across the diverse population and other considerations. The *Science and Decisions* report notes:

> . . . [A]n individual's risk from exposure to an environmental chemical is determined by the chemical itself, by concurrent background exposures to other environmental and endogenous chemicals that affect toxicity pathways and disease processes, and by the individual's biologic susceptibility due to genetic, lifestyle, health, and other factors. How the population responds to chemical insults depends on individual responses, which vary among individuals.[449]

In this regard, it is important to note that risk assessments are typically designed to estimate incremental risk in the population due to exposure to a single hazard. As discussed by the Academies, individual risk is determined by both the chemical exposure and an individual's unique circumstance of factors (e.g., co-exposures and susceptibilities). Cancer incidence in the population illustrates the significance of these additional factors in considering actual individual risk to a particular chemical exposure. Individual lifetime risk of developing cancer is 1 in 3, and 1 in 5 for dying from cancer,[450] indicating a substantial population baseline risk resulting from a large number of exposures and other risk factors. Assuming that there is somehow a threshold for everyone cannot be supported by the evidence. Therefore, given that the mission of EPA is to protect public health, the linear approach is most appropriate unless there is strong evidence in favor of an alternative as recommended in *Science and Decisions*.

EPA currently approaches risk assessment of 1) carcinogens and 2) noncarcinogens and carcinogens "acting through an MOA [mode of action] considered nonlinear at low doses"[451] separately—applying a linear dose-response framework for the former and a non-linear dose-response framework for the latter. The Academies strongly argued against this arbitrary distinction and recommended a uniform *linear* approach to the assessment of all chemicals. Indeed, for carcinogens purported to have a non-linear MOA, the Academies indicated:

> . . . omissions in this overall approach for low-dose nonlinear carcinogens could yield inaccurate and misleading assessments. . . . [T]he current EPA practice of determining "nonlinear" MOAs does not account for mechanistic factors that create linearity at low dose. The dose-response relationship can be linear at a low dose when an exposure contributes to an existing disease process. Effects of exposures that add to background processes and background endogenous and exogenous exposures can lack a threshold if a baseline level of dysfunction occurs without the toxicant and the toxicant adds to or augments the background process. Thus, even small doses may have a relevant biologic effect. That may be difficult

[449] National Academies, *Science and Decisions: Advancing Risk Assessment* 135 (2009).
[450] American Cancer Society, Lifetime Risk of Developing or Dying From Cancer, https://www.cancer.org/cancer/cancer-basics/lifetime-probability-of-developing-or-dying-from-cancer.html (last revised Jan. 4, 2018).
[451] National Academies, *Science and Decisions: Advancing Risk Assessment* 129 (2009).

> to measure because of background noise in the system but may be addressed through dose-response modeling procedures. Human variability with respect to individual thresholds for a nongenotoxic cancer mechanism can result in linear dose-response in the population.[452]

Similarly, for noncarcinogens, the Academies indicated that "noncarcinogens can exhibit low-dose linearity, for example, when there is considerable interindividual variability in susceptibility and each individual has his or her own threshold, especially when an underlying disease (such as cardiopulmonary disease) can interact with the toxicant (such as particulate matter [PM] or ozone)."[453]

The Academies ultimately and definitively recommended that "cancer and noncancer responses be assumed to be linear as a default. . . [and that] [a]n alternative analytic option. . . is available for cases in which it can be shown that background is unlikely to be an important contributor to risk, according to the recommended evaluation of MOAs and background."[454]

2. The proposal improperly dismisses defaults.

EPA's Proposal also indicates an interest and intent to move away from "default models, without consideration of alternatives or model uncertainty" which purportedly "can obscure the scientific justification for EPA actions."[455] Here, EPA demotes and ignores the purpose of science-based defaults, in suggesting that they "obscure the scientific justification for EPA actions" while simultaneously encouraging routine application of model alternatives without meaningful justification or substantiation.

Again, EPA's Proposal deviates significantly from the recommendations in *Science and Decisions* where the Academies wrote,

> [D]efaults need to be maintained for the steps in risk assessment that require inferences or to fill common data gaps. Criteria are needed for judging whether, in specific cases, data are adequate to support a different inference from the default (or whether data are sufficient to justify departure from a default).[456]

The Academies further recommended that 1) "EPA should continue and expand use of the best, most current science to support or revise its default assumptions," 2) "work toward the development of explicitly stated defaults to take place of implicit or missing defaults," and 3) that "departure [from defaults] should occur only when the evidence of the plausibility of alternatives is clearly superior to the evidence of the value of the default."[457] These recommendations underscore and reaffirm the role of defaults, and make clear that deviations

[452] National Academies, *Science and Decisions: Advancing Risk Assessment* 129-30 (2009).
[453] National Academies, *Science and Decisions: Advancing Risk Assessment* 131 (2009).
[454] National Academies, *Science and Decisions: Advancing Risk Assessment* 180 (2009).
[455] Proposed Rule, 83 Fed. Reg. at 18770.
[456] National Academies, *Science and Decisions: Advancing Risk Assessment* 207 (2009).
[457] *Id.*

from defaults are to be considered carefully, on a case-by-case basis, and only when adequately justified.

3. The Proposal arbitrarily promotes studies that include a variety of dose-response models.

EPA's Proposal promotes the use of studies that explore a variety of dose-response models. Use of dose-response models to estimate pollutant or chemical risk should generally address issues such as goodness-of-fit, confidence bounds around predicted risks, biological plausibility, and sensitivity of the prediction to untested assumptions.[458]

However, giving higher weight to studies that use a wide range of models just because they use a wide range models is wholly inappropriate, arbitrary, and without scientific or public health justification. In fact, it creates a perverse incentive to apply multiple models to data without regard to appropriateness of fit and underlying assumptions (among other key considerations), and importantly, without regard to public health and ecological protection. It is worth noting that nowhere in the Proposal has the agency articulated how this requirement would further its primary mission and purpose of protecting human health and the environment.

There are numerous dose-response analyses that could be applied to any data set. Any analysis of the data assumes an underlying statistical distribution of the data, models for mean response, variance structures, shapes, and other data fit considerations that are subject to choice in the formal analysis. Scientists have historically used a reduced set of science-based, empirically supported models for specific types of data that have obtained widespread acceptance. EPA's specification of various types of modeling approaches the agency should consider ignores this reality.

4. The proposed rule provides no justification for codifying scientific approaches into regulation.

The proposed rule's provisions addressing dose-response models are inappropriate for the numerous reasons discussed in this section. They also unnecessarily and inappropriately memorialize highly complex and technical scientific issues into regulation—a generally frowned approach given the inherently evolving nature of science. These issues are more appropriately dealt with in guidance, a more flexible vehicle better equipped for adapting to new scientific understanding and in this way supporting use of best available science.

V. EPA Fails to Adequately Consider Costs and Benefits of the Proposal.

It is arbitrary and capricious to "'entirely fai[l] to consider an important aspect of the problem' when deciding whether regulation is appropriate." *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (quoting *State Farm*, 463 U.S. at 43). As in *Michigan*, failure to consider the costs and benefits of a regulation where there is no statutory bar to doing so is arbitrary and capricious.

[458] Nat'l Research Council, Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment (2006), https://www.nap.edu/catalog/11688/health-risks-from-dioxin-and-related-compounds-evaluation-of-the.

The proposed rule entirely fails to comply with the requirements of non-arbitrary-and-capricious rulemaking because it fails to disclose, much less analyze or consider, any of the costs of the rule; barely discusses and does not analyze or quantify the benefits; does not provide any *reasoned* explanation of why the benefits of the rule justify its costs; and does not consider potential alternatives. The Proposal's discussion of costs and benefits is a scant two paragraphs[459] (and was apparently not included at all in the version sent to the Office of Management and Budget).[460] The proposed rule begins by conclusorily asserting that "EPA believes the benefits of this proposed rule justify the costs."[461] It then briefly discusses the perceived benefits, incorrectly suggesting that the National Academy of Sciences shares EPA's view by citing to a publication that discusses both *risks* and opportunities of expanding access to research data, and does not discuss *at all* the costs and benefits of *ignoring* relevant science in regulatory decisionmaking.[462] It then merely states that the "action should be implemented in a cost-effective manner," citing vaguely to "recent activities of the scientific community and other federal agencies" without any concrete examples or analysis.[463] The preamble's discussion emphasizes that the Proposal does not compel EPA to make information available where it concludes that doing so is not possible, but omits that if compliance is not possible, EPA will not consider the study, which has its own costs. It then concludes by citing the working paper of the Mercatus Center[464] that baldly asserts that improvements in reproducibility "can be thought of as increasing the net benefits of regulation because they would avoid situations in which costs or benefits are wrongly estimated to occur or in which regulatory costs are imposed without corresponding benefits."[465] Setting aside the lack of substantiation for this assertion, it entirely omits situations in which costs and benefits are wrongly estimated because the relevant science is not used—and the costs that would be imposed on society if EPA inadequately protects communities from harmful pollution or toxic exposures.

Indeed, the Proposal *nowhere* discusses its significant costs in either quantitative or qualitative terms, costs that have actually been examined by independent organizations, and that are susceptible to analysis. If the Proposal is truly "designed to provide a mechanism to increase access to" data "in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants," 83 Fed. Reg. at 18,770, then it will have significant costs. And if, as it appears, the Proposal's true "mechanism" is excluding science from regulatory decisionmaking, its costs will be even greater in the form of insufficiently protective regulations.

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[459] Proposed Rule, 83 Fed. Reg. at 18,772.
[460] *Compare*, EO 12866 Proposal 2080-AA14 OIRA Conclusion Document (Docket ID. No. EPA-HQ-OA-2018-0259-0006) *with* EO 12866 Proposal 2080-AA14 OIRA Review Start Document (Docket ID. No. EPA-HQ-OA-2018-0259-0007).
[461] Proposed Rule, 83 Fed. Reg. at 18,772.
[462] *Id.*
[463] *Id.*
[464] For a proposal allegedly aimed at increasing transparency, it is notable that EPA does not disclose that Charles Koch—an outspoken opponent of public health protections who stands to gain financially from deregulation—is a board member of the Mercatus Center. Mercatus Center, *Charles Koch*, https://www.mercatus.org/charles-koch (last accessed: Aug. 1, 2018).
[465] Proposed Rule, 83 Fed. Reg. at 18,772.

If it were not possible to quantify and monetize any of the costs, which is not the case here as discussed below, EPA would still be required under E.O. 12866 and the requirements of rational rulemaking to identify and discuss the qualitative costs of this Proposal. It is inherently irrational for an agency to take an action without any consideration of any costs, disadvantages or negative effects of that action. The qualitative costs of this Proposal include the costs to researchers of actions they must undertake to protect the confidentiality of patient and subject data, as well as to compile and make public their raw data, and the potential loss of subjects (and attendant damage to research efforts and results) due to confidentiality concerns. There are also various costs to the agency of administering the regulation, which include contacting researchers, gathering data, ensuring that patient confidentiality and confidential business information are not disclosed. Additional costs could also be incurred through conducting any additional peer reviews required by proposed section 30.7 and any additional analyses imposed by proposed section 30.6's requirement that "EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions." Most importantly, there are potentially huge costs of regulating without using the relevant science merely because the underlying raw data is not publicly available. If studies supporting a stronger standard are excluded and EPA can therefore only justify a weaker requirement that leaves large numbers of people at risk of health effects from a pollutant, pesticide, or chemical, then this Proposal could impose enormous costs for each insufficiently protective regulation.[466] Yet the Proposal fails even to mention these costs, let alone discuss their scope and significance.

In addition, many of these costs can be quantified and monetized, but EPA has neither attempted to do so nor explained why it could not. For example, EPA has extensive information available to it on what the agency would need to do to implement this Proposal and how much those activities would cost. In fact, EPA already gathered much of this data and provided it to the Congressional Budget Office for use in estimating the costs of a similar (though not identical) proposal from Congress, the HONEST Act. With respect to the Congressional proposal, CBO concluded, just with respect to the costs to EPA, that "based on information from the EPA and other federal agencies, as well as organizations and researchers in the scientific community that publish in peer-reviewed journals," EPA "could spend between a few million dollars per year to more than one hundred million dollars per year … to ensure that data and other information underlying studies are publicly available in a format sufficient to allow others to substantially reproduce the results of studies."[467] In the 2017 estimate, CBO concluded that "[i]f the EPA continued to rely on as many scientific studies as it has used in recent years … then CBO

[466] In footnote 3 of the Proposal, Proposed Rule, 83 Fed. Reg. at 18,769, EPA suggests that the studies underlying the NAAQS for particulate matter, at issue in the case cited—*Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 358 (D.C. Cir. 2002)—are an example of data the agency would be "preclude[d]" from using in the future. The benefits of these NAAQS included up to $75,100 million in annual benefits from avoided cases of mortality in 2010 alone for a partial attainment scenario. National Research Council (US) Committee, *Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations*, 43
National Academies Press (2002), https://www.ncbi.nlm.nih.gov/books/NBK221028/.

[467] Congressional Budget Cost Estimate for H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (Mar. 29, 2017) ("2017 CBO Estimate"); *see also* Congressional Budget Office Cost Estimate, S. 544, Secret Science Reform Act of 2015 (June 5, 2015) (estimating that another similar congressional proposal would cost up to $250 million per year).

estimates that the agency would need to spend at least $100 million dollars per year to upgrade the format and availability of those studies' data," "on average, $10,000 per scientific study."[468] Such costs would cover the costs of "obtaining all the underlying data used in a study, reviewing the data to address any confidentiality concerns, formatting the data for public access, providing access to the computer codes and models used in the study's analysis, and providing descriptions and documentation on how to access the data."[469] Notably, this does not include the cost to researchers to engage in this effort. As Deputy Assistant Administrator Nancy Beck noted, during the development of the Proposal, requiring "a huge amount of data to be submitted to the agency" would "be incredibly burdensome" and "not practical."[470]

Even the Mercatus working paper—apparently the only thing EPA relied upon in discussing the costs and benefits of the Proposal, 83 Fed. Reg. 18,772 n. 24, notes, with respect to the HONEST Act, that "[t]he cost of providing access to data has been one of the primary concerns about requiring access to data used by the federal government."[471] Far from concluding, as the Proposal suggests, an increase in net benefits from greater reproducibility, the Mercatus working paper simply explained a figure the authors were suggesting could be calculated (the point where net benefits would be positive); the authors do not themselves calculate the benefits, and admit that their "estimates of the benefits of public access to data supporting federal regulatory decisions fall short of proving that the benefits outweigh the associated costs."[472] And while the Mercatus working paper disagrees with CBO's cost estimates, it does not argue that that requiring access to data is cost-less; indeed, it discusses the "costly activities and services that need to be performed," including activities related to "data collection and data accessibility."[473] According to that working paper, data collection requires "correspond[ing] with researchers and publishers to obtain the data, review[ing] the data for confidentiality concerns, format[ting] the data for public access, publicly post[ing] the computer code and models used in each study's analysis, and provid[ing] descriptions and documentation on how to obtain the date."[474] Data accessibility requires "computer processing services to construct and maintain data bases to store study-related information."[475] While the actual calculations put forward by the Mercatus working paper appear faulty (for example, it entirely omits the cost to researchers to compile and make their data public, does not include the costs of ensuring patient privacy is protected,[476] and makes assumptions about the similarity of a chemical manufacturer collecting its own studies and EPA collecting and disseminating information of other researchers), the working paper at least acknowledges that there are costs, something EPA's Proposal completely ignores.

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[468] 2017 CBO Estimate at 3.
[469] *Id.*
[470] Email from Nancy Beck to Richard Yamada (Jan. 31, 2018 2:51 PM).
[471] Mercatus Working Paper 19.
[472] *Id.* at 27-29.
[473] *Id.* at 20.
[474] *Id.*
[475] *Id.* at 20-21 (quoting CBO, "Cost Estimate, S. 544, Secret Science Reform Act of 2015," June 5, 2015).
[476] For example, this may require special archiving and access arrangements to limit data sharing, such as those in NIH data sharing plans, which NIH requires only for studies that receive more than $500,000 in federal funding in a year. NIH, NIH Data Sharing Policy and Implementation Guidance, https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm (last accessed Aug. 16, 2018).

Nor does the proposed rule disclose the cost—highlighted on the very first page of a National Academy of Sciences (NAS) report on data access—that "perceived risks to privacy and confidentiality reduce survey participation," a cost that the NAS explains is "borne out by research."[477] NAS explains that this "threatens the research enterprise itself, because concerns about privacy and confidentiality are among the reasons often given by potential respondents for refusing to participate in surveys, and those concerns have been shown to affect behavior as well.[478] The NAS panel emphasized: "Any confidentiality breach that became known would be likely to heighten such concerns and, correspondingly, reduce survey response rates. Efforts to increase researchers' access to data must, therefore, take into account the need to avoid increasing the actual and perceived risks of confidentiality breaches."[479] The Proposal does not so much as discuss this potential cost.

This confidentiality risk has a further cost: it affects the quality of the data collected. As the NAS explained:

> The reason for confidentiality pledges and for stringent procedures to prevent disclosure is that they improve the quality of data collected from individuals, households, and firms. It is essential that respondents believe they can provide accurate, complete information without any fear that the information will be disclosed inappropriately. Indeed, if the information was disclosed, harm might come to an individual respondent.[480]

The Proposal's only acknowledgment of this complex problem and cost is its statement that "EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government."[481] Remarkably, EPA does not cite a single example of these common solutions, citing only vaguely to "examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau" and some hyperlinks not in the Proposal added to the docket almost a month into the comment period.[482] Accordingly, not only does the Proposal include no analysis of these alleged solutions and their costs and benefits, it does not even explain what the solutions are that EPA believes address this concern.

And if EPA complies with the regulation *not* by spending the money to make data publicly available, and if the research community does not bear those costs itself, *see* 83 Fed. Reg. at 18,770-71 ("Nothing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections."), then it appears that EPA would simply ignore studies that do not comply with the regulation. *See* 83 Fed. Reg. at 18,769 n. 3 ("EPA is proposing to exercise its discretionary authority to establish a

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[477] National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, vii National Academies Press (2005).
[478] *Id.* at 51; *see also id.* at 52-54 (describing the research supporting this risk).
[479] *Id.* at 51.
[480] *Id.*
[481] 83 Fed. Reg. at 18,770.
[482] *Id.*

policy that would preclude it from using such data in future regulatory actions."). That course of action has its own significant costs, and EPA provides no analysis in the Proposal of the magnitude of studies that it has previously relied upon that it could no longer rely upon in regulating. *See* 2017 CBO Estimate ("EPA officials have explained to CBO that the agency would implement H.R. 1430 with minimal funding and generally would not disseminate information for the scientific studies that it uses to support covered actions. That approach to implementing the legislation would significantly reduce the number of studies that the agency relies on when issuing or proposing covered actions…."). As the SAB noted in its May 12, 2018 letter, "[t]he proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs. Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits."[483]

Likewise, EPA has included only a cursory mention of the expected qualitative benefits of the Proposal, with no discussion of the anticipated likelihood, scope, or impact of the suggested benefits, let alone any effort to quantify them, much less monetize them. EPA simply assumes that the Proposal will "improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing an exploration of key data sets" without any analysis or evidence. In fact, as we have explained, the likely outcome of the Proposal is that it will degrade the data and scientific quality of the Agency's actions by ignoring relevant science simply because the underlying data is not publicly available. Moreover, EPA's finding is not consistent with the conclusions of the National Academies, as the Proposal suggests. As also explained above, the NAS report highlighted both the risks and benefits of making data publicly available and nowhere concluded that there were benefits to excluding data from the agency's regulatory decisions simply because the underlying data was not publicly available. Nor does the agency analyze how likely its Proposal is to actually facilitate expanded data sharing, and its main aim appears to be excluding science as it does not actually provide any funding, mechanisms, or best practices for sharing data.

It is more than ironic that EPA claims—without any data or analysis—that its Proposal will increase the net benefits of other regulations while it does nothing to actually consider the costs and benefits of the Proposal itself. Moreover, there is no reason to think that excluding relevant science merely because the underlying data is not publicly available would increase the net benefits of a regulation. For example, it appears that under the proposed rule EPA would exclude a peer-reviewed, published study whose conclusion had been reproduced based upon numerous different datasets (and whose underlying data, though not publicly available, had been reevaluated by outside experts), while including a study that had had no peer review, was not published, had no corroborating studies, and had not actually been replicated or reproduced, merely because the underlying data was made publicly available. That is simply not a recipe for more accurate decisionmaking.

The proposed rule also violates the APA and other statutes' requirements for reasoned decisionmaking by failing to consider any alternative approaches, much less their costs, here. This is particularly irrational in this context where it appears that many of the benefits sought by

[483] Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons 3 (May 18, 2018).

EPA could be largely achieved with much less burdensome and costly approaches. A critical element of reasoned decision making is consideration of alternatives which are congruent with agencies' statutory responsibilities and objectives. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48, 50 (1983) (safety agency acted arbitrarily in failing to consider alternative safety measures after rejecting passive restraints). EPA failed to consider other methods to ensure scientific robustness at the agency. For example, the SAB letter notes that "[t]he proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods."[484] The Proposal does not consider any alternatives to ensuring that studies are reliable even where the underlying data cannot be made public because of privacy or other concerns.

Furthermore, by failing to consider costs and benefits, the Proposal contravenes Executive Order 12866. Executive Order 12866 requires agencies to assess the costs and benefits of proposed regulations and propose or adopt a regulation only upon a reasoned determination that the benefits justify the costs.[485] For "significant regulatory actions," like the proposed rule, 83 Fed. Reg. at 18,772, the agency must provide:

> (i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;
> (ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and
> (iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.[486]

[484] *Id.* at 4 (pointing to the Health Effects Institute re-analysis of the Harvard Six Cities and American Cancer Society epidemiological studies).
[485] Exec. Order 12866 § 1(b)(6)-(7) (Oct. 4, 1993).
[486] Exec. Order 12866 § 6(a)(3)(C).

The agency must also make these assessments and analyses "available to the public."[487] Executive Order 13563 reaffirms these principles and requirements, explaining that agencies "must take into account benefits and costs, both quantitative and qualitative."[488]

Agencies are further encouraged to weigh the costs and benefits of developing higher information quality in OMB's Information Quality Guidelines.[489] Costs that the Guidelines encourage agencies to consider include "costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality."[490] EPA's existing information quality guidelines track the OMB Guidelines closely. EPA's disregard of the Guidelines' recommended weighing costs and benefits further contributes to the arbitrariness of EPA's failure to consider the costs of the Proposal.

The Proposal's failure to analyze and disclose costs and benefits cannot be cured in a final regulation. Should EPA not abandon this misguided Proposal, it must re-propose it after first analyzing its costs (both to public health, to researchers, and to the agency itself) and benefits, and providing the requisite opportunity for public comment on its analysis. As discussed further below in Section VIII.D, the public cannot meaningfully comment on the proposed rule without understanding the actual costs and benefits of the Proposal, the alternatives EPA considered, and the analyses underlying EPA's assessments.

VI. EPA Fails to Comply with the Paperwork Reduction Act.

EPA and the White House Office of Management and Budget (OMB) must scrutinize the Proposal for its information collection burden, as that concept is defined under the Paperwork Reduction Act (PRA).[491] The only reference to the PRA in the Proposal is EPA's denial that this action "contain[s] any information collection activities" or "impose[s] an information collection burden."[492] But if finalized, the Proposal would significantly increase that burden in the rulemakings to which it applies. EPA and OMB cannot rationally ignore such an entirely foreseeable impact when considering this Proposal.

The PRA institutes procedural safeguards to "minimize the paperwork burden for individuals, small business, educational and nonprofit institutions," and others.[493] It requires that, prior to initiating a "collection of information," agencies must "provide 60-day notice in the Federal Register . . . to solicit comment to," inter alia, "evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency," "evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,"

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[487] Exec. Order 12,866 § 6(a)(3)(E)(i).
[488] Exec. Order 13563 § 1(a) (Jan. 18, 2011).
[489] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002).
[490] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002).
[491] *See* 44 U.S.C. § 3502(2), (3) (defining "burden" and "collection of information").
[492] *See* 83 Fed. Reg. at 18,772.
[493] 44 U.S.C. § 3501(1).

and "minimize the burden of the collection of the information on those who are to respond."[494] After evaluating public comments, agencies must submit the proposed collection of information to OMB for additional review and publish a notice in the Federal Register setting forth "an estimate of the burden that shall result from the collection of information" and "notice that comments may be submitted to the agency and [OMB]."[495] Any such collection of information is subject to OMB approval.[496] OMB is required to determine "whether the collection of information . . . is necessary for the proper performance of the functions of the agency."[497] A negative determination precludes the agency from initiating the collection of information.[498]

The requirements that EPA would impose through this Proposal qualify as collections of information under the PRA. The statute defines "collection of information" to include "the obtaining [or] causing to be obtained . . . of facts or opinions by or for an agency, regardless of form or format, calling for . . . answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons . . . ."[499] OMB regulations emphasize the breadth of this definition, specifying that "[a] Collection of information may be in any form or format, including . . . reporting or recordkeeping requirements; . . . policy statements; . . . rules or regulations; . . . oral communications;" and others.[500] "Any recordkeeping, reporting, or disclosure requirement contained in a rule of general applicability is deemed to involve ten or more persons."[501] The definition of "collection of information" is agnostic as to whether disclosure is "mandatory, voluntary, or required to obtain or retain a benefit," and to whether disclosure is to an agency or "members of the public or the public at large."[502]

The Proposal would impose a burden that falls squarely within the definition of "collection of information." In order to use scientific research, the agency would "obtain[] or caus[e] to be obtained . . . facts." Assuming the requirements are applied consistently, the "questions posed," or "reporting or recordkeeping requirements imposed," would be "identical." As the requirements are "contained in a rule of general applicability"—i.e., the instant Proposal—they are "deemed to involve ten or more persons." It makes no difference whether the agency seeks the information through a questionnaire, telephone call, or some other format. Nor does it matter whether the agency directly mandates that entities provide the information, or provides that entities must "voluntary[ily]" provide the information in order for research to be eligible for consideration in important rulemakings.

While EPA has refrained from detailing the mechanics by which entities would provide the information, the agency expressly contemplates that the burden of providing such information would fall at least partly to members of the public whom the PRA exists to

[494] 44 U.S.C. § 3506(c)(2)(i), (ii), (iv).
[495] *Id.* § 3507(a)(1)(D)(ii)(V), (VI).
[496] *See id.* § 3507(a)(2).
[497] *Id.* § 3508.
[498] *Id.*
[499] 44 U.S.C. § 3502(3)(A)(i).
[500] 5 C.F.R. § 1320.3(c)(1).
[501] *Id.* § 1320.3(c)(4)(i).
[502] *Id.* § 1320.3(c), (c)(2).

protect.[503] For example, proposed regulation 40 C.F.R. § 30.5 provides that, "[w]here data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section." Moreover, the agency specifically "solicits comment on how to incorporate stronger data and model access requirements in the terms and conditions of cooperative agreements and grants."[504] As noted above, the PRA is implicated when collection of information is "required to obtain or retain a benefit,"[505] and OMB guidance has identified grants as a "Federal benefit" for purposes of the PRA.[506]

EPA cannot evade the PRA requirements by narrowly asserting that "this action" imposes no information collection burden and ignoring the action's entirely foreseeable future impacts. The proposal expressly "is intended to apply prospectively," suggesting that it "prospectively" requires burdensome collections of information in future rulemakings. EPA must not ignore the PRA in this rulemaking, only to claim in future rulemakings that this rule moots or constrains the PRA's application by compelling certain collections of information.

In the alternative, if EPA genuinely believes that this Proposal would not burden the public with new collections of information, then EPA's stated basis for this rulemaking is exposed as a farce. EPA claims that the Proposal would "ensure" that certain data "are publicly available" and expresses specific concern for science "developed outside the agency."[507] Collection of information, including from researchers employed outside of the federal government, is central to the purpose—and essential to the implementation—of the Proposal. Providing this information would inevitably impose a burden on researchers. If the agency does not actually intend to collect information under this Proposal, it underscores that EPA's true purpose is not to increase transparency, but rather to thwart the development and maintenance of vital public health protections on the grounds that the agency lacks the information it would need to support them.

At a minimum, EPA must acknowledge and describe the information collection burden that this Proposal would impose so that OMB and the public can conduct a proper evaluation and provide responsive comments.

VII. The Circumstances Surrounding the Proposed Rule Indicate that it Was Based on a Desire to Suppress Vital Public Health Science for the Benefit of Certain Regulated Industries.

The circumstances surrounding the development of this proposed rule underscore that it is not intended to "strengthen the transparency of EPA regulatory science."[508] Far from furthering EPA's mission of protecting human health and the environment based on the best available science, the Proposal is EPA's effort to implement failed congressional legislation that

[503] *Cf. id.* § 1320.3(k) (defining "person" for purposes of the PRA).
[504] 83 Fed. Reg. at 18,771.
[505] 5 C.F.R. § 1320.3(c).
[506] *See* Memorandum from Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs, re: Information Collection Under the Paperwork Reduction Act 3 (Apr. 7, 2010), *available at* www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/PRAPrimer_04072010.pdf.
[507] 83 Fed. Reg. at 18,768, 18770.
[508] 83 Fed. Reg. 18,768.

was intended to suppress rigorous science for the benefit of private industry and at the expense of public health.

EPA's Proposal is largely based upon the HONEST Act of 2017, an unenacted House bill that aimed at undermining climate and regulatory science. Available information about the Proposal's evolution indicates that regulated industries had a disproportionate role in its development. In addition, the Proposal mirrors advocacy tactics employed by the tobacco industry in the 1990's in order to suppress scientific research demonstrating the adverse health effects of cigarettes and second-hand smoke. Finally, the Proposal follows a host of instances in which the Agency, under former EPA Administrator Scott Pruitt, suppressed science and transparency—underscoring the bad faith nature of the purported justifications for this rule.

A. The Proposed Rule is an Attempt by EPA to Implement an Unenacted Congressional Bill, The HONEST Act.

EPA's Proposal is an outgrowth of a failed congressional bill, the HONEST Act. The bill was vigorously supported by Congress members with strong ties to the precise industries that would have benefited from its enactment. Internal and external EPA communications illustrate that the HONEST Act served as a precursor to EPA's Proposal. The intertwined history of the HONEST Act and EPA's Proposal cast doubt on the Agency's proffered rationale.

The HONEST Act

The HONEST Act[509] is a House bill introduced in 2017 by sponsor Representative Lamar Smith (R-TX), and is the latest manifestation of various bills aimed at undermining EPA regulation through limitations on the types of scientific research the Agency may use.[510] The HONEST Act and these related bills were introduced and passed in the House three times, but each time, failed to progress in the Senate.[511]

Like the current Proposal, the HONEST Act was touted by its proponents as an effort to enhance the transparency and credibility of regulatory science at EPA. But the HONEST Act—like the Proposal—would in fact have had the effect of limiting the scope and quality of science underlying EPA actions. Indeed the HONEST Act was widely criticized and opposed by scientists, scientific organizations, medical organizations and other scientific authorities for precisely this reason. For example, eight public health and medical associations including the American Lung Association, American Public Health Association, National Medical Association, and Physicians for Social Responsibility issued an open letter to Congress in spring 2017 opposing the HONEST Act because it "would limit the kinds of scientific data EPA can use

[509] HONEST Act, H.R. 1430, 115th Cong. (2017).
[510] *See* Secret Science Reform Act of 2014, H.R. 4012, 113th Cong. (2014); Secret Science Reform Act of 2015, H.R. 1030, 114th Cong. (2015); H.R. 1430; HONEST Act, S. 1794, 115th Cong. (2017).
[511] On March 2017, Representative Smith introduced the HONEST Act in the 115th Congress. On March 29, 2017, the bill passed the House without amendment. Most recently, Senator Mike Rounds (R-SD) introduced a Senate version of the HONEST Act on September 12, 2017. As with past versions of the bill, the Senate referred the Bill to the Committee on Environment and Public Works, but took no further action.

as it develops policy to protect the American public from environmental exposures and permit violation of patient confidentiality."[512] The American Association for the Advancement of Science and twenty-two other leading scientific organizations and research universities likewise sent a letter to House Majority Whip Kevin McCarthy in March 2017 opposing the bill and warning that it could lead to a "situation where the EPA would be prevented from using the best available science and disseminating public information in a timely fashion."[513] As we have noted elsewhere in these comments, the Congressional Budget Office – after consulting with EPA staff – likewise concluded that the HONEST Act would "significantly reduce the number of studies that the agency relies on when issuing or proposing covered actions."[514]

That the HONEST Act would suppress rather than promote good science at EPA is not surprising, given that the sponsors of the HONEST Act have a history of rejecting established climate science and strong ties to industries that would benefit from limiting the role of science in EPA rulemakings. Representative Lamar Smith is widely known as an opponent of mainstream climate science and public health and environmental safeguards.[515] In a July 24, 2017 opinion piece, Representative Smith lauded the benefits of increased atmospheric carbon dioxide: "A higher concentration of carbon dioxide in our atmosphere would aid photosynthesis, which in turn contributes to increased plant growth."[516] Smith and the sponsor of the Senate version, Mike Rounds, also receive substantial contributions from the same industries that will benefit from the proposal.[517]

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[512] Letter from Alliance of Nurses for Health Environments, American Lung Association, American Public Health Association, American Thoracic Society, Asthma and Allergy Foundation of America, Health Care Without Harm, National Medical Association, and Physicians for Social Responsibility to U.S. House (Mar. 27, 2017), http://www.lung.org/assets/documents/advocacy-archive/letter-to-us-house-opposing-2.pdf.

[513] Letter from American Association for the Advancement of Science et al. to Rep. Kevin McCarthy (Mar. 28, 2017), https://mcmprodaaas.s3.amazonaws.com/s3fs-public/HR%201430%20HONEST%20Act%20Multisociety%20Letter%20of%20Concern.pdf.

[514] CBO, H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 at 2 (Mar. 29, 2017), *https://www.cbo.gov/system/files?file=115th-congress-2017-2018/costestimate/hr1430.pdf*.

[515] *See, e.g.*, Rep. Lamar Smith, *Climate Change: Seven Indisputable Facts*, The Hill (Sept. 8, 2017, 5:46 PM), http://thehill.com/opinion/op-ed/252989-climate-change-seven-indisputable-facts ("Like all climate alarmists, the president wants Americans to believe there is no uncertainty about climate change….But the truth is there are more questions about climate change than there are answers. For instance, even the most advanced climate models all failed to predict the lack of warming the Earth has experienced over the last 18 years."); Lamar Smith, *The Climate Change Religion*, The Wall Street Journal: Opinion | Commentary (Apr. 23, 2015, 7:35 PM), https://www.wsj.com/articles/the-climate-change-religion-1429832149, ("When assessing climate change, we should focus on good science, not politically correct science."); Lamar Smith, *Smith: EPA Hides Truth about Climate Regulations*, Media Center: Press Releases (Aug. 13, 2014), https://lamarsmith.house.gov/media-center/press-releases/smith-epa-hides-truth-about-climate-regulations.

[516] Lamar Smith, *Don't Believe the Hysteria over Carbon*, The Daily Signal Energy: Commentary (July 24, 2017), https://www.dailysignal.com/2017/07/24/dont-believe-hysteria-carbon-dioxide/

[517] Throughout his congressional career, Representative Smith received over $787,047 in contributions from the oil and gas sector. Center for Responsive Politics, *Rep. Lamar Smith – Texas District 21: Summary*, Open Secrets: Congress, https://www.opensecrets.org/members-of-congress/summary?cid=N00001811&cycle=CAREER&type=I (last visited June 6, 2018). From 2011 to 2018, Senator Rounds received over $215,000 from oil and gas companies alone. Center for Responsive Politics, *Sen. Mike Rounds – South Dakota: Summary*, Open Secrets: Congress, https://www.opensecrets.org/members-of-congress/summary?cid=N00035187&cycle=CAREER&type=I (last visited June 14, 2018).

Representative Smith also has ties to EPA staff who drafted the proposal, underscoring the close connection between his failed legislation and this proposed rule. Dr. Richard Yamada, former professional staff member on Smith's House Committee on Science, Space & Technology now serves as the Deputy Assistant Administrator for EPA's Office of Research and Development.[518] At EPA, Dr. Yamada has participated in the drafting and development of the Agency's version of the proposal.[519]

The HONEST Act as Predecessor for the Proposal

As this section details, it is clear that the HONEST Act is a direct predecessor of this proposed rule and that both initiatives share the same purpose: to undermine EPA's use of rigorous science in crafting health and environmental protections. The language used in the proposal shares strong similarities with the HONEST Act. Furthermore, internal and external communications from EPA leadership demonstrate the proposal's origins in the HONEST Act.

While lengthier than the congressional HONEST Act, EPA's proposal contains parallel language to the bill. One can compare examples from the text of the 2017 HONEST Act as passed in the House, to the text of the proposal from the Final Federal Register Notice:

> *The HONEST Act of 2017*
> An Act: To prohibit the [EPA] from proposing, finalizing, or disseminating regulations or assessments based upon science that is not transparent or reproducible…..
>
> The Administrator shall not proposed, finalize, or disseminate a covered action unless all scientific and technical information relied on to support such covered action is—(A) the best available science; (B) specifically identified; and (C) publicly available online in a manner that is sufficient for independent analysis and substantial reproduction of search results….[520]
>
> *Strengthening Transparency in Regulatory Science Proposal*
> EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final action. EPA should make all studies available to the public to the extent practicable . . . When promulgating significant regulatory actions, the Agency shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.[521]

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[518] EPA, *Dr. Richard Yamada*, EPA Research, https://www.epa.gov/research/dr-richard-yamada. (last updated Jan. 12, 2018).
[519] Email from Richard Yamada, Deptuy Assistant Adm'r, Office of Researh and Dev., to Drew Feeley, Policy Counsel, Office of Policy; Brittany Bolen, Acting Assoc. Adm'r, Office of Policy; Clint Woods, Deputy Assistant Adm'r, Office of Air and Radiation; Justin Schwab, Deputy Gen. Counsel, Office of Gen. Counsel; Erik Baptist, Senior Deputy Gen. Counsel, Office of Gen. Counsel; and Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention (Jan. 29, 2019, 10:58 PM), https://drive.google.com/file/d/1peMXjBhq6lUYGGNBWbSjpOu1Zh-qLl4p/.
[520] H.R.1430 § 2(b)(1).
[521] Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768, 18,773 (Apr. 30, 2018) (proposed 40 C.F.R. §§ 30.4, 30.5).

The best available science must serve as the foundation of EPA's regulatory actions.[522]

Responsive records released to the Union of Concerned Scientists ("UCS") make evident that the HONEST Act served a predecessor to the proposal. Administrator Pruitt's schedule reveals that he met with Representative Smith on January 9, 2018, less than four months before the Federal Register announcement of the proposal.[523] Emails from Pruitt and his staff, dated just over a week after that meeting, indicate that Smith was working on a "pitch that EPA internally implement the HONEST Act."[524] Subsequent emails sent between Pruitt's EPA staff in February 2018 demonstrate that EPA officials promptly began drafting the proposal.[525]

Before Smith's internal EPA 'pitch,' Agency leadership commented favorably on the HONEST Act of 2017. Although EPA initially estimated that implementation of the act would cost over $250 million per year,[526] that estimate was never reported to the Congressional Budget Office ("CBO"). As CBO's cost estimate determination indicates, EPA political leadership diverged from the earlier estimate and instead assured CBO that the bill could be implemented "with minimal funding."[527] Several news sources have reported that the Administrator's Office of the EPA became involved in communications with CBO, and decided to respond to CBO directly with the assurance the bill could be implemented at 'no cost.'[528]

Finally, in an exclusive interview with the Daily Caller shortly before the proposal's publication, former Administrator Pruitt promised:

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[522] *Id.* at 18,769.

[523] EPA, *Calendar for Scott Pruitt, Administrator*, Senior Leaders Calendars, https://archive.epa.gov/epa/senior-leaders-calendars/calendar-scott-pruitt-former-administrator.html (last visited Aug. 3, 2018) (search starting point field for "Smith," then see entry for Jan. 9, 2018).

[524] Email from Aaron Ringel, Deputy Assoc. Adm'r, Office of Intergovernmental Affairs, to Troy Lyons, Assoc. Adm'r, Office of Congressional and Intergovernmental Relations; David Fotouhi, Deputy Gen. Counsel, Office of Gen. Counsel; Mandy Gunasekara, Principal Deputy Assistant Adm'r, Office of Air and Radiation; and Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev. (Jan. 16, 2018, 2:28 PM)(on file with Union of Concerned Scientists), https://drive.google.com/file/d/15Z6RKok51uqwkgAmhK3rseTOEJhFo8Sj/.

[525] *See, e.g.*, Email from Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev., to Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention (Jan. 29, 2018, 6:07 PM)(on file with Union of Concerned Scientists), https://drive.google.com/file/d/1DvwXyjzZlPstQx3tVL-jW_Yjv-S7VD2H/; Email from Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev., to Drew Feeley, Policy Counsel, Office of Policy; Brittany Bolen, Acting Assoc. Adm'r, Office of Policy; Clint Woods, Deputy Assistant Adm'r, Office of Air and Radiation; Justin Schwab, Deputy Gen. Counsel, Office of Gen. Counsel; Erik Baptist, Senior Deputy Gen. Counsel, Office of Gen. Counsel; and Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention (Jan. 29, 2019, 10:58 PM), https://drive.google.com/file/d/1peMXjBhq6lUYGGNBWbSjpOu1Zh-qLl4p/.

[526] EPA, Comments on CBO Questions for EPA regarding H.R. xxxx, the HONEST Act of 2017 (n.d.) (on file with Bloomberg Bureau of National Affairs), http://src.bna.com/nAj.

[527] CBO, Cost Estimate: H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 1 (2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.

[528] *E.g.*, Scott Tong, *Critics Say HONEST Act undercuts EPA's use of science*, Marketplace: Sustainability (Apr. 10, 2017, 1:08 PM), https://www.marketplace.org/2017/04/10/sustainability/honest-act-seen-critics-undercutting-epa-s-use-science.

> If we use a third party to engage in scientific review or inquiry, and that's the basis of rulemaking, you and every American citizen across the country deserve to know what's the data, what's the methodology that was used to reach that conclusion that was the underpinning of what — rules that were adopted by this agency.[529]

The Daily Caller directly linked the proposal to the HONEST Act, "Pruitt's pending science transparency policy mirrors Smith's HONEST Act, which passed the House in March 2017."[530]

Spokeswoman for Chairman Smith's House Committee on Science, Space, and Technology, Thea McDonald, also told the Daily Caller: "[t]he chairman has long worked toward a more open and transparent rule-making process at EPA, and he looks forward to any announcement from Administrator Pruitt that would achieve that goal."[531]

1. Available information on the development of the proposal illustrate its industry origins.

The history of the proposal's internal development indicates that certain representatives of regulated industries had a nearly exclusive role in its promulgation, and that industry concerns were given special solicitude by EPA's senior political leadership. Meanwhile, the scientific community and the EPA's own Science Advisory Board were neither involved in the evolution of the proposal nor notified of its initiation until after its official publication in the Federal Register, further suggesting that this proposal is not grounded in a genuine concern for advancing science at EPA and is, in fact, at odds with EPA's mission of protecting human health and the environment.

Nancy Beck, key decision maker and EPA's current Deputy Assistant Administrator of the Office of Chemical Safety and Pollution Prevention, previously served as the Senior Director, Regulatory & Technical Affairs for the American Chemistry Council.[532] While employed by the ACC, Beck submitted a written statement in general support of the HONEST Act.[533]

In internal EPA emails released pursuant to Union of Concerned Scientists' Freedom of Information Act ("FOIA") request, Beck expressed concerns that repeated those of industry. Her concerns that certain language in the proposal might compromise industry confidential business information ("CBI") or alter individual party adjudications were met with assurances by Deputy Assistant Administrator for the Office of Research and Development, Richard Yamada, that the

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[529] Michael Bastach, *Exclusive: Scott Pruitt Will End EPA's Use of 'Secret Science' to Justify Regulations*, The Daily Caller (Mar. 20, 2018, 1:06 AM), http://dailycaller.com/2018/03/19/epa-scott-pruitt-secret-science/.
[530] *Id.*
[531] *Id.*
[532] Nancy Beck, LinkedIn, https://www.linkedin.com/in/nancybbeck/ (last visited June 6, 2018).
[533] *Written Statement of Nancy B. Beck Before the U.S. Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Regulatory Affairs and Federal Management Regarding a Hearing on the Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability*, American Chemistry Council 1 (Mar. 9, 2017), https://www.hsgac.senate.gov/imo/media/doc/BECK%20TESTIMONY.pdf.

agency would "thread" the proposal "real tight."[534] Concerns about protecting CBI, expressed in Beck's emails, echo her statement in support of the HONEST Act to the House Subcommittee on Regulatory Affairs and Federal Management while she was employed by the ACC.[535]

The proposal's justifications regarding the private-sector burden of regulatory costs reiterates concerns and suggestions about EPA's policy for evaluating science that the Agency received from industry itself. In emails to EPA leadership from May 2014, the National Association of Manufacturers ("NAM") specifically identified dozens of EPA regulations that were "affecting its members," many of which were chemical, air, and water regulations which were based upon the types of research and studies that would be excluded under EPA's proposed rule.[536]

In response to EPA's 2017 proposed rule, Procedures for Prioritization of Chemicals for Risk Evaluations, NAM made recommendations that EPA ensure that TSCA prioritization relied upon "the best available science" in a process that requires "a heightened level of transparency."[537] NAM also provided the EPA with materials that called for reform of EPA's "process for evaluating science to improve transparency and better involve the public."[538] This parallels NAM's 2014 letter to the House in support of that year's version of Rep. Smith's HONEST Act.[539]

The American Petroleum Institute's ("API") Senior Director of Regulatory and Scientific Affairs wrote to the EPA: "[t]he science and data used to support a regulation should be reviewed to determine if they are still valid based on scientific integrity, consistent with EPA's Principles of Scientific Integrity and Policy (2012), with meaningful disclosure of all potential areas of bias, guarding against manipulation or misinterpretation."[540]

API also issued a press release on that same day, May 15, 2017, in which the organization summarized its conversations with EPA: "API today urged the EPA to adopt a

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[534] Email from Richard Yamada, Deputy Assistant Adm'r, Office of Research and Dev., to Nancy Beck, Deputy Assistant Adm'r, Office of Chem. Safety and Pollution Prevention; Erik Baptist, Senior Deputy Gen. Counsel, Office of Gen. Counsel; and Justin Schwab, Deputy Gen. Counsel, Office of Gen. Counsel (Jan. 31, 2018, 7:54 PM)(on file with Union of Concerned Scientists), https://drive.google.com/file/d/1VIUUz2wDTT7c7oxBAU3gSP8lMfipieO5/.

[535] American Chemistry Council, *supra* note 34, at 7.

[536] Letter from the Nat'l Ass'n of Mfs. to Regulatory Reform Officer and Associate Administrator, Samantha K. Dravis (May 15, 2017) *in* Maxine Joselow, *Emails: EPA all ears as industry pitched 'secret science'*, E&E News: Regulations (May 18, 2018), https://www.eenews.net/greenwire/2018/05/17/stories/1060081997, at 169-88.

[537] *Id*. at 184.

[538] *EPA Meeting Briefing Paper*, Nat'l Ass'n of Mfs. (n.d.), *in* Joselow, at 772-6.

[539] Letter from the Nat'l Ass'n of Mfs. to U.S. House of Representatives (Nov. 19, 2014) *in* Nat'l Ass'n of Mfs., *Key Manufacturing Votes: 113th Congress*, Advocacy: Congressional Voting Record, http://www.nam.org/Advocacy/Key-Manufacturing-Votes/113th-Congress/House/HR-4012--the-Secret-Science-Reform-Act-of-2014-sponsored-by-Representative-Dave-Schweikert-(R-AZ)/?__taxonomyid=211. (last visited June 6, 2018).

[540] Letter from the Am. Petroleum Inst. to Regulatory Reform Officer and Associate Administrator, Samantha K. Dravis (May 15, 2017) *in* Joselow, at 1140.

regulatory system that enhances safety and protects the environment while prioritizing the production and refining of American natural gas and oil."[541]

In contrast, EPA's Science Advisory Board ("SAB") leadership was not notified of the rulemaking activity until it was published in the Federal Register, in contravention of Agency practices for communicating major actions such as the proposed rule.[542] EPA also failed to provide the SAB with a description of the proposal.[543]

Despite the SAB's Congressionally-mandated role to formally review and comment on EPA actions of this nature,[544] the SAB and scientific community were not consulted in the development of the rule.[545] Indeed, SAB leadership questioned the scientific support behind the proposal: "[a]lthough the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community."[546]

SAB leadership took note of the HONEST Act's connection to the proposal, stating the rule was "highly controversial" as indicated by the fact that "a similar legislative effort in the House has been stalled in Congress for several years."[547]

B. EPA's Proposed Rule Mirrors Policies That the Tobacco Industry Advocated for in the 1990's to Suppress Unfavorable Science.

Both this proposed rule and the HONEST Act bear close similarities to policies promoted by the tobacco industry in the 1990's to suppress unfavorable science—further confirming that the proposed rule would degrade the quality of science at EPA and undermine public health. Before EPA's proposed rule and the HONEST Act, Philip Morris (today, Altria) and public-relations firm APCO partnered to establish The Advancement of Sound Science Coalition ("TASSC") in order to "inform the market of the problem with unsound science" that demonstrated adverse health effects of tobacco and second-hand smoke.[548] TASSC led a worldwide publicity campaign in the 1990s to promote "Good Epidemiological Practices" that

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[541] Reid Porter, *API: Regulatory System Should Promote Technological Innovations and Industry Best Practices*, Am. Petroleum Inst.: News (May 15, 2017), http://www.api.org/news-policy-and-issues/news/2017/05/15/regulatory-system-should-promote-technol. (last visited June 6, 2018).
[542] Memorandum from Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, Alison Cullen, to Members of the Chartered SAB and SAB Liaisons (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf//E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.
[543] *Id.*
[544] Environmental Research, Development, and Demonstration Authorization Act of 1978, 42 U.S.C. § 4365 (1978).
[545] Memorandum from Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, Alison Cullen, to Members of the Chartered SAB and SAB Liaisons (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf//E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.
[546] *Id.*
[547] *Id.*
[548] *See* APCO Assocs., Revised Plan for the Public Launching of TASSC (Through 1993) (Oct. 15, 1993) (internal document) (on file with UCSF, available online through Truth Tobacco Industry Documents portal).

aimed at undermining U.S. and international regulatory efforts based on epidemiologic studies of passive smoking and lung cancer.[549]

During the same period, Philip Morris made it a strategic priority to pursue legislation and policies to require public disclosure of epidemiological data. A May 1997 planning document advocated for using "existing political and business coalitions" that opposed clean air regulations to promote "legislative solutions to ensure that public policy is based on sound science" and "require epidemiological studies to meet a minimum set of criteria and/or require researchers to make public the underlying data before these studies can be used as a basis for regulations at the state or federal level."[550] In 1998, Powell Tate – a lobbying firm that represented R.J. Reynolds – organized a "secret science" working group focused on "requiring the disclosure of taxpayer-funded analytical data upon which federal and state rules and regulations are based, as well as the analytic data underlying health and safety studies funded by the government . . . ."[551]

Although TASSC no longer exists, its executive director, Steve Milloy, continues the organization's "sound science" rhetoric against other types of regulation through his website, JunkScience.com.[552] In fact, Milloy has personally taken credit for EPA's proposal and was one of a select few invited to Pruitt's public announcement of the proposal earlier this year.[553] After the proposed rule was announced, Milloy told reporters, "I look at this as one of my proudest achievements. The reason this is anywhere is because of Steve Milloy."[554]

C. EPA, Under the Trump Administration, Has a History Of Suppressing Science and Transparency, Undermining the Purported Justifications for the Proposal.

A FOIA request submitted by E&E News uncovered a document emailed by former EPA official David Schnare laying out a strategy to overturn the 2009 Greenhouse Gas Endangerment Finding.[555] In the document, one of the steps contemplated as part of the reconsideration included EPA only relying "on information, data and studies where the original data upon which assessment is based is available to the public. . . . EPA would not rely on any study whose authors refuse to

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[549] Elisa K. Ong and Stanton A. Glantz, *Constructing "Sound Science" and "Good Epidemiology": Tobacco, Lawyers, and Public Relations Firms*, 91 Am. J. of Public Health 1749, 1753 (2001).
[550] Annamaria Baba et al., *Legislating "Sound Science": the Role of the Tobacco Industry,* 95 Am. J. of Public Health S20, S22 (2005).
[551] Memorandum from Leslie Gianelli, Powell Tate, to "Secret Science" Work Group (Apr. 10, 1998), available at https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=klyc0069.
[552] Emily Atkin, *The EPA is Acting Like Big Tobacco,* The New Republic (Apr. 26, 2018), available at https://newrepublic.com/article/148126/epa-acting-like-big-tobacco.
[553] Robin Bravender, *Pruitt to unveil 'secret science' effort today—sources,* E&E News: EPA (Apr. 24, 2018), https://www.eenews.net/stories/1060079891.
[554] Robin Bravender, *Trump team wanted to kill agency authority on CO2—emails,* E&E News (June 1, 2018), https://www.eenews.net/stories/1060083175.
[555] Document entitled GHG Endangerment Finding Redux, https://www.eenews.net/assets/2018/06/01/document_cw_13.pdf.

provide the underlying data, including computer code used to evaluate and analyze the data."[556] This is just one example among numerous others that this proceeding is not intended to increase transparency, but rather aimed at weakening EPA standards that the current Administration disapproves of, despite their grounding in robust scientific evidence.

EPA's non-transparent approach to this rulemaking, as well as other Agency actions, underscore that the proposal was not offered in good faith. The Agency has removed thousands of webpages from its website, limited public and press access to Agency events, and withheld key data underlying rulemakings and proceedings. These practices cast doubt on EPA's proffered justifications of transparency and accountability.

In EPA's stay of the Oil and Natural Gas Sector: Emissions Standards for New, Reconstructed, and Modified Sources, EPA failed to disclose directly relevant evidence for the basis of revision of the standards consisting of industry compliance reports.[557] Despite the fact that these compliance reports were in the agency's possession and comprised of public documents containing factual data that should have been available for public inspection, EPA has to date still not released all of the compliance reports in its possession.

In August 2017, EDF received information pursuant a FOIA request revealing that more than 1,900 climate-related webpages and files on EPA's website were removed or modified.[558] Many of the removed and modified pages were related to climate change science and impacts, such as "Climate Impact on Health Through Life Stages," "Climate Change Science," and "Methane and Black Carbon Impacts on the Arctic: Communicating the Science."[559]

In January 2018, EDF received additional responsive records to another FOIA request demonstrating that former Administrator Pruitt directed the removal of many climate change science, impacts, and resources pages as well as all material related to the Clean Power Plan on EPA.gov.[560]

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[556] Document entitled GHG Endangerment Finding Redux, https://www.eenews.net/assets/2018/06/01/document_cw_13.pdf.

[557] Comments of Clean Air Council, Clean Air Task Force, Center for Biological Diversity, Earthjustice, Earthworks, Environmental Defense Fund, Environmental Integrity Project, Environmental Law and Policy Center, Natural Resources Defense Council, Sierra Club, and National Parks Conservation Association on Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources: Stay of Certain Requirements and Oil and Natural Gas Sector Emission Standards for New, Reconstructed, and Modified Sources: Three Month Stay of Certain Requirements Docket No. EPA-HQ-OAR-2010-0505 and Docket No. EPA-HQ-OAR-2017-0346 (Dec. 8, 2017).

[558] *Environmental Defense Fund Obtains Information on Over 1,900 Climate-Related Items Removed from or Modified on EPA Website*, EDF: Press release archive (Aug. 11, 2017), https://www.edf.org/media/environmental-defense-fund-obtains-information-over-1900-climate-related-items-removed-or.

[559] *Id.*

[560] E-mail from Lincoln Ferguson, Senior Advisor, Office of Public Affairs, to Amy Graham, Advisor, Office of Public Affairs; John Konkus, Deputy Associate Administrator, Office of Public Affairs; JP Freier, Associate Administrator, Office of Public Affairs; Liz Bowman, Acting Associate Administrator, Office of Public Affairs; and Jahan Wilcox, Strategic Communications Advisor, Office of Public Affairs (Apr. 5, 2017, 4:15 PM) *in* EDF, *Newly Released Records Refer to Pruitt's Personal Involvement in Removal of Climate Information from EPA Website*, EDF: Press release archive (Jan. 29, 2018), https://www.edf.org/sites/default/files/2018.01.05-partial-production.pdf.

At the same time, EPA was soliciting comments on its proposal to repeal the Clean Power Plan. The removal of webpages related to climate and Clean Power Plan topics from the EPA website restricted the public's ability to formulate informed comments throughout the rulemaking process.[561] Thus, the public lacked the same "access to data and influential scientific information used to inform federal regulation"[562] which EPA claims to observe in its proposal.

The Administration has not rigorously pursued its purported goal of transparency in other contexts by limiting public and press access to Agency events and withholding key data underlying several recent rulemaking proceedings.

At the event where former Administrator Pruitt announced the proposal, reporters were not invited to attend.[563] Documents received in response to a Sierra Club FOIA request to the EPA reveal that the Administrator had requested press access and advertisement to the public be limited for other events.

For his speaking engagement at a Federalist Society event in March 2017, Pruitt's scheduling director asked that organizers not advertise to press directly and directed organized to tell media that the event "is not open to press and is off the record."[564] Emails also demonstrate that the Agency worked with a public relations firm to devise a plan to promote positive comments and censor negative comments on media from the Administrator's facility visits.[565]

EPA additionally failed to provide the public with access to data in key rulemakings and proceedings. For example, in EPA's rulemaking to repeal emissions requirements for glider vehicles, engines, and kits, commenced in November 2017, the Agency failed to release the underlying reports and data before the public comment period closed.[566] At this date, EPA still has not released data used in a key study cited in the Agency's proposal.

In the words of the proposal, EPA acted in contravention of its goals of "better informing the public," "enhancing the public's ability to understand and meaningfully participate in the

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[561] Environmental Data & Governance Initiative on EPA's Proposal, *Repeal of Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units*, 82 Fed. Reg. 48,035 (Apr. 26, 2018), *available at* https://envirodatagov.org/edgi_cpp_proposed_rule_comments_042618/.
[562] 83 Fed. Reg. 18,768, 18,768 (Apr. 30, 2018).
[563] Miranda Green, *Pruitt signs proposed rule to erase 'secret science' from EPA*, The Hill (Apr. 24, 2018, 2:40 PM), http://thehill.com/policy/energy-environment/384636-pruitt-signs-proposed-rule-to-erase-secret-science-from-agency.
[564] Email from Juli Nix, Director of Conferences, Federalist Society, to Millan Hupp, Director of Scheduling and Advance, EPA (Mar. 17, 2017, 12:30 PM)(on file with Sierra Club), https://www.documentcloud.org/documents/4453164-Pruitt-Sierra-Club-NYT-Foia.html#document/p29/a422141.
[565] Email from Gus Wagner, Partner and Creative Dir., ARC Media, forwarded to Barry Hart, CEO, Nat'l Rural Electric Coop. Ass'n; Amy Graham, Dir. of Commc'n, EPA; Tate Bennett, Assoc. Adm'r, Office of Public Engagement and Envvtl. Educ.; Joe Wilkinson, Sr. Vice Pres., Assoc. Electric Coop. (Apr. 18, 2017).
[566] EDF Supplemental Comment on EPA's Proposed Rule, *Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits*, 82 Fed. Reg. 53,442 (Mar. 11, 2018), *https://www.edf.org/sites/default/files/content/EDF%20Third%20Supplemental%20Comment%20re%20TTU%20Study%203.11.18.pdf*.

regulatory process," and "ensur[ing] that its decision-making is marked by independence, transparency, clarity, and reproducibility" as it proceeded through rulemakings that "will affect the public" and where "the public is likely to bear the cost of compliance."[567]

VIII. The Proposal Violates Procedural Requirements of the APA, CAA, and Other Statutes and Executive Orders

The proposed rule fails to meet even the most basic procedural and substantive obligations. The Administrative Procedure Act (APA) requires that the "opportunity for comment must be a meaningful opportunity," and "[t]hat means enough time with enough information to comment and for the agency to consider and respond to the comments." *Prometheus Radio Project v. FCC*, 652 F.3d 431, 450 (3d Cir. 2011) (internal citation and quotation marks omitted). *See also Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044-45 (D.C. Cir. 1987) (noting the "obvious importance of the [APA's] policy goals of maximum participation and full information."). For its part, the Clean Air Act (CAA) "requires a much more detailed notice of proposed rulemaking than does the APA." *Union Oil Co. of Cal. v. EPA*, 821 F.2d 678, 682 (D.C. Cir. 1987); *see Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 550 (D.C. Cir. 1983) ("[T]he additional notice requirements in § 307(d)(3) suggest that Congress intended agency notice under the Clean Air Act to be more, not less, extensive than under the APA."). Executive Order 13563 underscores these obligations requiring that to promote "open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole," agencies "shall endeavor to provide the public with an opportunity to participate in the regulatory process."[568]

Moreover, notice has to be provided by the agency; it cannot be bootstrapped from the public comments.[569] The reasons are evident: there is no requirement for parties to monitor all of the thousands or tens of thousands of submitted comments in order to guess the issues on which to comment.[570] A contrary rule "would turn notice into an elaborate treasure hunt, in which interested parties, assisted by high-priced guides (called 'lawyers'), must search the record for the buried treasure of a possibly relevant comment."[571]

Drafting these comments has entailed a great deal of guesswork. The comments of EDF or any other commenter on a particular issue thus should not be taken to mean that EPA provided sufficient notice of that issue.

The proposed rule lacks essential elements needed to understand it, rendering the opportunity for comment meaningless. The Proposal contains vague and contradictory statements about its actual substance and effect, fails entirely to analyze and disclose its costs

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[567] 83 Fed. Reg. 18,768, 18,768-9 (Apr. 30, 2018).
[568] Exec. Order 13563 § 2.
[569] *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983); *Shell Oil Co. v. EPA*, 950 F.2d 741, 760-61 (D.C. Cir. 1991); *CSX Trans. v. Surface Transp. Bd.* 584 F.3d 1076, 1082 (D.C. Cir. 2009); *City of Waukesha v. EPA*, 320 F.3d 228, 234 (D.C. Cir. 2003).
[570] *Am. Fed'n of Labor v. Donovan*, 757 F.2d 330, 340 (D.C. Cir. 1985); *Fertilizer Inst.v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991).
[571] *Small Refiner Lead Phase Down*, 705 F.2d at 550.

and benefits, and is littered with vague references to entire websites and executive branch departments. The cursory reasoning and wholly inadequate record offered in support of the proposed rule prevents stakeholders from engaging with the agency on its rationale for the proposed action and its costs and benefits, or offering contrary evidence. Finally, EPA has not provided any basis whatsoever to warrant the gross inadequacies of the proposed rule and the process to consider it. With such a deeply deficient basis for action, the only legally viable course is to withdraw the Proposal.

A. The Proposed Rule is a Binding, Legislative Rule and Subject to the Requirements of the APA

The Administrative Procedure Act, the Clean Air Act, and other federal statutes proscribe procedures that must be followed in agency rulemaking, and which EPA has failed to meet in its Proposal. This proposed rule does not fit into any of the exceptions the APA provides for the procedural requirements of rulemaking—it is neither an interpretive rule, general statement of policy, or a rule of agency organization, procedure or practice.[572]

The proposed rule does not purport to clarify or explain an already existing statute or rule, and thus is not an interpretive rule.[573] The proposed rule is not a general statement of policy, because it establishes a standard of conduct, which has the force of law. It uses mandatory language indicating a requirement: "When promulgating significant regulatory actions, the Agency *shall* ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation."[574] Unlike a general statement of policy, which "does not establish a 'binding norm,'. . . [and] is not finally determinative of the issues or rights to which it is addressed," EPA here makes no qualifications that it has any leeway to not follow the Proposal's new requirements in all future regulatory actions.[575] The provision allowing the EPA Administrator to grant exceptions in a limited number of cases does not turn this rule into a general statement of policy because it also binds the Administrator's discretion, allowing deviation from the policy only when they make specific findings.[576] EPA has not indicated that "in subsequent proceedings it will thoroughly consider not only the policy's applicability to the facts of a given case but also the underlying validity of the policy itself," but seems poised to apply the policy in all instances—granting exceptions only in limited circumstances where compliance is deemed impracticable.[577] It nowhere indicates that EPA may reassess in each case whether following this rule is the best means to achieve scientific integrity as it undertakes regulatory action. The Proposal has other indications of a binding rule, including that EPA intends to codify it in the Code of Federal Regulations, and EPA has itself characterized the Proposal as a binding rule.[578]

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[572] 5 U.S.C. § 553.
[573] *Guardian Fed. Sav. & Loan Asso. v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 665 (D.C. Cir. 1978).
[574] Proposed Rule, 83 Fed. Reg. at 18,773 (emphasis added); *Pac. Gas & Elec. Co. v. Fed. Power Com.*, 506 F.2d 33, 38-39 (D.C. Cir. 1974).
[575] *Pac. Gas & Elec. Co. v. Fed. Power Com.*, 506 F.2d 33, 38 (D.C. Cir. 1974).
[576] Proposed Rule, 83 Fed. Reg. at 18,774.
[577] *Pac. Gas & Elec. Co. v. Fed. Power Com.*, 506 F.2d 33, 39 (D.C. Cir. 1974).
[578] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 24, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/ (as

This rule is also not a rule of agency organization, procedure or practice, for purposes of the APA. Agency actions in this category are those "that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency."[579] An agency action that "trenches on substantial private rights and interests" does not fall under this exemption.[580] By restricting the scientific studies on which EPA may base final significant regulatory actions, EPA severely limits parties from relying on excluded studies in advocating for particular safeguards. In the preamble, EPA makes clear that the rule is about "EPA's regulatory actions" and underlying conclusions.[581] Because the rule substantively impacts agency conclusions and regulations, it impacts private rights and interests. The rule does not allow private individuals to submit for consideration (or renders such submittal a nullity) studies that they would have been permitted to prior to the proposed rule, thus impacting the substantive standards that EPA is able to justify setting—which has implications for the regulated community as well as for public health. The Proposal "encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior" by requiring regulatory actions to be supported only by certain scientific information deemed acceptable by the proposed rule.[582]

In *CropLife Am. v. E.P.A.*, the Court held that a similar rule promulgated by EPA, barring third-party human studies from agency consideration during pesticide registrations was a binding regulation because it used "clear and unequivocal language" reflecting "an obvious change in established agency practice" that created a "binding norm."[583] The Court stated: "EPA's stated rule is binding on petitioners, who are now barred from relying on third-party human studies (even in cases where such studies formerly were approved), and is binding on the agency because EPA has made it clear that it simply 'will not consider' human studies."[584] Similarly, the Proposal appears to bind EPA to not consider scientific information it could consider before, unless it falls under certain narrow, ambiguously defined exceptions, and binds the public and organizations such as EDF who can no longer submit studies to EPA that EPA would previously have been required to consider as part of the rulemaking process.

B. The Proposal is Subject to the Procedural Requirements of the Clean Air Act.

Administrator Pruitt signed the Proposal, he stated: "This is not a policy. This is not a memo. This is a proposed rule.").

[579] *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980).

[580] *Batterton v. Marshall*, 648 F.2d 694, 708 (D.C. Cir. 1980).

[581] 83 Fed. Reg. 18,769.

[582] *Am. Hosp. Asso. v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987). *See also Pharm. Mfrs. Asso. v. Finch*, 307 F. Supp. 858, 865 (D. Del. 1970) (finding that a regulation promulgating new criteria for clinical investigations that will meet the standards of evidence necessary to demonstrate the effectiveness of drug products, and excluding certain kinds of clinical investigations, was not merely a procedural rule, because they "did effect a material narrowing of the range of evidence which previously had been considered relevant in evaluating a drug's efficacy. Because of the important clarification of acceptable testing standards effected by the September regulations and because of the substantial impact of these regulations on the drug industry. . . . ")

[583] 329 F.3d 876, 881 (D.C. Cir. 2003).

[584] *Id.*

Section 307(d) applies to "such. . . actions as the Administrator may determine."[585] EPA claims to take this action under "authority of the statutes it administers. . . including Clean Air Act sections 103, 301(a)."[586] By issuing this Proposal through notice and comment procedures, Administrator Pruitt appears to have determined that 307(d) procedures apply.

Even without that invocation, the proposed rule is subject to these procedural requirements because it materially impacts many of the actions delineated in 307(d)(1) to which the CAA rulemaking procedures explicitly apply. The Proposal applies to "significant regulatory actions," which many of these actions are. The CAA requires science-based decision-making that the Proposal will materially affect. For example, by restricting the science EPA may rely on in regulatory actions, the Proposal materially impacts residual risk determinations for hazardous air pollutants (§ 307(d)(1)(C)), standards for mobile source air toxics (§ 307 (d)(1)(K)), and residual risk standards for municipal solid waste combustors (§ 307(d)(1)(D)).[587]

This proposed rule directly affects EPA's setting and review of National Ambient Air Quality Standards (NAAQS),[588] the promulgation or revision of which is subject to the CAA rulemaking requirements.[589] Section 108(a) of the Clean Air Act requires the Administrator to set air quality criteria for air pollutants that "reflect the latest scientific knowledge." This Proposal amends the science EPA can consider for air quality criteria. Under CAA section 109 EPA must use the air quality criteria to set primary and secondary NAAQS and periodically review them—which EPA is currently doing for Particulate Matter.[590] In the Proposal, EPA cites *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 358 (D.C. Cir. 2002) as an example of an instance where EPA relied on a scientific study where the underlying data was not publicly available. EPA states that under the Proposal use of such science would be "preclude[d]".[591] In *Am. Trucking Ass'ns* the Court upheld EPA's use of key studies underlying the NAAQS for PM. Under the Proposal, EPA would not have been permitted to use those studies, and it is unclear how the Proposal will affect EPA's reliance on these studies as it undertakes its review. This demonstrates how this Proposal would have an immediate impact on EPA NAAQS-setting under the CAA. EPA is thus subject to the CAA 307(d) procedural requirements for this Proposal.

C. EPA Has Failed to Provide a Properly Developed Docket and Record as Required by the APA and CAA and Has Thereby Violated the Notice Requirements of these Statutes

EPA has failed to provide a properly developed record in support of the proposed rule. EPA has not identified sufficient supporting evidence in the Proposal or in its docket and has failed to provide adequate notice of the supporting evidence for the public to respond to

[585] 42 U.S.C.S. § 7607(d)(1)(V).
[586] 83 Fed. Reg. at 18,769.
[587] 83 Fed. Reg. at 18,773.
[588] CAA Section 108(a).
[589] CAA Section 307(d)(1)(A).
[590] *See Release of the Final Integrated Review Plan for the National Ambient Air Quality*, 81 Fed. Reg. 87,933 (Dec. 6, 2016).
[591] 83 Fed. Reg. at 18,769 n. 3.

meaningfully, as the Administrative Procedure Act, the Clean Air Act, and other substantive statutes require.

Under the APA, agencies must base their actions on examination of the facts, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"[592] The factual determination underlying the agency decision must be based on substantial evidence and will be set aside "if the agency 'relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'"[593]

Rulemaking under the Clean Air Act is subject to the same general requirements of statutory conformity and reasoned decision-making derived from the APA and basic principles of administrative law. Clean Air Act rules cannot be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law."

As noted in Appendix A and below in Section VIII.D EPA's citations for support in the Proposal are vague and uninformative, and even where the particular citation can be identified and located, it is often not clear how EPA thinks the citation supports the Proposal. This does not meet the standards of the APA and CAA.

Additionally, EPA has failed to meet the docket requirements of the CAA. CAA section 307(d)(3) requires that publication of the proposed rule in the Federal Register include a summary of the factual data on which the proposed rule is based, the methodology used in obtaining the data and in analyzing the data, and the major legal interpretations and policy consideration underlying the proposed rule. It also requires the agency to place "[a]ll data, information, and documents. . . on which the proposed rule relies" in the rulemaking docket on the date of publication of the proposed rule.[594] The undifferentiated citation of articles and policies, most of which contradict the Proposal or otherwise offer no support for it, fails abjectly to satisfy these requirements.[595] Any document that becomes available after the proposed rule

[592] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43-44, (1983).
[593] *Cablevision Sys. Corp. v. FCC*, 597 F.3d 1306, 1310 (D.C. Cir. 2010).
[594] CAA Section 307(d)(3).
[595] *See Kennecott v. EPA*, 684 F.2d 1007, 1018 (D.C. Cir. 1982)("Section 307(d)(3) requires that notice of proposed … regulations be accompanied by a statement of their basis and purpose, including the factual data on which the proposed regulations are based, the methodology used in obtaining and analyzing the data, and the major legal interpretations and policy considerations underlying the proposed regulations. . . . Though EPA states in its preamble to the final regulations that its current eligibility test is based upon a closure policy adopted by EPA before 1977, and that it has used financial tests similar to the present closure test under the agency's existing policy, no documents embodying those tests or demonstrating the methodology used before 1977 were ever placed in the docket. The only document in the docket purporting to explain that a closure test was ever employed by EPA was a memorandum in which EPA economist Hale sets forth his recollection that such a test had been used before 1977 to determine whether smelters would be permitted to rely upon dispersion techniques to meet the ambient standards. That memo, dated August 17, 1979, was placed in the docket on March 12, 1980, approximately eleven months after

has been published and that is of central relevance to the rulemaking must also be placed in the docket as soon as possible after its availability.[596] The agency must allow enough time for participants in the rulemaking to respond to those documents with comments.[597]

As of the date of the publication of the Proposal, the docket at regulations.gov contained only the following 12 documents: (1) OIRA Review Start Document (Apr. 17, 2018); (2) OIRA Review Conclusion Document (Apr. 23, 2018); (3) White House Memorandum on Scientific Integrity (Mar. 9, 2009); (4) *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*; Republication, 67 Fed. Reg. 8,452 (Feb. 22, 2002); (5) Exec. Order 13,777, *Enforcing the Regulatory Reform Agenda*, 82 Fed. Reg. 12,285 (Feb. 24, 2017); (6) EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* (Nov. 29, 2016); (7) OMB Memorandum M-05-03 on Issuance of OMB's "Final Information Quality Bulletin for Peer Review" (Dec. 16, 2018); (8) EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (Oct. 2002); (9) Exec. Order 13,563, *Improving Regulation and Regulatory Review*, 76 Fed. Reg. 3,821 (Jan. 18, 2011); (10) Exec. Order 16, 093, *Promoting Energy Independence and Economic Growth*, 82 Fed. Reg. 16,093 (Mar. 28, 2017); (11) OMB Memorandum M-13-13: Open Data Policy-Managing Information as an Asset (May 9, 2013); (12) Commission on Evidence-Based Policymaking, *The Promise of Evidence-Based Policymaking* (Sep. 2017).

This clearly is not enough to meet the APA's or CAA's requirements. Aside from the drafts of the proposed rule submitted to OIRA, each of these documents was a pre-existing memorandum, policy document, or executive order that contains no specific analysis—factual, legal, policy or otherwise—that pertains to the impacts of or at all justifies *this* proposed rule. While EPA in the proposed rule cites to some of these documents as purportedly being consistent with these prior policies, *see, e.g.*, 83 Fed. Reg. at 18,769-70, as is discussed in Section II and in Appendix A, these policies do not in fact provide any basis for the Proposal. The record that EPA provides clearly fails to support its proposed action. Some of the factual data, legal interpretations, and policy considerations that EPA has not sufficiently provided evidence for include: the number of scientific studies that would be precluded from consideration under the Proposal; whether there are fields of research where the Proposal would result in insufficient scientific information available for EPA to meet its statutory duties; how EPA will address the substantial privacy concerns implicated by the Proposal; how application of this Proposal will impact substantive agency actions; what the costs of implementing this Proposal are if EPA intends to not just exclude studies from consideration where too costly to provide access, etc.

EPA, for instance, includes Executive Order 13,563 in the docket to support its statement that "[t]he best available science must serve as the foundation of EPA's regulatory actions."[598] While Executive Order 13,563 makes that statement, it does not support EPA's Proposal, which

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the close of the public comment period, and reveals neither the actual tests nor the methodology used by EPA**.** The failure of EPA to observe the procedures mandated by §§ 307(d)(3) and 307(d)(6) was thus arbitrary and capricious.")

[596] CAA Section 307(d)(4).

[597] *Sierra Club v. Costle*, 657 F.2d 298, 352 (D.C. Cir. 1981); *Union Oil Co. v. EPA*, 821 F.2d 678, 683 (D.C. Cir. 1987).

[598] 83 Fed. Reg. at 18,769 n. 1.

as explained above, hinders EPA's use of the best available science. EPA provides no evidence or explanation in the docket or Proposal for why EPA believes this policy would further that goal. The executive order only states that agencies should make available to the public the scientific or technological *findings or conclusions* on which rules rely, as opposed to underlying raw data that EPA has targeted with this Proposal. Meanwhile, EPA blatantly violates the executive order's provisions requiring agencies to weigh costs and benefits; to write regulations that are easy to understand; and to provide the scientific and technical findings underlying the rule for the public to comment on.

Section 307(d)(3) of the CAA requires that "[a]ll data, information, and documents … on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule." Many items that EPA cites to in the Proposal as providing a basis for the proposed rule do not appear in the docket. For example, EPA states: "The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science."[599] In a footnote, EPA provides: "These include policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data,* and *Access to Research Data in the 21st Century;* the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project."[600] Many of these policies and recommendations did not appear in the docket on the data of publication of the Proposal and still do not appear in the docket—a clear violation of the CAA—nor are the specific documents or reports even identified or properly cited so that they may be tracked down. This is evidently prejudicial to commenters—it undermines commenters ability to submit meaningful feedback when the agency is hiding the ball in this manner.

These policies and recommendations are not easily identifiable on their own either, even after significant internet research. This is also true of footnote 16, where EPA lists a number of agencies to support its claim that the federal government is already implementing solutions to data disclosure.[601] EPA cites, for example, the National Institute of Standards of Technology. NIST has numerous policy documents on protecting privacy concerns and keeping data secure as well as its own internal policies on releasing data. It is hard to see how any are relevant here, but without a particular cite the public is denied even a chance to respond to whatever EPA is trying to use as support—or must respond to *everything* that might be being referenced, creating a burdensome task. Throughout these comments, as we attempt to respond to EPA's Proposal, we have been very practically limited by our inability, even after much research and consideration, to be fully certain we have identified the appropriate policies to respond to. This presents a situation that the CAA's docket requirement was exactly formulated to prevent.

[599] 83 Fed. Reg. at 18,770.
[600] 83 Fed. Reg. at 18,770 n. 10.
[601] 83 Fed. Reg. at 18,770 n. 16.

On May 25, 2018, EPA added a memorandum to the docket for this rulemaking.[602] This memorandum contains hyperlinks apparently intended to accompany various citations in the footnotes of the Proposal. This document does not cure the former procedural defect, as the CAA requires information the proposed rule relies on to be placed in the docket on the day the proposed rule is published.[603] Further, these hyperlinks still link ambiguously to various documents and agency websites without providing any information about what specifically EPA intends to cite or how the cited information is being used or considered by EPA. Additionally, simply adding such a document to the docket does not provide adequate notice to the public. Someone who had access only to the proposed rule and was not carefully monitoring the docket would have no indication or notice of this new document.

Either EPA is failing to comply with the CAA's requirements by failing to include in the docket factual data, legal interpretations, and policy considerations that support the Proposal, or these supporting items do not exist, deeming this rulemaking completely arbitrary—in either case the Proposal fails to meet the standards of the APA and CAA. Under the CAA the rulemaking docket "must provide the entire basis for the final rule and the exclusive record for judicial review," this docket clearly cannot support a final rule.[604]

D. The Proposal is too Vague for Meaningful Comment.

Section 553 of the APA, 5 U.S.C. § 553(b)(3), requires that an agency proposing a rule "provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully."[605] The Clean Air Act requires even more, that the Federal Register notice be accompanied by a statement of basis and purpose that includes a summary of the factual data on which the proposed rule is based, the methodology used in obtaining the data and in analyzing the data; and the major legal interpretations and policy considerations underlying the proposed rule.[606] As discussed above, all data, information, and documents on which the proposed rule relies must be included in the docket on the date of publication of the proposed rule.[607]

These core requirements are "designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review."[608] In addition, "a chance to comment … [enables] the agency [to] maintain[] a flexible and open-minded attitude towards its

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[602] EPA Memorandum RE: Omitted Hyperlinks for Footnotes in the Proposed Rule (May 25, 2018), EPA-HQ-OA-2018-0259-0812.
[603] Section 307(d)(3).
[604] *Union Oil Co. of California v. EPA.*, 821 F.2d 678, 681-82 (D.C. Cir. 1987).
[605] *United States Telecom Assn. v. FCC*, 825 F.3d 674, 700 (D.C. Cir. 2016) (quoting *Honeywell Intl., Inc. v. EPA*, 372 F.3d 441, 445 (D.C. Cir. 2004) (internal quotation marks omitted).
[606] 42 U.S.C. § 7607(d)(3).
[607] 42 U.S.C. § 7607(d)(3).
[608] *Int'l Union, United Mine Workers of Am. v. Mine Safety and Health Admin*., 407 F.3d 1250, 1259 (D.C. Cir. 2005).

own rules,"[609] and "avoid[s] the inherently arbitrary nature of unpublished ad hoc determinations."[610] The "notice required by the APA … must disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based …. [A]n agency proposing informal rulemaking has an obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible." *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977); *see also Horsehead Res. Dev. Co., Inc. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) ("[A]n agency must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making.") (internal citations and quotation marks omitted).

The failure to include critical documents relevant to the proposed rule in the docket, as required by the Clean Air Act, itself constitutes a notice violation because "absence of those documents, or of comparable materials. . . makes impossible any meaningful comment on the merits of EPA's assertions."[611] By failing to provide a more developed docket, EPA is frustrating the terms and purposes of these statute's notice requirements. These procedures are in place to form a "specific" proposal that can serve as a "focus for comments," *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 548-49 (D.C. Cir. 1983); *see Home Box Office, Inc. v. FCC*, 567 F.2d 9, 36 (D.C. Cir. 1977) (agency must "make its views known . . . in a concrete and focused form so as to make criticism or formulation of alternatives possible"). Because EPA has not provided supporting evidence, has not included key items it points to as major considerations underlying the Proposal, and has generally presented a vague and unspecified proposed rule and docket, EDF and the public are hindered in our ability to provide specific comment focused on the underpinnings of the Proposal, because we do not know and can only guess as to what they are.[612]

Even the text of EPA's proposed rule and the statement of basis and purpose fails to provide the requisite notice to allow meaningful comment. At the most fundamental level, it contains vague and contradictory statements about the actual effect of the Proposal. The Proposal generally appears to make its requirements mandatory—i.e., failure to make information publicly available will preclude the agency from relying on the study at all. *See* 83 Fed. Reg. at 18,769 n. 3 ("EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions."); *id.* at 18,771 ("the regulatory text would impose requirements"); *see also id.* at 18,769 ("EPA *will* ensure that the data and models underlying the science is publicly available…") (emphasis added) and proposed section 30.5 ("When promulgating significant regulatory actions, the Agency shall ensure that does response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation"). In a few places, however, the Proposal makes it sound as if its aims are more aspirational. *See id.* at 18,770 ("Where *available and appropriate*, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures,

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[609] *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1325 (D.C. Cir. 1988) (internal citation and quotation marks omitted).
[610] *United States v. Reynolds*, 710 F.3d 498, 519-20 (3d Cir. 2013).
[611] *Kennecott Corp. v. EPA*, 684 F.2d 1007, 1018 (D.C. Cir. 1982).
[612] "Without a readily accessible statement of the agency's rationale, interested parties [could not] comment meaningfully during the rulemaking process." *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 949 (D.C. Cir. 2004).

and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments.") (emphasis added); *id.* at 18,772 ("The proposed rule directs EPA to make *all reasonable efforts* to" make data publicly available, but "does not compel the Agency to make that information available where it concludes after all such reasonable efforts that doing so in way [sic] that complies with the law and appropriate protections is not possible.") (emphasis added); *see also id.* at 18,768 ("EPA *should* ensure that the data underlying those are publicly available…") (emphasis added). The difference between a *requirement precluding* use of science and making *all best efforts* to make data publicly available is enormous.

To the extent EPA intends to propose a rule that would *preclude* use of science, as it appears the Proposal would do, the proposed rule is further flawed because it contains no analysis of how that would affect regulations. How many studies does EPA typically rely on in promulgating regulations? What percentage of these would meet EPA's new requirements? For those that do not, how many could not meet these requirements for patient privacy, confidential business information, or other reasons? How would EPA set standards if it must rely on many fewer studies? Would EPA be precautionary in the face of less evidence? Would EPA delay promulgating regulations in order to comply with this new mandate? How does this mandate interact with statutory deadlines or statutory requirements that EPA look at a wide range of science? None of these very basic questions are addressed in the proposed rule and without answering them, it is impossible for the public to assess the import and likely consequences of the Proposal. Even more basically, the agency gives no notice as to the Proposal's impacts, its costs, its benefits, why it applies only to regulatory requirements but not to any regulatory actions (like licensing or permitting) that confer a benefit, substantive and procedural criteria for adjudicating waivers, or even the legal theory under which the Proposal issues—the plaintive solicitation for comment as to "additional or alternative sources" of authority, 83 Fed. Reg. at 18771, does not suffice.

To the extent the Proposal is intended to solicit comment on how EPA may make reasonable efforts to make data publicly available it is also unlawfully vague. The proposed rule includes numerous footnotes referencing entire websites or even Departments of the Executive Branch. For example, the Proposal claims that "EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly used across some parts of the Federal government."[613] To support this proposition, EPA remarkably cites (without any further elaboration or explanation in the proposal itself) to "examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau."[614] *See Small Lead Refiner Phase Down*, 705 F. 2d at 548 (requirement that comments are to raise issues with "reasonable specificity" applies equally to the agency giving notice). For example, it is not possible to identify whether the sources referenced support EPA's claim that there are approaches available to address the serious privacy issues raised by the Proposal—without providing the specific policies and recommendations, a public commenter has no way of knowing whether they are consistent or why EPA believes them to be consistent. It is impossible to respond in a meaningful way without significant guesswork.

[613] Proposed Rule, 83 Fed. Reg. at 18,770.
[614] *Id.* at 18,770 n. 16.

Similarly, in footnote 10, where EPA lists a number of organizations whose "policies and recommendations" the Proposal allegedly took under consideration—no explanation is provided.[615] In addition, in the proposed rule EPA fails to adequately define key terms like "validation", "independence", "reproducibility," "replication," and "uncertainty," while also citing a "replication crisis" in science. It is important that these terms are defined clearly as these terms are not defined consistently across the scientific community nor governments—which has implications for the scope and purview of the proposed rule.

This amount of information is wholly insufficient to allow a public commenter to provide meaningful comments about these issues.

Courts have been reluctant to find that important information appearing solely in the footnote of a rulemaking document satisfied the notice requirement of the APA, holding that "an agency may not turn the provision of notice into a bureaucratic game of hide and seek."[616] Referencing a key document without further discussion in the rulemaking document itself, and without incorporating it by reference or publishing it in the Federal Register, also does not satisfy the notice requirements of the APA.[617] Subsequent publication of the document may not be enough to cure a defect of notice where an important issue is "belied by the obscurity of the footnote intended to give notice" and further agency procedure is required to provide the public with "the opportunity to comment on a significant part of the agency's decisionmaking process as required by section 553."[618] Thus, the undifferentiated citations in the footnotes of the Proposal do not give adequate notice for public comment.[619]

E. EPA Must Comply With Other Requirements of the Clean Air Act

As discussed above, the Proposal impacts EPA's process for setting NAAAQs in material ways by amending the scientific information that can be used as air quality criteria. Under the CAA air quality criteria cannot be amended without review by the Clean Air Science Advisory Committee (CASAC).[620] Thus, EPA must submit this proposal to CASAC for review, consider

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[615] 83 Fed. Reg. at 18,770. n. 10 ("These include policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data*, and *Access to Research Data in the 21st Century;* the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.)

[616] *MCI Telcommunications Corp. v. FCC*, 57 F.3d 1136, 1142 (D.C. Cir. 1995).

[617] *PPG Indus., Inc. v. Costle*, 659 F.2d 1239, 1249-50 (D.C. Cir. 1981).

[618] *PPG Indus., Inc. v. Costle*, 659 F.2d 1239, 1250 (D.C. Cir. 1981).

[619] *See, e.g., Chamber of Commerce v. SEC*, 443 F. 3d 890, 899 (D.C. Cir. 2006); *Jackson v. Des Moines Mun. Housing Agency*, No. 4:07-cv-00438-HDV, 2008 U.S. Dist. LEXIS 125003, at *8-9 (S.D. Iowa June 4, 2008); *Billington v. Underwood*, 613 F.2d 91, 94 (5th Cir. 1980) ("Such a statement must be sufficiently specific for it to enable an applicant to prepare rebuttal evidence to introduce at his hearing appearance."); *Edgecomb v. Housing Auth.*, 824 F.Supp. at 312, 314-15 (1993); *Driver v. Housing Auth.*, 713 N.W.2d 670,673 (Wis. Ct. App. 2006); *Owner-Operator Independent Drivers Ass'n, Inc. v. Federal Motor Carrier Safety Admin*., 494 F.3d 188, 209 (D.C. Cir. 2007) ("It is certainly true that a notice can be "too general to be adequate.").

[620] CAA § 109(d)(2)(B).

their recommendations, and provide reasonable explanation for deviation from those recommendations.[621]

F. EPA Failed to Submit the Proposal to the SAB or to Consult with the Scientific and Technical Community

There is no indication that EPA consulted with the scientific and technical community—or even its own Science Advisory Board—before proposing to require that the underlying data and models be made publicly available for all pivotal regulatory science regardless of ethical, feasibility, or confidentiality constraints. As detailed in a June 28, 2018 letter from the chair of the SAB, the SAB learned of the rule only through a press event, federal register notice, and news articles.[622] The letter further explained that the proposed rule "was not identified as a major action in either of the Spring 2017 or Fall 2017 semi-annual Regulatory Agendas," and that SAB members "had no information regarding the timeline for finalizing the rule . . . ."[623] The letter also points out that "the precise design of the proposed rule appears to have been developed without a public process for soliciting input specifically from the scientific community," even though the proposed rule raises important scientific questions.[624]

Not surprisingly, the SAB concluded in its May 31, 2018 meeting that the Proposal merits SAB review because it "deals with issues of scientific practice and proposes constraints to the use of scientific studies in particular contexts."[625] Moreover, the SAB chair's June 28 letter raises a number of questions that echo the concerns we have detailed in our comments, including the feasibility of providing access to data and methods for already-completed studies; "legitimate confidentiality and privacy interests" that would counsel against providing "complete public access"; the costs and effort associated with implementing the Proposal; the relationship between the Proposal and previous EPA efforts to encourage transparency; and the need to consider "the multiple existing methods to assess the validity of prior epidemiologic studies" that "do not provide public access to data and analytic methods."[626]

EPA's failure to consult with the SAB is contrary to statute and to EPA's well-established practice. EPA must submit its Proposal to the SAB pursuant to the requirements of 42 U.S.C. § 4365(c)(1) (the Environmental Research Development Demonstration Authorization Act or "ERDAA"), which requires the Administrator to submit to the SAB any proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the (EPA) on which the proposed action is based at the time it provides that proposal to another agency of the government for formal review. The SAB must

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[621] CAA § 109(d)(2)(B); 307(d)(3).
[622] Letter from Dr. Michael Honeycutt, Chair, Science Advisory Board, to Scott Pruitt, EPA Administrator (June 28, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf.
[623] *Id.*
[624] *Id.*
[625] *Id.*
[626] *Id.*

then review and comment on the proposal.[627] While the Administrator need not receive the SAB's final approval, the Administrator must consider the SAB's advice and comments.[628]

As the SAB chair's letter notes, EPA's "usual process" is to inform the SAB about the publication of the agency's semi-annual regulatory agenda and provide descriptions of actions that are contained in the agenda, including "available information regarding the science that is informing these agency actions."[629] That procedure was not followed here. In its evident zeal in the name of purported "transparency," EPA has ignored major statutory and regulatory requirements that provide *actual* transparency to the Clean Air Act's scientific review process.[630] Should EPA decide to move forward with this Proposal, it must first allow the SAB to complete its review and take into account the SAB's recommendations in any final rule.

G. EPA's Proposal Fails to Meet the Procedural Requirements of FIFRA

The Proposal lists FIFRA section 25 as an authority for the rulemaking.[631] The agency, however, has already failed to follow several required procedures for issuing a valid regulation under this section of FIFRA. FIFRA section 25 requires the agency to seek comments from the Secretary of Agriculture on all draft proposed regulations 60 days prior to signing a proposed regulation for publication,[632] and 30 days prior to publication for a final rule. If the Secretary of Agriculture provides comments, the Administrator must also respond in writing as part of the proposed rulemaking package.[633] FIFRA additionally requires EPA to publish a notice in the Federal Register simultaneously with the transmission of the proposed rule to USDA.[634] And the statute requires the agency to submit a copy of the proposed rule for comment to the Scientific Advisory Panel ("SAP"),[635] as well as a copy to the Agriculture Committees in the House and Senate *any time* the agency is required to consult with the Secretary of Agriculture.[636] This means that EPA here should have provided both committees and the SAP with a copy of the proposed regulation at least 60 days prior to publication of the Proposal in the Federal Register.

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[627] 42 U.S.C. §4365(c)(2).
[628] *See* H. Rep. No. 95-722 (95th Cong. 1st Sees. (1977) (Conference Report).
[629] Letter from Dr. Michael Honeycutt, Chair, Science Advisory Board, to Scott Pruitt, EPA Administrator (June 28, 2018).
[630] *See* Memorandum "Identifying EPA Planned Actions for Science Advisory Board Consideration of the Underlying Science" from Michael Goo, Assistant Administrator for Policy, Glenn Paulsen, EPA Science Advisor, and Vanessa Vu, Science Advisory Board Office Director (Dec. 27, 2012;) Memorandum from James Mihelcic, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons (Nov. 12, 2013) (explaining SAB Work Group process, where EPA sent to the SAB "short descriptions of major planned actions that were not yet proposed" and the SAB Work Group determined which of the actions merited their consideration in a public forum).
[631] 83 Fed. Reg. 18769.
[632] 7 U.S.C. 136w(a)(2)(A).
[633] 7 U.S.C. 136w(a)(2)(B).
[634] 7 U.S.C. 136w(a)(2)(D).
[635] 7 U.S.C. 136w(d)(1).
[636] 7 U.S.C. 136w(a)(3).

The agency did not comply with any of these requirements, and does not indicate that it will in any final rule. The Proposal is therefore unlawful.[637]

To be sure, in some instances the Administrator and Secretary may together agree to waive some of the consultation requirements among themselves,[638] but there is no indication that Administrator Pruitt did that with this Proposal. And even if the Administrator and Secretary later agree to waive the consultation requirement section 25(a)(2)(A) and (B), that waiver would not alter EPA's obligation to provide the SAP and the House and Senate Committees with a copy of the regulation. Nor would it change the fact that the Administrator illegally issued the Proposal without consulting the Secretary of Agriculture. A very serious consequence of these procedural mistakes is to deprive the agency of a full understanding of how the proposed rulemaking might affect the regulation of pesticides and thereby affect agriculture, human health, and the environment.[639] Therefore, the only lawful path forward here is for the Agency to withdraw the Proposal, consult with the entities required by FIFRA, and then subsequently re-notice the Proposal.

H. EPA's Proposal Fails to Meet the Procedural Requirements of the Safe Drinking Water Act, 42 U.S.C. § 300f Et Seq.

EPA cites the Safe Drinking Water Act as an authority for the Proposal, but has failed to comply with the procedural requirements of the statute. The SDWA provides authority to promulgate regulations at 42 U.S.C. 300g-1(d). Though EPA does not cite this particular section, it is the only provision of the SDWA that provides EPA with rulemaking authority. The SDWA requires the Administrator to consult with the Secretary of Health and Human Services and the National Drinking Water Advisory Council in proposing and promulgating regulations under this section. EPA has not met these requirements here, and as such cannot claim to be using SDWA authority to promulgate this rule.

I. EPA Unlawfully Failed to Consult with Other Agencies as Required by TSCA.

When promulgating the Proposal, EPA unlawfully failed to consult with other entities as required by TSCA. For example, consider the sole statutory authority EPA cites under TSCA—§ 10.

To the extent EPA acts under TSCA § 10, TSCA § 10 repeatedly directs EPA to consult, cooperate, and/or coordinate with the Secretary of Health and Human Services, and sometimes other agencies as well.[640] EPA has not identified any specific provision of TSCA § 10 that authorizes the proposed rule, and as noted above, no provision does. But if EPA acts under TSCA § 10, then EPA needs to comply with the requirements of whichever provision EPA

[637] If finalized, the proposal will also have to be transmitted to the Secretary of the Senate and Clerk of the House of Representatives. See 7 U.S.C. 136w(a)(4). The rule does not become effective until 60 days after this rule or regulation is transmitted.
[638] 7 U.S.C. 136w(a)(2)(C).
[639] *See also,* Section II.D.8.
[640] 15 U.S.C. § 2609(a), (b)(2)(A), (b)(2)(B), (c), (d), (e), (g).

considers relevant. Most of the provisions of TSCA § 10 expressly require that EPA consult, coordinate, or cooperate with, at least, the Secretary of Health and Human Services (section 10(a), 10(b)(2)(A), 10(b)(2)(B), 10(c), 10(d), 10(e), 10(g)). For example, the provision that mentions "research and development results" states that EPA shall act "in consultation with the Secretary of Health and Human Services and other heads of appropriate departments and agencies."[641] EPA does not appear to have complied with any of the procedural requirements of TSCA § 10.

J. EPA Has Failed to Consult with the Science Advisory Committee on Chemicals

As discussed above, this proposed rule has severe implications for the implementation of TSCA. The Science Advisory Committee on Chemicals' purpose is "to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this subchapter."[642] This rulemaking specifically involves "the scientific and technical aspects of issues relating to the implementation of [this Act]," yet there is no indication that the Administrator has consulted with the committee.[643] Congress specifically created this Committee to consult on these types of issues, and thus EPA is abusing its discretion to not consult with this Committee about a proposal that will so radically affect the scientific and technical aspects of issues relating to the implementation of TSCA.

K. EPA Has Failed to Provide Documents in Response to EDF's FOIA Requests

EDF currently has two Freedom of Information Act Requests directly related to the substance of this rulemaking pending at EPA, for which we have received *no* responsive documents thus far, despite the passage of the statutory deadlines for a response. The first request (No. EPA-HQ-2018-005636) was submitted on March 20, with a determination from EPA statutorily due by April 19—which has not been provided. EDF submitted a second request (No. EPA-HQ-2018-007397) on May 4. Given the lack of transparency and information around the basis for this rule, its impacts, and its true motivations, EDF and the public cannot provide informed comment on this rule without the public records that have been requested. For EPA to close the public comment period on this Proposal before all relevant records are released to the public is arbitrary and prevents our ability to meaningfully comment.

L. The OIRA Review Process for the Proposal Was Too Rushed to be Meaningful and EPA Has Not Sufficiently Coordinated with Other Federal Agencies

EPA did not provide enough time for the Office of Information and Regulatory Affairs ("OIRA") to meaningfully review the Proposal. Executive Order 12,866 requires agencies to

[641] 15 U.S.C. § 2609(g).
[642] 15 U.S.C. § 2625(o)(2).
[643] 15 U.S.C. § 2625(o)(2).

submit all significant regulatory actions to OIRA.[644] This submission must contain "an assessment of the potential costs and benefits of the regulatory action" in addition to other analyses.[645] Executive Order 12,866 provides OIRA 90 days to review and return the draft regulatory action to the agency.[646] As indicated above, the Proposal gives scant consideration to the costs of the proposed action. The April 17, 2018 draft sent to OIRA for review contained *no* mention of cost and benefits of the Proposal at all.[647] It appears that OMB drafted the two paragraphs on costs that appear in the Proposal as published in the federal register.[648]

EPA transmitted the Proposal to OIRA on April 19, and OIRA's website indicates that its review concluded on April 23.[649] This is not nearly sufficient time for White House review of this far-reaching Proposal that raises important inter-agency issues. Further, media outlets report that there were discrepancies in the date when OIRA concluded its review of the proposed rule, suggesting that the date was backdated from April 25 to April 23 only after Administrator Pruitt signed the proposed rule on April 24.[650] The public record also shows OIRA convened no Executive Order 12,866 meetings in regards to this rule. EDF requested such a meeting on the morning of April 24; our request was not granted, even though the Proposal was still listed as under OIRA review.

The rushed process is particularly concerning given the proposed rule's complex cross-agency impacts. A letter from a group of Democratic senators to OIRA raising these concerns highlighted that, on average, OIRA review of EPA rules takes 55 days.[651] Given how bare-bones EPA's proposed rule was, lacking many of the elements required by Executive Order 12,866, it seems that OIRA should have required even more time to review the Proposal. Because this rule affects EPA's regulatory actions across program areas and statutes and interacts with the work of other agencies, as discussed more in Section II.D.8, adequate OIRA review was required to ensure consistency across the federal government. Certain other agencies base their standards on standards set by EPA. For example, FDA and EPA work together to promulgate advice on fish consumption, based on the reference dose calculated by EPA. The Proposal could thus have an impact on FDA's ability to promulgate advice on fish consumption sufficient to protect human health.[652] Thus, EPA's disregard of scientific evidence as it sets these standards will directly impact the sufficiency of standards set by these agencies.

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[644] Exec. Order 12,866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (Sept. 30, 1993).
[645] *Id*.
[646] *Id*.
[647] EO 12866 Proposal 2080-AA14 OIRA Review Start Document (Apr. 17, 2018), ID EPA-HQ-OA-2018-0259-0007.
[648] *Compare* EO 12866 Proposal 2080-AA14 OIRA Review Start Document (Apr. 17, 2018), ID EPA-HQ-OA-2018-0259-0007 *with* EO 12866 Proposal 2080-AA14 OIRA Conclusion Document (Apr. 23, 2018), ID EPA-HQ-OA-2018-0259-0006.
[649] OIRA, *OIRA Conclusion of EO 12866 Regulatory Review for Strengthening Transparency and Validity in Regulatory Science*, https://www.reginfo.gov/public/do/eoDetails?rrid=128014 (last accessed Aug. 16, 2018).
[650] *See* Sean Reilly, *OMB backdates completion date for 'secret science' review*, E&E News (Apr. 27, 2018), https://www.eenews.net/greenwire/2018/04/27/stories/1060080331.
[651] Letter from Senators Hassan, Carper, McCaskill, Markey, Harris, and Whitehouse to Neomi Rao, Administrator, OIRA (May 9, 2018), https://www.hassan.senate.gov/imo/media/doc/RaoEPALetterFinal.pdf.
[652] FDA, *Technical Information on Development of Fish Consumption Advice - FDA/EPA Advice on What Pregnant Women and Parents Should Know about Eating Fish*,

As noted above, EPA failed to consult with other federal agencies before proposing this rule. EPA also violated its own data access plan, which says EPA "will consider how, when, and whether to apply the EPA policy to research that is subject to public access policies from other agencies" as it recognizes that "duplicative or conflicting requirements might result when research is subject to public access policies from multiple federal agencies".[653] There is no evidence that EPA considered these issues or that EPA followed its own policy to "coordinate with other agencies and the private sector" as it implements new data access policies.[654]

The usual procedures appear to have been set aside for this proposed rule, and EPA has provided no explanation for why shortened review procedures were necessary. It was initially reported that this Proposal was categorized as a "tier 3" measure, subject to the lowest amount of scrutiny in EPA's own internal review process, and developed largely by political appointees with no input from career staff, despite having characteristics of a "tier 1" measure, subject to the highest level of scrutiny.[655] These characteristics include being precedent-setting; controversial; having cross-Agency, cross-media, and inter-agency impacts and controversies; and raising external interest, all of which are present here. Though the agency appears to have now raised it to "tier 1" status, the Proposal that is now available for public comment was subject only to these initial hasty procedures, calling into question its validity.[656]

EPA must withdraw the Proposal and release it only under the full, proper procedures.

https://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm531136.htm (last accessed Aug. 1, 2018).
[653] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* at 8 (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.
[654] *Id.* at 15.
[655] Inside EPA, *EPA Science Plan Skirted Usual Process, Raising Finalization, Legal Doubts* (May 14, 2018), https://insideepa.com/daily-news/epa-science-plan-skirted-usual-process-raising-finalization-legal-doubts.
[656] Inside EPA, *EPA Strengthens Internal Review Of Science Rule As SAB Seeks Scrutiny* (June 1, 2018), https://insideepa.com/daily-news/epa-strengthens-internal-review-science-rule-sab-seeks-scrutiny.

Appendix A. Analysis of Sources Cited to in the Proposal

This appendix provides an analysis of the sources EPA cites in the proposed rule, showing ultimately that EPA has provided no sources or authorities that support or provide a reasoned basis for the proposed rule and that many of the sources raise key implementation concerns that EPA fails at all to address—rendering the proposal arbitrary and capricious.

Footnote 1: See Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011). "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science."

Exec. Order No. 13563 requires agencies to utilize the "best available science" in regulatory actions.[657] This requirement is further encoded in numerous statutes and policies that EPA implements. EPA states in the proposed rule that: "The best available science must serve as the foundation of EPA's regulatory actions."[658] However, as the comments raise more thoroughly, by arbitrarily restricting the scientific studies EPA will consider, this proposed rule will *hinder* EPA's use of the best available science and therefore violates the command of Exec. Order No. 13563 and other versions of these requirements.

Furthermore, this executive order requires agencies to "ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions" consistent with the President's Memorandum for the Heads of Executive Departments and Agencies, ''Scientific Integrity'' (March 9, 2009). As the comments note, however, the proposed rule along with the provision allowing the Administrator to grant discretionary exemptions will harm the objectivity of scientific and technological information and processes at EPA by paving the way for politics, rather than objective scientific criteria, to dictate which scientific studies are considered.

Footnote 2: See Memorandum for the Heads of Executive Department[sic] and Agencies on Scientific Integrity (Mar. 9, 2009). "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

EPA claims about the proposal that "[b]y better informing the public, the Agency in[sic] enhancing the public's ability to understand and meaningfully participate in the regulatory process." EPA then cites to the Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity. [659] Not only does the proposal conflict with this memorandum, but it will make it more difficult for the public to meaningfully participate in the regulatory process.

[657] Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011).
[658] 83 Fed. Reg. at 18,769.
[659] 83 Fed. Reg. at 18,769 n. 2.

The memorandum sets out a number of actions for agencies to take to ensure scientific integrity.[660] Just *one* of these factors involves making scientific and technological information publicly available, notably specifying, "*Except for information that is properly restricted from disclosure* under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological *findings or conclusions* considered or relied on in policy decisions."[661] The memorandum thus supports only making scientific findings and conclusions publicly available, not the data underlying those findings and conclusions. Further, it correctly notes that some information is properly restricted from disclosure. It does not say that the inability to disclose such information should prevent it from being considered by agencies. The memorandum thus provides *no* support for the notion that agencies should be barred from relying on studies where the underlying data cannot be disclosed. The memorandum's narrow approach to public disclosure should not be taken to support EPA's proposal but rather counsels against the proposal's mandate that all underlying data be made publicly available.

EPA's proposal fundamentally conflicts with the heart of the memorandum—that "[t]he public must be able to trust the science and scientific process informing public policy decisions."[662] To earn this trust, the memorandum declares: "Political officials should not suppress or alter scientific or technological findings and conclusions."[663] By discarding scientific studies where underlying data cannot be made publicly available, this proposal will result in scientific findings being suppressed. By allowing the Administrator to grant exemptions to this policy based on their discretion with no public record or explanation, the proposal allows for the Administrator to pick and choose based on their preference the science informing the agency's actions, eroding the public's trust in the science informing public policy decisions.

The memorandum provides a number of ways in which agencies can ensure scientific integrity which the proposal does not consider including: hiring candidates for science and technology position based on their "knowledge, credentials, experience, and integrity," having in place appropriate rules and procedures to ensure integrity of the scientific process, establishing scientific processes such as peer review and accurately reflecting scientific and technological information, establishing procedures to identify when scientific integrity may be compromised, including establishing whistleblower protections.[664] EPA does not explain why any of these pathways would not serve as a better means of ensuring scientific integrity.

Footnote 3: EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use

[660] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).
[661] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009) (emphasis added).
[662] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).
[663] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).
[664] Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (Mar. 9, 2009), 74 Fed. Reg. 10671 (Mar. 11, 2009).

non-public data in support of its regulatory actions. See Coalition of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 623 (D.C. Cir. 2010); American Trucking Ass'ns v. EPA, 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

In footnote 3 of the proposal, EPA notes that "courts have at times upheld EPA's use [sic] non-public data in support of its regulatory actions" and cites to *Coalition of Battery Recyclers Ass'n* v. *EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010) and *American Trucking Ass'ns* v. *EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). [665] These cases indeed held that EPA's prior, long-standing position of relying on scientific studies even when the underlying data could not be made publicly available was reasonable. It is well-established that agencies must acknowledge changes in position and "show that there are good reasons for the new policy."[666] This footnote, the only mention of EPA's previous policy, does not sufficiently acknowledge or explain why EPA is now changing its position.

In *American Trucking Ass'ns* v. *EPA* the Court held that the Clean Air Act did not require EPA to make public underlying data where EPA relied on the study itself and not the raw data underlying the study.[667] The Court stated that such a requirement "would be impractical and unnecessary."[668] They agreed with EPA's then statement that:

> If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment…. Such data are often the property of scientific investigators and are often not readily available because of … proprietary interests … or because of [confidentiality] arrangements [with study participants].[669]

In *Coalition of Battery Recyclers Ass'n* v. *EPA*, the Court cited *American Trucking Ass'ns* v. *EPA* and held, again, that EPA was permitted to rely on studies without making the underlying data public.[670] They noted, "raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants."[671] These court cases thus not only upheld EPA's prior practice as permissible, but went on to agree that EPA's prior practice was preferable and necessary in light of these other policy concerns.

EPA provides no response to this history, saying only: "Historically, EPA has not consistently observed the policies underlying this proposal. . . . "[672] EPA fails explicitly to

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[665] 83 Fed. Reg. at 18, 769.
[666] *FCC v. Fox Television Stations, Inc*. 556 U.S. 502, 515 (2009).
[667] 283 F.3d 355, 372 (D.C. Cir. 2002).
[668] *Id. at 372* (quoting Particulate Matter NAAQS, 62 Fed. Reg. at 38,689.)
[669] *Id.*
[670] 604 F.3d 613, 623 (D.C. Cir. 2010).
[671] *Id.* at 315.
[672] 83 Fed. Reg. at 18, 769.

recognize that this proposal changes its past policy and provides no justification in light of the compelling opposing points that both EPA and the Courts previously recognized as deterring this approach.

Footnote 4: Exec. Order No. 13777, 82 Fed. Reg. 12285 (Mar. 1, 2017). Regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

EPA claims that the proposal is consistent with Exec. Order No. 13777.[673] This executive order provides no support for the proposal, and in fact is targeted at eliminating regulations including those that are "unnecessary" and "ineffective," which, as our comments detail, the proposal clearly would be.[674]

This executive order creates a Regulatory Reform Task Force and calls for them to identify for repeal, replacement, or modification regulations that among other criteria

> are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note), or the guidance issued pursuant to that provision, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility.[675]

As described in detail in our comments and below, contrary to the inference drawn here in Exec. Order No. 13777, the Data Quality Act and OMB's guidelines issued pursuant to it *do not* require research data and models to be made publicly available for reproducibility purposes in order for agencies to rely on the scientific findings and conclusions produced using that data.

Executive orders cannot override the statutory requirements that EPA use the best available science or the laws governing administrative procedure including the APA. The proposal's "consistency" with this executive order then cannot serve as a legal basis for EPA to adopt an arbitrary and capricious policy that contravenes these best available science requirements reflected in the statutes EPA administers.

Additionally, Exec. Order No. 13777 by its terms requires only the identification of regulations that rely in whole or in part on data not publicly available, it says nothing about precluding agencies from relying on such studies and does not and cannot require agencies to adopt such practices. However, if the proposed rule is to be "consistent" with the executive order then it must also follow section 3(e):

> In performing the evaluation described in subsection (d) of this section, each Regulatory Reform Task Force shall seek input and other assistance, as permitted by law, from entities significantly affected by Federal regulations, including State, local, and tribal

[673] 83 Fed. Reg. at 18, 769.
[674] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017).
[675] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017).

governments, small businesses, consumers, non-governmental organizations, and trade associations.[676]

There is no evidence that EPA consulted with the many stakeholders impacted by this policy, including the medical or scientific research communities, which have been largely opposed to this policy.

Footnote 5: Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017). "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

EPA claims the proposal is consistent with Exec. Order No. 13783.[677] However, Exec. Order No. 13783 calls for agencies to consider salient information that the proposal has patently ignored. Exec. Order No. 13783 calls for agencies to consider the costs and benefits "that are based on the best available science and economics" to ensure sound regulatory decision-making.[678] The proposal provides no analysis of the costs and benefits of implementing this new policy, despite there likely being high costs to making research data public with little evidence of significant benefits achieved from this policy alone.

Further, by arbitrarily excluding scientific information that EPA may use in its regulatory analyses, the proposal conflicts with the executive order's command to employ the best available science and economics.[679]

Footnote 6: February 22, 2002 (67 F.R 8453) OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information (2002) https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for- ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.

EPA wrongly claims that the proposal is "consistent with. . . the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*."[680] To say that OMB's Guidelines have a "focus on transparency" that is furthered by EPA's proposal is a gross oversimplification. EPA here appears to suggest that transparency is the highest objective to be achieved, divorced from any consideration of whether transparency hinders or furthers any other goals. The OMB Guidelines, while imposing high standards of quality, objectivity, utility, and integrity of information disseminated by Federal Agencies, recognize the need to implement controls "flexibly, and in a

[676] Exec. Order No. 13777, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017).
[677] 83 Fed. Reg. at 18,769.
[678] Exec. Order No. 13783, 82 Fed. Reg. 16093, 16095 (Mar. 31, 2017).
[679] Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017).
[680] 83 Fed. Reg. at 18,769-70.

manner appropriate to the nature. . . of the information to be disseminated."[681] They suggest thinking about transparency strategically to further the aims of good government, unlike the proposal, which conflates transparency and quality without consideration of other factors.

As part of ensuring "objectivity" of information these guidelines encourage agencies which disseminate influential scientific, financial, or statistical information, "to include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." [682] However, they emphasize the need to treat certain data differently, due to privacy and confidentiality concerns.[683] While they recommend agencies "identify the sources of the disseminated information" they note that this is "to the extent possible, consistent with confidentiality protections."[684] Importantly, they take great pains to urge agencies *not* to subject all data to a reproducibility requirement where this could hamper agencies.[685] They require agencies, instead, to consult with "the relevant scientific and technical communities" to identify data that "can practicable [sic] be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints."[686] There is no indication that EPA consulted with the scientific and technical community, with EPA's own Science Advisory Board raising concerns about the proposal and finding that "[t]his action merits further review by the SAB."[687] The Guidelines make clear:

> Making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.[688]

In direct conflict with the reasoning underlying EPA's proposal, the Guidelines specifically provide that it is possible to verify the objectivity of information that cannot be made publicly available through other types of "robustness checks."[689] As an example, they point to the Harvard Six Cities Study, where underlying data could not be made publicly available due to confidentiality concerns, but the raw data was released instead to researchers at the Health Effects Institute, bound to the same confidentiality requirements as the original researchers, who were able to replicate its results.[690] In contrast, EPA's proposal would not allow for the consideration of this study.[691]

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[681] *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information*, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002).
[682] 67 Fed. Reg. 8452, 8460.
[683] *Id*.
[684] 67 Fed. Reg. 8452, 8459.
[685] 67 Fed. Reg. 8452, 8460 ("With regard to original and supporting data related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement.")
[686] *Id*.
[687] Memorandum from SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science (May 12, 2018).
[688] 67 Fed. Reg. 8452, 8460.
[689] *Id*.
[690] 67 Fed. Reg. 8452, 8456.
[691] 83 Fed. Reg. at 18769 n. 3 (citing to a case challenging EPA's reliance on this study and saying the rule "would preclude it from using such data in future regulatory actions.")

The guidelines also recommend agencies recognize that information quality comes at a cost, and that agencies should weigh the costs and benefits, which EPA has not done in the proposal.[692]

Thus, the proposal completely turns away from OMB's guidelines where OMB "urges caution in the treatment of original and supporting data because it may often be impractical or even impermissible or unethical to apply the reproducibility standard to such data." [693] As the comments discuss further, the proposal rule thus unlawfully conflicts with this flexible approach that prioritizes agencies' ability to use science as set out by OMB under the Information Quality Act.

Footnote 7: Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset (https://project-open-data.cio.gov/policy-memo/). "Specifically, this Memorandum requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities. This includes using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts. It also includes agencies ensuring information stewardship through the use of open licenses and review of information for privacy, confidentiality, security, or other restrictions to release."

EPA claims the proposal is consistent with OMB's memorandum on Open Data Policy.[694] This is incorrect, however, as the memorandum supports downstream information processing and dissemination—not through complete public disclosure without regard to privacy or security—but through instituting a framework of data collection, formatting, and storage that allows for public dissemination, *if possible*.[695] Recognizing that not all data can be publicly disclosed, and that such data is still useful, the memorandum declares: "Whether or not particular information can be made public, agencies can apply this framework to all information resources to promote efficiency and produce value."[696]

The proposal is thus inconsistent with the memorandum, which stresses the importance of information stewardship and "review of information for privacy, confidentiality, security, or other restrictions to release."[697] When information cannot be released, the memorandum does not suggest agencies ignore the information or not rely on it for regulatory purposes. It focuses on prescribing agency practices to maximize the downstream usability of data that *can* be made publicly available, including through "using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts"[698] as well as "building or modernizing information systems in a way that maximizes interoperability and information accessibility, maintains internal and external data asset

[692] 67 Fed. Reg. 8452, 8452-53.
[693] 67 Fed. Reg. 8452, 8456.
[694] 83 Fed. Reg. at 18,769-70.
[695] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 (May 9, 2013).
[696] *Id.* at 1.
[697] *Id.* at 2.
[698] *Id.* at 1-2.

inventories, enhances information safeguards, and clarifies information management responsibilities."[699] Thus, while the memorandum centers on how agencies can marginally increase the utility of information they possess for use by the public, the proposal turns this on its head by advocating for discard of otherwise high quality scientific information if the data underlying such information cannot be made publicly available.

OMB stresses that to achieve "open data," agencies should adopt a presumption in favor of openness that is importantly limited by countervailing privacy, confidentiality, security, or other valid restrictions.[700] Thus, agencies are expected to "exercise judgment before publicly distributing data residing in an existing system by weighing the value of openness against the cost of making those data public."[701] The proposal does not at all weigh the costs, to the agency or to the public, of requiring all underlying data to be made publicly available.

While requiring agencies to adopt measures to strengthen privacy protections and data security, the memorandum recognizes serious limitation to data disclosure that EPA completely fails to consider. For example, the memorandum mandates that agencies take into consideration the "mosaic effect,"[702] which EPA does not at all acknowledge—all while making superficial and unsupported statements about how privacy concerns can be easily addressed.[703] The memorandum recognizes and stresses the challenge of responding to this threat, which requires undertaking a "risk-based analysis, often utilizing statistical methods whose parameters can change over time, depending on the nature of the information, the availability of other information, and the technology in place that could facilitate the process of identification."[704] OMB importantly notes this analysis "may affect the amount, type, form, and detail of data released by agencies."[705] Because it ignores these concerns, EPA's proposal is arbitrary and capricious.

Footnote 8: Plan to Increase Access to Results of EPA-Funded Scientific Research; EPA Open Government Plan 4.0; Open Data Implementation Plan; EPA's Scientific Integrity

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[699] *Id.* at 2.
[700] *Id.* at 5.
[701] *Id.* at 6.
[702] OMB explains: "The mosaic effect occurs when the information in an individual dataset, in isolation, may not pose a risk of identifying an individual (or threatening some other important interest such as security), but when combined with other available information, could pose such risk. Before disclosing potential PIT or other potentially sensitive information, agencies must consider other publicly available data–in any medium and from any source--to determine whether some combination of existing data and the data intended to be' publicly released could allow for the identification of an individual or pose another security concern." Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 4-5 (May 9, 2013).
[703] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 9-10 (May 9, 2013). *See, e.g.*, 83 Fed. Reg. at 18,770 ("EPA believes that concerns about access to confidential or private information can, in many cases, be addressed. . . .")
[704] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 9-10 (May 9, 2013).
[705] Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset, M-13-13 at 10 (May 9, 2013).

Policy; Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.

Rather than acknowledge the drastic change in EPA policy this proposal would implement, EPA contrarily claims that the proposal simply "builds upon prior EPA actions."[706] None of the sources EPA cites here call into question the validity of scientific research for which underlying data and models cannot be made public. Indeed, they consistently recognize the legitimate limitation on data disclosure while also acknowledging the need for the agency to rely on information for which underlying data may not be released without compromising important privacy and confidentially concerns.

I. Plan to Increase Access to Results of EPA-Funded Scientific Research, https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

Contrary to EPA's claim that the proposal "builds upon" prior EPA policy, it is actually a radical shift away from the view EPA takes in its *Plan to Increase Access to Results of EPA-Funded Scientific Research*, which notes even though "some research data cannot be made fully available to the public but instead may need to be made available in more limited ways," this availability "does not affect the validity of the scientific conclusions from peer-reviewed research publications."[707] The *Plan to Increase Access to Results of EPA-Funded Scientific Research* thus dictates the view EPA has consistently espoused in the past, that it may make data available when it can without compromising other critical values, but that it will not exclude information from its consideration when it cannot. Yet EPA denies, rather than acknowledging and explaining, its new decision to reverse its past stance.

The *Plan* requires EPA to make publications resulting from EPA-funded research publicly accessible on NIH's PubMed Central (PMC).[708] It aims to "maximize access, by the general public and without charge, to digitally formatted data resulting from EPA funded research, *while protecting confidentiality and personal privacy, recognizing proprietary interests, business confidential information and intellectual property rights, and preserving the balance between the relative benefits and costs of long-term preservation and access.*"[709] It recognizes important exceptions for when "the research data cannot be released due to one or more constraints, such as requirements to protect confidentiality, personal privacy, proprietary interest, or property rights."[710] It specifically declares: "The validity of scientific conclusions drawn from research publications or their associated research data, or EPA's ability to consider those conclusions and data in its actions, does not depend on compliance with this Plan."[711]

[706] 83 Fed. Reg. at 18,770.
[707] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research* 4-5 (Nov. 29, 2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf
[708] *Id.* at 8.
[709] *Id.* at 11 (emphasis added).
[710] *Id.*
[711] *Id.* at 6.

The *Plan* acknowledges making more limited releases of data "e.g., establishing data use agreements with researchers that respect necessary protections," that fall short of full public disclosure.[712] Unlike the proposal, which fails to account for the costs of implementation, the plan also acknowledges the need to "balance between the value of providing long-term access and its associated costs."[713]

The *Plan* thus further enshrines the view that this rule is unnecessary—where EPA has access to data and can release it without compromising other interests, it already does so. It further supports the notion that this type of disclosure is not necessary, and will not help, to ensure EPA's reliance on valid scientific conclusion. EPA must fully explain its decision to deviate from this prior-held stance.

II. EPA Open Government Plan 4.0, https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf

EPA's *Open Government Plan 4.0* also acknowledges that not all data is releasable to the public, even as it aims to "increase publicly accessible EPA data to support citizens' participation in government and promote transparency and accountability of Agency operations."[714] EPA states in the *Plan*: "By providing *releasable* information in open and machine-readable formats, EPA enables the public and other organizations to better leverage the rich wealth of information available."[715] Further, in the *Plan* EPA notes the stringent requirements it has in place on the "collection, access, use, dissemination, and storage of personally identifiable information (PII) and Privacy Act information to prevent unwarranted invasions of personal privacy."[716]

Rather than suggesting that EPA release underlying data to the public in order to rely on scientific information, the *Plan* only speaks to utilizing a careful approach—with due regard for privacy and limitations to data release—to making EPA data more accessible to the public where possible.

III. Open Data Implementation Plan, https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf

EPA's own Open Data Policy, which implements the requirements of White House "Open Data Policy – Managing Information as an Asset" Memorandum M-13-13, notes that it is important to develop "policies and processes to ensure that only appropriate data are released to

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[712] *Id.* at 4.
[713] *Id.*
[714] EPA, *Open Government Plan 4.0* 4 (Sep. 2016), https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf.
[715] EPA, *Open Government Plan 4.0* 4 (Sep. 2016), https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf (emphasis added).
[716] EPA, *Open Government Plan 4.0* 23 (Sep. 2016), https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf.

the public and made available online."[717] To do so, EPA uses different "access levels" for different data sets, (public, restricted public, and non-public) and notes that it may not be able to publicize data due to "law, regulation or policy, which address privacy, confidentiality, security or other valid restrictions."[718]

Thus, while the Open Data Policy applies a multi-level, nuanced approach to data disclosure, the Proposal completely does away with this by applying a blanket requirement to make all underlying data and models publicly available. The Open Data Policy this conflicts with, rather than supports, the Proposal.

IV. EPA's Scientific Integrity Policy, https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf

Contrary to EPA's claim, the Proposal turns away from EPA's Scientific Integrity Policy, which stresses "a firm commitment to evidence," endorses use of "the best available science" and "[r]equire[s] reviews. . . regarding the content of a scientific product to be based only on scientific quality considerations."[719] The Proposal, on the other hand, inhibits use of sound scientific information and evidence by arbitrarily excluding science from EPA's consideration for reasons unrelated to its quality.[720]

While the policy "[r]ecognizes the value of independent validation of scientific methods"[721] and facilitating "the free flow of scientific information" by making information available "including access to data and non-proprietary models underlying Agency policy decisions,"[722] this is a flexible standard and an ideal to aspire to, not to take priority over other competing interests—such as use of the best available science. This measure is meant to "facilitate[] the free flow of scientific information" and "expand and promote access to scientific information."[723] The Proposal, however, limits the free flow of scientific information and restricts access to scientific information by restricting EPA's consideration of scientific studies.

As discussed in our comments, this Administration has blatantly violated key aspects of the policy by silencing scientists and the limiting the dissemination of scientific information, directly undoing "EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information – uncompromised by political or other interference" and goal to communicate scientific findings openly and actively to the public.[724] The Scientific Integrity Policy is meant to uphold scientific ideals—and prevent arbitrary, politicized decisions about which science to utilize—and the Proposal is thus in strong conflict with it.

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[717] EPA, *Open Data Policy Implementation Plan* 4 (Feb. 2015), https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf.
[718] EPA, *Open Data Policy Implementation Plan* 4 (Feb. 2015), https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf.
[719] EPA, *Scientific Integrity Policy* 4, https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf.
[720] *Id.* at 3-4.
[721] *Id.* at 4.
[722] *Id.*
[723] *Id.*
[724] *Id.* at 5.

V. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information

EPA's Proposal also does not "build upon" its *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. The *Guidelines* note that it may not be possible for underlying data and models to be subject to same degree of disclosure as analytic results, and highlight other methods of ensuring the quality of scientific research where disclosure is not possible.

The *Guidelines* start by noting, "[t]he mission of the EPA is to protect human health and safeguard the natural environment upon which life depends" and "[t]he collection, use, and dissemination of information of known and appropriate quality are integral to ensuring that EPA achieves its mission."[725] They thus highlight that the controls on data quality exist to allow EPA to meet its mission—unlike the Proposal, which makes no mention of EPA's mission or how the Proposal would further that mission. Because the Proposal restricts EPA's ability to rely on the best available science, it obscures EPA in achieving its mission to set safeguards that are protective of human health and the environment, and thus such a statement could not truthfully be made.

While the *Guidelines* seek to maximize the quality of influential information by facilitating the reproducibility of the information—they note:

> In addition, if access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken. Original and supporting data may not be subject to the high and specific degree of transparency provided for analytic results; however, EPA should apply, to the extent practicable, relevant Agency policies and procedures to achieve reproducibility, given ethical, feasibility, and confidentiality constraints.[726]

EPA's *Guidelines* detail EPA's long-standing position, that it may validate research studies even when data cannot be made publicly available—unlike the Proposal, which apparently assumes disclosure of underlying data and models is necessary to ensure scientific validity. The *Guidelines* discuss existing programs, such as EPA's Quality System and EPA's Peer Review

[725] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* 5 (Oct. 2002), https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information.
[726] *Id.* at 21.

Policy[727] that are in place to assure the high quality of EPA information disseminates. EPA does not explain in the Proposal why these other checks are now insufficient.

Footnote 9: For example, see related policies from the National Science Foundation, National Institute of Science and Technology, the National Institutes of Health; and the US Census Bureau, which provides secure access to data from several agencies in an environment that protects against unauthorized disclosure (https://www.census.gov/fsrdc).

EPA purports that the Proposal builds upon "the experience of other federal agencies in this space" but the citations reveal that is simply not the case.[728] To support this statement, EPA provides only a hyperlink to a U.S. Census Bureau website along with vague references to entire executive branch agencies, with no explanation or discussion of which of their policies EPA believes the Proposal is building upon. Without a more specific citation, it is impossible to know which policies EPA is referencing or to respond to them meaningfully.

EPA cites to the U.S. Census Bureau's Federal Statistical Research Data Centers as an example of use of secure facilities that allow the Census Bureau to provide controlled access to authorized researchers to use restricted-use microdata for statistical purposes only. In order to gain access, researchers must obtain Census Bureau Special Sworn Status by passing a moderate risk background check and swearing to protect respondent confidentiality for life. While this "solution" meets the U.S. Census Bureau's needs by allowing access to confidential information only to researchers whose proposals meet certain criteria, who go through a vetting process, and who agree to protect the information, this is done at a cost—which EPA has not accounted for—and would not satisfy EPA's requirement to make data and models "publicly available." Thus, this example provides no support for the Proposal.

Footnote 10: These include policies and recommendations from: the Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data, and Access to Research Data in the 21st Century; the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.

In footnote 10, EPA lists a number of organizations whose recommendations and policies the Proposal allegedly took into consideration. In fact, since the Proposal was published, many of these organizations have issued statements opposing the Proposal and contesting EPA's claim that their policies and recommendations endorse the Proposal. In this footnote, EPA provided no hyperlinks or specific citations for which recommendations and policies it was referencing, making it impossible to understand why EPA believed these organizations supported the Proposal or to respond to them.

[727] *Id.* at 10-13.
[728] 83 Fed. Reg. at 18,770.

I. The Administrative Conference of the United States' Science in the Administrative Process Project

EPA cites to the Administrative Conference of the United States' Science in the Administrative Process Project—*Recommendation 2013-3: Science in the Administrative Process*. Wendy Wagner, sole author of ACUS's final report *Science in Regulation: A Study of Agency Decisionmaking Approaches* and who served on the panel that produced the recommendations strongly opposed the notion that the Proposal builds upon these recommendations, saying: "They don't adopt any of our recommendations, and they go in a direction that's completely opposite, completely different. . . . They don't adopt any of the recommendations of *any* of the sources they cite. I'm not sure why they cited them."[729]

While ACUS recommends agencies increase transparency of how they rely on scientific information and strive to make data underlying scientific information publicly available, nowhere do they suggest that agencies should not consider or rely on studies where underlying data and models cannot be made publicly available, or that these circumstances make scientific information less valid. They instead suggest that information be made publicly available for assessment and reproducibility purposes "[c]onsistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines."[730] They acknowledge valid limitations such as legal protections for privacy, trade secrets, and confidential business information.[731] Thus, they recommend data be made public only "[t]o the extent practicable and permitted by law and applicable policies."[732] Unlike the Proposal, the recommendation acknowledges that agencies may still use information where underlying data cannot be publicly disclosed, and suggest agencies "note that fact and explain why they used the results if they chose to do so."[733] It thus provides a much more nuanced policy recommendation than that outlined in the Proposal—which suggests EPA either find a way to make underlying data and models public, despite the numerous potential obstacles and concerns in doing so, or completely disregard the research study.

II. National Academies Improving Access to and Confidentiality of Research Data

Rather than containing any particular recommendations or policy proposals, this report discusses a number of issues pertaining to data disclosure and privacy protection, the tradeoffs "between increasing data access on the one hand and improving data security and confidentiality

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[729] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 25, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/.
[730] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process*, 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).
[731] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process*, 78 Fed. Reg. 41,352, 41,356 (July 10, 2013).
[732] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process*, 78 Fed. Reg. 41,352, 41,357 (July 10, 2013).
[733] *Administrative Conference Recommendation 2013-3: Science in the Administrative Process*, 78 Fed. Reg. 41,352, 41,358 (July 10, 2013).

on the other,"[734] and "alternative approaches to limiting disclosure risk while facilitating data access the benefits and limitation of various approaches to these issues."[735] Thus, rather than calling on agencies to rely only on scientific studies where the underlying data and models are made public, the report in fact discusses challenges and obstacles to achieving greater data disclosure, for which the Proposal provides no substantive or meaningful explanation.

The report discusses why exercising caution with respect to disclosing confidential personal information is so important, because if such information is exposed it could lead to

> being arrested for a crime, being denied eligibility for welfare or Medicaid, being charged with tax evasion, losing a job or an election, failing to qualify for a mortgage, or having trouble getting into college. Disclosure of a history of alcoholism, mental illness, venereal disease, or illegitimacy can result in embarrassment and loss of reputation. Less directly, research results based on personal data can cause harm by affecting perceptions about a group to which a person belongs.[736]

The report reveals very legitimate reasons why researchers and study participants would be reluctant to allow underlying data to be made publicly available—and these reasons in no way compromise the validity of the scientific conclusions based upon this data.

The report also discusses the nuances of selecting methods to protect privacy while making underlying data publicly available. For example, while EPA casually makes claims that controlled access is an example of a solution in place across federal agencies[737]—this report points out the drawbacks of such an approach:

> The use of restricted access arrangements, which has been deemed necessary to provide adequate protection for confidential information about individuals and businesses, results in increased costs to conduct research. Custodians of the data files need additional resources to process applications, operate inspection systems, staff research data centers, and inspect outputs to ensure that disclosure does not occur. Researchers require resources to prepare applications for access, to provide appropriate physical security for the data, or to visit a secure site.[738]

The report also discusses the difficulty of funding such centers—noting that while the costs are currently covered by a combination of federal agency budgets and user fees, including grants from the National Science Foundation and National Institute on Aging, federal funding may no longer be able to support such efforts.[739] EPA's cursory mention to use of restricted access facilities as a potential solution to the concerns implicated by the Proposal fail to mention or address any of these challenges.

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[734] The National Academies, *Improving Access to and Confidentiality of Research Data: Report of a Workshop*, National Academies Press 2-3 (2000).
[735] *Id.* at 3.
[736] *Id.* at 19.
[737] 83 Fed. Reg. at 18,771.
[738] *Id.* at 48.
[739] *Id.*

III. National Academies Expanding Access to Research Data: Reconciling Risks and Opportunities

EPA's Proposal in no way takes into consideration the recommendations of the National Academies report *Expanding Access to Research Data: Reconciling Risks and Opportunities*. This report considers competing approaches to increase use of research data while protecting confidentiality, and concludes that "no one way is optimal for all data users or all purposes" and, importantly, that "the nation's statistical and research agencies must provide both unrestricted access to anonymized public-use files and restricted access to detailed, individually identifiable confidential data for researchers under carefully specified conditions."[740] In other words, the report finds that making data publicly available without restriction while respecting confidentiality concerns is not currently feasible or compatible with the missions of federal agencies.

Furthermore, the report mainly concerns itself with how agencies might increase access to data in their control and possession to allow for more research in social issues and provide a better basis for more informed policy decisions—it does not discuss whether federal agencies should make data publicly available in order to allow for independent validation of scientific research they rely on for regulatory purposes and thus cannot be a basis for the Proposal.[741] While the report discusses that one of the benefits of data sharing is that it allows for "verification, refutation, or refinement of original results," nowhere does the report suggest that agencies should rely only on research studies that make data publicly available or that such verification is necessary to validate a research study.[742] Indeed, it details a discussion on this topic that presents competing views on requirements to make research data available to the public to allow for replication. John Bailar raised concerns that researchers would be deterred from doing certain kinds of work if they feared it would be subject to "hostile scrutiny" and that competitors could seize data for their interests.[743] Others disagreed with this position.[744] However, EPA failed to engage any of these considerations or at all justify its decision to implement a policy that could have severe negative implications. None of the researchers stated agencies should disregard the study if underlying data could not be made public.

The "recommendations" made by the report do not endorse EPA's proposal. The report provides 15 recommendations in Chapter 5.[745] Recommendations 1-4 concern documentation and data access and call on agencies to better document how the data they make available is used; to use a variety of modes to provide access to data they produce or fund using a combination of restricted access to confidential data and unrestricted access to appropriately altered public-use data; to support research to guide more efficient allocation of resources among different data access modes; and to involve users in planning modes of access to their data.[746]

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[740] The National Academies, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, National Academies Press 2 (2005).
[741] *Id.* at 7.
[742] *Id.* at 39.
[743] *Id.* at 105-06.
[744] *See id*. at 107.
[745] *Id.* at 63.
[746] *Id.* at 66-69.

In this Proposal, EPA does nothing to better document use of data that it makes public, has only called for a requirement to make research data and models "publicly available" rather than recognizing that a variety of modes and levels of access may be necessary, and does nothing to support more research into methods of making data more widely available without compromising confidentiality—indeed blithely assuming that such means are already available and sufficient—and also has not indicated that there has been any widespread call for EPA to make such data available or pointed to any comments of users of this data in this process.

Recommendations 5-8 concern public use data and call on agencies to support research on techniques to provide useful innovative public-use data that minimizes the risk of disclosure; streamlined procedures to allow researchers access to public-use microdata through existing and new data archives; a warning on all public-use data that they are provided for statistical purposes only and that any attempt to identify an individual is a violation, and requiring users to attest to having read the warning; and restricting access to public-use data to those who agree to abide by confidentiality protections, subject to meaningful penalties.[747]

EPA's proposal once again ignores these recommendations that call for greater research and a measured approach to making data more widely available. The Proposal provides no ideas or methods or support for research that would help strengthen confidentiality protections while making data more available.

Recommendations 9-13 concern research data centers, remote access, and licensing agreements and call on the Census Bureau to (1) broaden the interpretation of the criteria for assessing the benefits of access to data; (2) maintain the continuous review cycle; and (3) take account of prior scientific review of research proposals by established peer review processes when awarding access to research data centers; for more research on cost effective means of providing secure access to confidential data by remote access; increasing use of licensing agreements for access to confidential data; working with data users to develop flexible, consistent standards for licensing agreements and implementation procedures for access to confidential data; and including auditing procedures and legal penalties in licensing agreements for willful misuse of confidential data.[748]

EPA's proposal does not increase any research into use of remote data centers or licensing agreements, simply making passing references to these modes as potential solutions with no discussion or explanation—and ignoring the recommendations here suggesting that more work is needed to realize their potential.

Recommendations 14-15 concern maintaining the public's trust and call on agencies to give certain basic information about confidentiality and data access to everyone asked to participate in statistical surveys; and to support continuing research on the views of data providers and the public about research benefits and risks.[749]

[747] *Id.* at 69-74.
[748] *Id.* at 74-80.
[749] *Id.* at 80-81.

EPA's proposal does not involve anything that increases the public knowledge about confidentiality protections or their views on research benefits and risks.

Recommendations 16-19 concern training, monitoring, and education to complement other protections on data. They call on data collection agencies to provide employees with continually updated written guidelines on confidentiality protection and training in confidentiality practices and data management and to institute procedures for monitoring violations of confidentiality protections practices and confidentiality breaches. They also call on educational and professional organizations to provide training in ethical issues for all those involved in the design, collection, distribution, and use of data obtained under pledges of confidentiality and for the development of strong codes of ethical conduct that reflect the need to protection confidentiality.[750]

EPA's proposal also contains no provisions on increasing training, monitoring, or education, within the agency or among researchers to allow for more careful handling of confidential data.

Thus, EPA's Proposal completely ignores the careful research and thinking the National Academies and researchers have done on what is needed from federal agencies in order to make data more publicly available, and how to do so in a responsible manner. It does not implement any of the recommendations in the report, and in no way builds upon this work.

IV. National Academies Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of Workshop

EPA cites to the National Academies' *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of Workshop* as one for which it took into consideration "policies or recommendations," despite the fact that this report comes with the explicit limitation that:

> The goal of the workshop was not to reach conclusions or recommendations; nor could it address other pressing issues beyond the regulatory process, such as protection of intellectual property, the influence of broader access on scientific competition, the potential for increased administrative burdens and changes in the research process, and the challenge of providing data access in an increasingly electronic world.[751]

Thus, this report stresses the many unanswered, challenging policy questions that must be addressed as agencies contemplate how to make data publicly available. These are the questions EPA should have addressed in its Proposal, but did not.

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[750] *Id.* at 81-84.

[751] Science, Technology, and Law Panel; Policy and Global Affairs; National Research Council, *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of Workshop*, The National Academies Press ix (2002).

The Report offers a look into the scientific review process that also calls into question the underlying assumption in EPA's proposal—that making data publicly available is necessary to ensure the validity of a scientific finding. The report notes that scientific claims "are not 'binary'" they instead "fall in the category of being uncertain to various degrees."[752] The reliability of a particular scientific finding can be assessed using various mechanisms, starting with an examination of the strength of the design, methods, and statistical results.[753] Then "one asks whether there is consistency within the data (pertaining to mechanisms of effect or related outcomes) and with other studies and scientific theories."[754] Finally, "the robustness of the findings is evaluated through the use of different analytical approaches."[755]

The report describes how studies may be validated through a range of approaches.[756] While it notes that in some cases it is possible to exactly replicate the original study, this is not always the case, especially in large epidemiological studies where "repeating a study is seldom either possible or desirable."[757] Then "replication" can take a variety of forms, not all of which require access to underlying data, including:

- Additional analyses done on the data set by the original or collaborating Investigators;
- New results generated from older data sets;
- New studies addressing the same hypothesis;
- Independent analysis of the same data set by different people;
- Monitoring of the results of actions taken on the basis of the findings.[758]

Another form of replication the report describes is

> meta-analysis, which is a systematic strategy for comprehensively describing and summarizing a body of research evidence from two or more studies. The goal is to produce a quantitative synthesis of the evidence presented in multiple studies that relate to a research question. In a typical meta-analysis, all the data used have been published in the public domain and are easy to inspect and analyze.[759]

The report specifically mentions the Harvard Six Cities Study as an example of a study where data could not be made publicly available, but which was verified to allow the agency to justifiably rely on it to set important air standards.[760] Thus, unlike the Proposal the report acknowledges the many different pathways that exist to for researchers to assess other studies, and does not suggest that allowing the general public access to underlying data and models is necessary.

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[752] *Id.* at 5.
[753] *Id.* at 7.
[754] *Id.*
[755] *Id.*
[756] *Id.*
[757] *Id.*
[758] *Id.* at 7-8.
[759] *Id.* at 8.
[760] *Id.* at 8-12.

One of the panels of the workshop discussed the Shelby Amendment, and public access to data underlying agency regulation. A bench scientist expressed concerns that, though the idea of sharing data was a good idea, because any person could request information for any reason, this mechanism could be used to harass scientists whose work was found objectionable.[761] A representative of NIH similarly stated that while sharing data with other researchers was good scientific practice, allowing for indiscriminate public access to data serves "little purpose for those without the skills to reanalyze it."[762] Additionally, access through FOIA does not allow for limitations to be put on the use of the data, which is typically available in other data-sharing modes.[763] A representative from EPA raised issues including:

> The Shelby Amendment. . .raises several questions for the EPA about rule making as a legal and deliberative process. At what point should the agency disclose what type of regulation is going to be considered or issued? The timing of the release can influence its reception. Should the agency use contracts to support the research needed for regulations? Contracting, as opposed to grants that support more flexible work, might narrow the type of information the agency receives and could possibly limit the scope of the science underlying the regulation.[764]

These questions and concerns are highly relevant to the Proposal as well, yet EPA provides no indication that it has given them any consideration.

Finally, a representative from NRDC pointed to other mechanisms that are already in place to ensure agencies rely on high quality data. For example, under the Administrative Procedure Act, agencies must respond to any comments that raise questions about a scientific studies design, performance, or conclusion.[765] Courts can determine whether an agency was reasonable in its decision to refuse to accept the findings of a study because it could not access underlying data or refuses a request from a study participant.[766] EPA does not explain why these existing mechanisms are not sufficient to ensure the integrity of the science it relies on.

V. The Health Effects Institute

In the original federal register notice, EPA provided no specificity as to which Health Effects policy EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

VI. Center for Open Science

[761] *Id.* at 14.
[762] *Id.* at 15.
[763] *Id.*
[764] *Id.* at 16.
[765] *Id.* at 17.
[766] *Id.*

In the original federal register notice, EPA provided no specificity as to which Center for Open Science policy EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

VII. Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology

In the original federal register notice, EPA provided no specificity as to which policy of the Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

VIII. Bipartisan Policy Center's Science for Policy Project

In the original federal register notice, EPA provided no specificity as to which Bipartisan Policy Center's Science for Policy Project policy EPA was referring to or why it supported the Proposal. Such a vague and unspecified reference does not meet the notice requirements of the APA and other statutes, and makes it impossible to respond.

Footnote 11: For example, see related policies from the Proceedings of the National Academy of Sciences, PLOS ONE, Science, and Nature

EPA claims that the Proposal takes into consideration policies adopted by scientific journals, but does not specify which "related policies" from these journals.[767] While some of these journals have adopted certain policies encouraging or requiring researchers to share underlying data for the studies they publish, they all allow for exceptions when data cannot be released for compelling reasons, such as confidentiality protections.

Furthermore, the editors of these journals have issued a joint statement opposing the Proposal and noting that their policies do not endorse such an approach by EPA. They note that some data sets cannot be shared publicly, and that there are still other methods available to verify scientific findings. The statement also strongly condemns the notion of excluding scientific information from consideration when underlying data cannot be made publicly available:

> It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.[768]

[767] 83 Fed. Reg. at 18,770.
[768] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

Thus, EPA cannot claim that the Proposal is in any way supported by the data sharing policies of these scientific journals.

Footnote 12: See: https://www.nature.com/articles/s41562- 016-0021; http://journals.plos.org/plosmedicine/ article?id=10.1371/journal.pmed.0020124; http://science.sciencemag.org/content/343/6168/229.long; https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong.; http://stm.sciencemag.org/content/8/341/341ps12.full.

EPA claims that the Proposal is informed by the policies of scientific journals in response to the "replication crisis."[769] EPA provides no explanation or evidence to support the fact that such a "crisis" is occurring or that EPA's Proposal would do anything to address the crisis. The sources EPA cites for this proposition speak to a concern about scientific studies being reproducible or replicable due to a number of different conditions related to poor scientific practices. While some of the articles speak about making data more available as an ideal to aspire to, none of them support the idea that a research study whose underlying data has not been made publicly available should, for that reason alone, be considered invalid. Further, many of these articles speak to how current scientific norms do not result in underlying data being available, which is a huge barrier to EPA's Proposal that EPA does not at all address.

I. Marcus R. Munafó et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1 (2017)

Far from suggesting that agencies rely only on scientific studies if the underlying data is made public, or even that making underlying data public is necessary to ensure validity of scientific conclusions, the article discusses at a high level a number of systemic and cultural challenges to reproducible science. By ignoring the nuances of this article and presenting it without any explanation as support for its Proposal, EPA runs into the problem the article specifically cautions against, warning: "Some solutions may be ineffective or even harmful to the efficiency and reliability of science, even if conceptually they appear sensible."[770]

This article does not endorse the existence of a "replication crisis" and in fact says, "[w]hether 'crisis' is the appropriate term to describe the current state or trajectory of science is debatable."[771] Instead it notes a very different problem than the one EPA appears to target with the Proposal. It points broadly to an issue of there being "substantial room for improvement with regard to research practices to maximize the efficiency of the research community's use of the public's financial investment in research."[772]

[769] 83 Fed. Reg. at 18,770.
[770] Marcus R. Munafó et. al, *A Manifesto for Reproducible Science*, 1 Nature Human Behavior 1, 7 (2017).
[771] *Id.* at 1.
[772] *Id.* at 1.

This article makes clear that open data requirements are just *one* of many solutions and steps to take towards increasing efficiency of use of resources and robustness of scientific findings—and never suggests that a lack of publicly available underlying data should automatically disqualify a research finding from consideration. It discusses a number of other improvements including protecting against cognitive biases through blinding, improving methodological training, implementing methodological support, encouraging collaboration and team science, promoting study pre-registration, improving quality of reporting, diversifying peer review, and changing incentives to promote efficient and effective research instead of just innovative outcomes.

While the article recognizes transparency as a "scientific ideal"[773] it notes many challenges that currently exist to achieving this ideal, which EPA does not at all address. The article notes, "In reality, science often lacks openness: many published articles are not available to people without a personal or institutional subscription, and most data, materials and code supporting research outcomes are not made accessible, for example, in a public repository."[774] It further finds "substantial barriers to meeting these ideals, including vested financial interests (particularly in scholarly publishing) and few incentives for researchers to pursue open practices." Nowhere does the article suggest that the many scientific studies for which data is not available due to prevailing scientific norms and practices be completely discarded. These challenges suggest that many studies EPA wishes to rely on may not be able to meet the rigid requirements of EPA's proposal severely restricting the science EPA can use, degrading the quality of its decision-making.

Marcus R. Munafó, lead author on this paper, has since published a piece specifically dismissing science policy approaches that overemphasize the importance of replication.[775] It states that the overemphasis on replicability is detrimental to science—that "[i]f a study is skewed and replications recapitulate that approach, findings will be consistently incorrect or biased."[776] Instead, the author suggests that "an essential protection against flawed ideas is triangulation" or "the strategic use of multiple approaches to address one question."[777] This involves looking at a broad base of different scientific studies and does not require underlying data to be made publicly available, not individual studies based on whether or not they can be replicated.[778] By excluding scientific studies from EPA's consideration, the Proposal overemphasizes the value of replication to the detriment of being able to evaluate a study in the context of many other studies examining the same issue through a variety of methods. The Proposal may well lead to reliance on less robust science and is thus arbitrary.

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[773] *Id.* at 5.
[774] *Id.*
[775] Marcus R. Munafó & George Davey Smith, *Robust research needs many lines of evidence*, Nature (Jan. 23, 2018), https://www.nature.com/articles/d41586-018-01023-3#ref-CR3.
[776] *Id.*
[777] *Id.*
[778] *Id.*

II. John P.A. Ioannidis, *Why Most Published Research is False*, 2 PLoS Medicine 0696 (2005)

The article suggests"the high rate of nonreplication (lack of confirmation) of research discoveries is a consequence of the convenient, yet ill-founded strategy of claiming conclusive research findings solely on the basis of a single study assessed by formal statistical significance, typically for a *p*-value less than 0.05."[779] It looks at a number of different contributors to false positive findings and discusses solutions to this problem. Importantly, it stresses the need to focus on large studies, consider the totality of the evidence, and improve understanding of pre-study odds.[780] These solutions each involve considering more evidence and more scientific studies to contextualize any one given study. Nowhere does the article suggests requiring underlying data be made public or fewer studies be considered. EPA's proposal contrarily emphasizes data disclosure above all other practices for ensuring scientific integrity—and will result in fewer studies being considered to shed light on the scientific truth.

The author of this article has specifically criticized EPA's Proposal, saying that, if it is finalized, "science will be practically eliminated from all decision-making processes" and "[r]egulation would then depend uniquely on opinion and whim."[781] The author highlights the inherent problem in EPA's Proposal, that "most of the raw data from past studies are not publicly available" and that indeed "[i]n a random sample of the biomedical literature (2000–2014) none of 268 papers shared all of their raw data. . . [and] [o]nly one shared a full research protocol."[782] EPA has not addressed this major issue that suggests the Proposal would bar EPA from relying on massive amounts of scientific research. The article notes that reproducibility issues vary across the disciplines and that in many areas in which EPA operates, a solid and large foundation of scientific research has produced credible and widely-affirmed findings, including "in fields such as air pollution and climate change."[783] Even in these other fields, however, it firmly states that "simply ignoring science that has not yet attained such standards, is a nightmare."[784]

III. Marcia McNutt, *Reproducibility*, 343 Science 229 (2014), http://science.sciencemag.org/content/343/6168/229.long

EPA cites an announcement by Science that, in response to reports "that a troubling proportion of peer-reviewed preclinical studies are not reproducible,"[785] Science is adopting new policies requiring authors making submissions to the journal to disclose "whether there was a pre-experimental plan for data handling (such as how to deal with outliers), whether they conducted a sample size estimation to ensure a sufficient signal-to-noise ratio, whether samples were treated randomly, and whether the experimenter was blind to the conduct of the

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[779] John P.A. Ioannidis, *Why Most Published Research is False*, 2 PLoS Medicine 0696 (2005).
[780] *Id.* at 0700-0701
[781] John P.A. Ioannidis, *All science should inform policy and regulation*, 15 PLOS Med 1, 2 (May 3, 2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576.
[782] *Id.* at 1.
[783] *Id.* at 2.
[784] *Id.* at 2.
[785] Marcia McNutt, *Reproducibility*, 343 Science 229 (2014), http://science.sciencemag.org/content/343/6168/229.long.

experiment."[786] While the article considers steps to increase reproducibility of science, it notes that data availability is not a necessary or sufficient step to ensure credibility of research findings, and that "ultimate responsibility lies with authors to be completely open with their methods, all of their findings, and the possible pitfalls that could invalidate their conclusions."[787] EPA's Proposal ignores the ability to assess studies through these other important indicators to assure their validity.

VI. *How Science Goes Wrong*, Economist (Oct. 21, 2013), https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong

This article opposes the view that verification of a study depends solely on the underlying data being made publicly available. While it identifies that much scientific research is unable to be replicated, the solution it proposes include tightening standards, particularly in statistics, registering research protocols in advance and monitoring them, and: "[w]here possible, trial data also should be open for other researchers to inspect and test."[788] Thus, even to the extent it discusses data availability, it suggests data should be open for other *researchers*, as opposed to the public, and recognizes this may not always be possible.[789]

VII. Steve N. Goodman, *What does research reproducibility mean?*, 8 Science Translational Medicine 1 (2016), http://stm.sciencemag.org/content/8/341/341ps12.full

Rather than saying anything about agencies relying only on scientific studies where underlying data is made public, this article discusses the importance of clearly defining key terms in the discussion about scientific reproducibility, noting that there is a lack of standardized definitions of terms such as "reproducibility, replicability, reliability, robustness, and generalizability."[790] This raises a key issue of vagueness in EPA's proposal—EPA does not provide definition for key terms such as "independently validate" or "reproducible" and confusing mentions a "replication crisis" while citing to articles that speak to a "reproducibility crisis."

While providing definitions for these various terms, the article notes that there terms all represent various methods of attempting to verify studies to ensure "scientific claims based on scientific results are true" and cautions against "treating reproducibility as an end in itself—rather than as an imperfect surrogate for scientific truth."[791] Instead, it promoted the view of looking across studies to "assess their cumulative evidential weight."[792] EPA Proposal thus directly contradicts the suggestions of this article.

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[786] *Id.*
[787] *Id.*
[788] *How Science Goes Wrong*, Economist (Oct. 21, 2013), https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong.
[789] *Id.*
[790] Steve N. Goodman, *What does research reproducibility mean?*, 8 Science Translational Medicine 1 (2016), http://stm.sciencemag.org/content/8/341/341ps12.full.
[791] *Id.*
[792] *Id.* at 3.

Footnote 13: EPA has not consistently followed previous EPA policy (e.g, EPA's Scientific Integrity Guidance, referenced above) that encouraged the use of non-proprietary data and models.

While EPA in a footnotes suggests that EPA has not consistently followed EPA's EPA's Scientific Integrity Policy encouraging the use of non-proprietary data and models, it misses the fact that EPA's policy was not written as an absolute standard, but was intended to be a flexible one. The policy states only that "the use of non-proprietary data and models are encouraged, when feasible, to increase transparency."[793] EPA must thus explain and justify its deviation from its prior flexible approach that the Proposal now imposes.

Footnote 14: https://www.whitehouse.gov/wp-content/uploads/2017/11/2005-M-05-03-Issuance-of-OMBs-Final-Information-Quality-Bulletin-for-Peer-Review-December-16-2004.pdf

The Proposal appears to issue a requirement for independent peer review of all *pivotal regulatory science* used to justify *regulatory decisions,* consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review. EPA cites to OMB's Final Information Quality Bulletin for Peer Review, explaining existing peer review requirements that nowhere does EPA suggest are not already being complied with.

As discussed in our comments, there is some vagueness as to whether the Proposal maintains, expands, or narrows these already existing requirements. OMB's bulletin underwent a rigorous stakeholder process including response to comments on multiple drafts from stakeholders, a federal agency workshop at NAS, outreach to major scientific organizations and societies, a formal interagency review.[794] EPA's Proposal has not gone through nearly the same level of review, or as our comments detail, even met the minimum legal requirements for consultation and review. OMB's guidance further provides that agencies should consider the "tradeoffs between depth of peer review and timeliness"[795] This includes considering a benefit-cost framework for peer review that takes into account "the direct costs of the peer review activity and those stemming from potential delay in government and private actions that can result from peer review."[796] As our comments detail, EPA has not provided any meaningful benefit-cost analysis of the Proposal. Thus, it would be improper and in conflict with OMB's guidance for EPA to be expanding the peer review requirements through this Proposal.

Footnote 15: February 22, 2002 (67 FR 8453) OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information (2002)

[793] EPA, *Scientific Integrity Policy* at 4.
[794] *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664 (Jan. 14, 2005).
[795] *Id.* at 2,668.
[796] *Id.* at 2,668

https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.

As discussed above in the Section on footnote 6, EPA's attempt to align its proposal with OMB's guidelines is misguided.

Footnote 16: See examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau.

In the original Proposal EPA provided no specific "examples" and this vague cite provided very little direction about what EPA was referencing here—making it impossible to review these examples or respond to them.

Footnote 17: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

EPA states that other agencies have tools to de-identify information private information, but fails to recognize that these methods are not transferable to EPA's context.[797] EPA links to guidance on de-identification requirements under HIPAA. This guidance provides two methods for de-identifying data: (1) expert determination method, where an expert determines that, after application of statistical and scientific principals and methods, the risk is very small that the information alone or with other available information could be used to identify the subject; and (2) the safe harbor method, requiring that a number of identifiers are removed. The first method requires case-by-case work and EPA has provided no information regarding how EPA could implement it or how much it might cost and thus the feasibility of requiring researchers or EPA to de-identify data this way is questionable. The second method requires removal of much information useful for research that may be necessary to be able to independently validate the research, so it is unclear that it would satisfy the Proposal's demands. Furthermore, the safe harbor method has been shown to provide potentially insufficient privacy protections.[798]

Footnote 18: https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.

In this footnote, EPA cites to a report by the National Academies for the proposition that "The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century. . . " [799] This incorrectly makes it seem as though the National Academies have identified simple techniques to de-identify data for public release without compromising personal piracy. A full review of the report reveals the

[797] 83 Fed. Reg. at 18,771.
[798] Latanya Sweeney, Ji Su Yon, Laura Perovich, Katherine E Boronow, Phil Brown, and Julia Green Brody, *Re-identifcation Risks in HIPAA Safe Harbor Data: A Study of Data From One Environmental Health Study*, Technology Science (August 28, 2017).
[799] 83 Fed. Reg. at 18,771; National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, National Academies Press (2005).

opposite is true, that The National Academies in fact recognize that complex, evolving, and yet undeveloped techniques are needed to resolve these concerns. It offers recommendations that are intended to *improve upon* existing techniques, indicating that this area is under constant change and many advances are left to be made.[800] Further, the report notes this improvement requires "strong partnership between the research community and statistical and research agencies in the design of innovative research on disclosure avoidance techniques and data access modalities and in the implementation of the advances that result from such research."[801] The Proposal takes no steps towards advancing design of new techniques or providing resources to undertake all that needs to be done to make the Proposal remotely feasible.

Further, the Report notes that a changing landscape is making it increasingly difficult to apply past techniques to sufficiently protect data from identification, saying: "Initially, relatively simple data masking techniques, such as top coding income amounts. . . were used to generate restricted data products [,] [d]uring the last decade the increasing risks of confidentiality breaches have led researchers to develop increasingly sophisticated methodologies for restricted data products."[802] They state, "more research is clearly needed to assess the relative ability of different masking methods, and of synthetic data, to reduce the risk of disclosure while preserving data utility."[803] EPA does not acknowledge these newly emerging concerns.

The National Academies recognize the current limitations of producing restricted data that sufficiently limits identifiability to allow it to be made publicly available in a useful form. They note that "well-informed policy making" requires "[r]esearch using detailed confidential data" that cannot be made public—which the Proposal fails to acknowledge to the detriment of the quality of EPA's policy decisions.[804] Just because certain information cannot be made public for legitimate reasons does not mean the government should refuse to use it to inform policy. And much of the data useful for environmental and health research is particularly sensitive—the report notes there is increased vulnerability in "[d]ata with geographic detail, such as census block data" and longitudinal data obtained in panel surveys, which is often salient in environmental research.[805] In the meantime, the National Academies state that more work is needed to allow "[h]igh-quality public-use files" that still assure "the inferential validity of the data while safeguarding their confidentiality."[806]

They also point to broader implications of not implementing sufficient privacy protections that EPA does not consider at all may result from the Proposal. The quality of data collected is likely to suffer as "[i]t is essential that respondents believe they can provide accurate, complete information without any fear that the information will be disclosed inappropriately."[807] Essentially, the report leaves as an open question "decisions about how much disclosure risk is acceptable in order to achieve the benefits of greater access to research data involve weighing the

[800] *Id.* at 35.
[801] *Id.* at 35.
[802] *Id.* at 27
[803] *Id.* at 28.
[804] *Id.* at 2.
[805] *Id.* at 22.
[806] *Id.* at 2.
[807] *Id.* at 51.

potential harm posed by disclosure against the benefits potentially foregone."[808] Thus, EPA wrongfully points to this report as supporting the notion that simple techniques exist to address privacy concerns. The report recommends only more research to reduce risks and increase data utility along with consultation with data users and providers about these issues—which the Proposal does not implement and thus the report does not support the Proposal.[809]

Footnote 19: https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf; https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy; https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps.

EPA claims that "the National Academies and the Bipartisan Commission on Evidence Based Policy have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts."[810] The proposal does not explain how these examples are relevant, as there is no indication that secure access to underlying data would meet the requirements of making underlying data "publicly available." Further, even if it were relevant, a review of the sources cited reveal that they do discuss many challenges in this space—which the Proposal does not at all address—and provide no support for the Proposal.

I. Commission on Evidence-Based Policymaking, The Promise of Evidence-Based Policymaking (2017)

This report centers on how to enhance infrastructure to increase the access and use of data between federal agencies to support government policy-making, rather than increase public access to data to non-governmental analysts for purposes of independently validating regulatory science.[811] Further, its focus is to help efforts to make *more* data available for government purposes to better inform policies. The Proposal on the other hand seeks to make data available to validate individual studies while ultimately making *less* data available for EPA to consider as it creates policies.

To the extent the report does speak to making more data *publicly* available, it envisions an entirely new framework to provide adequate privacy protections. Chapter Three of the report discusses increasing threats to privacy as "the amount of information about individuals that is publicly available has grown and the technology that can permit unauthorized re-identification has improved."[812] It notes that forming solutions to this problem while preserving the quality of data is difficult, and that a challenge is "ensuring that enhanced statistical disclosure methods do not change the data in ways that increase the difficulty of reproducing research results." It thus specifically notes that protecting confidentiality can be in tension with allowing data to be used for reproducibility purposes.

[808] *Id.* at 62.
[809] *Id.*
[810] 83 Fed. Reg. at 18,771.
[811] Commission on Evidence-Based Policymaking, *The Promise of Evidence-Based Policymaking* (2017).
[812] *Id.* at 54-55.

The report recommends: (1) amending federal statutes to require Federal departments to conduct a comprehensive risk assessment on de-identified confidential data intended for public release and release de-identified confidential data subject to the Privacy Act and CIPSEA only after a disclosure review board approves the release and publicly provides the risk assessment and a description of steps taken to mitigate risk; (2) federal departments to adopt state-of-the-art database, cryptography, privacy-preserving, and privacy-enhancing technologies for confidential data used for evidence building; (3) federal departments assign a senior official the responsibility for coordinating access to and stewardship of the department's data resources; (4) new legislation ensuring that data acquired under a pledge of confidentiality are kept confidential and used exclusively for statistical purposes.[813] The Proposal does not discuss or contribute to any of these efforts.

Chapter Four recognizes that some data cannot be made publicly available without sacrificing the utility of the evidence and thus sets forth recommendations for creating a new National Secure Database Service to allow researchers to access "detailed data that cannot be made publicly available, and only for exclusively statistical purposes."[814] This report thus implicitly recognizes the value of using confidential data to "securely generate evidence about government policies and programs."[815] While transparency is a crucial goal, using data that cannot be made publicly available can help inform government policies in important ways.

The Report details the many obstacles to making data publicly available, and ultimately concludes that much more work is needed in this area, none of which is being furthered by EPA's Proposal.

II. NAS, Innovations in Federal Statistics: Combining Data Sources While Protecting Privacy (2017)

This report provides recommendations to increase sharing and use of data by the federal government and between agencies.[816] It places maintaining privacy and confidentiality at the forefront. The report provides a discussion of the benefits and challenges to allowing external researchers to access data held by government agencies. This assumes that agency has access to data in the first place—which may not be the case with the studies EPA wishes to rely on that would be barred by its Proposal.

The report notes multiple risks to privacy and confidentiality from data breaches, identity theft, and the threat from the ability to combine multiple data sources to re-identify anonymized data as more and more data is made publicly available.[817] The solutions that the report proposes to minimize these risks include: data minimization, restricted data, restricted access (including licensing agreements, federal statistical research data centers, nongovernment data enclaves).[818]

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[813] *Id.* at 47.
[814] *Id.* at 66.
[815] *Id.* at 68.
[816] NAS, *Innovations in Federal Statistics: Combining Data Sources While Protecting Privacy*, National Academies Press (2017).
[817] *Id.* at 76-79.
[818] *Id.* at 82-88.

The Proposal does not allow for data minimization since it is aimed at making public complete underlying data that is likely to involve salient personally identifiable information for an unlimited amount of time.[819] Data restriction involves "removing explicit identifiers and applying a variety of statistical disclosure limitation methods to the dataset to reduce the risk of disclosure."[820] However, because these techniques "decrease the precision of the variables in the dataset and. . . introduce errors" it is unclear that they would preserve data for independent validation while also sufficiently protecting privacy.[821] Restricted access involves using "administrative procedures and technology to restrict who can access the dataset and what kinds of analyses can be done with the data to reduce the risk of disclosure."[822] This specifically limits access to data from the general public, which seemingly would not meet the requirements of EPA's proposal. Thus, EPA has not addressed how it would meet any of the challenges raised in this document.

III. NAS, Federal Statistics, Multiple Data Sources, and Privacy Protection: Next Steps (2017)

This report is not directly relevant as it discusses ways to combine diverse data sources from government and private sector sources and the privacy issues that arise from combining multiple data sets.[823] The purpose of the report is to help "federal statistical agencies examine and evaluate data from alternative sources and then combine them as appropriate to provide the country with more timely, actionable, and useful information for policy makers, businesses, and individuals."[824] EPA's proposal will in fact restrict the information that EPA can use.

The report notes that the "privacy status of data is dynamic over time, that datasets that are not individually identifiable today may in the future become individually identifiable" with the availability of new techniques and auxiliary data. [825] It notes that as data sets are linked, these privacy threats increase.[826] The Proposal does not discuss or address threats to privacy from data linkages.

The panel highlighted a number of threats to privacy and data security, including from security threats and inferential disclosure, and concluded "there is awareness of weaknesses of current statistical disclosure limitation methods, but the feasibility for federal statistical agencies of implementing new technologies, such as differential privacy, has not been clearly demonstrated."[827] Finally, they state:

[819] *Id.* at 82-83.
[820] *Id.* at 83.
[821] *Id.*
[822] *Id.* at 85.
[823] NAS, *Federal Statistics, Multiple Data Sources, and Privacy Protection: Next Steps*, National Academies Press (2017).
[824] *Id*. at 2.
[825] *Id.* at 71.
[826] *Id.* at 72.
[827] *Id.* at 105.

> Overall, much work, interaction, and collaboration will be needed across the various disciplines and stakeholders as agencies seek to move forward to provide stronger privacy protection for the data they either collect from respondents or acquire access to from other administrative and private-sector sources for statistical purposes. It will be critical for there to be robust discussions of the implications of this approach for all stakeholders and these discussions will need to be informed by concrete examples to help everyone understand how use of these technologies will affect them.[828]

The report notes that in order to provide greater access to data much more research and resources are needed. The Proposal identifies no such resources or processes needed to develop needed methods and techniques to allow for greater data disclosure.

Footnote 20: For example, see policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature

EPA cites to "policies or recommendation" of several journals that require data be deposited in public data repositories as an example of the Proposal's requirement of data availability.[829] EPA provided only a list of journals with no reference to any specific policies making it difficult to respond fully to this statement.

Each of these journals, however, has exceptions to its data availability requirements when there are valid reasons preventing authors from making their data publicly available via a public data repository. Further, the editors of these journals released a joint statement that explains why their policies with regards to data availability should not be used to support a policy by a federal agency that would in fact restrict the scientific studies it could rely on.[830] Given the vastly different contexts and aims of federal agencies and scientific journals when it comes to making data publicly available, journal policies should not inform EPA's direction. None of these journals claims that lack of data availability in itself calls into question the validity of a scientific conclusion based on that data—and thus these policies do not support the Proposal.

Footnote 21: For example: https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/; https://www.census.gov/fsrdc

As examples of controlled access to data in federal research data centers, EPA cites to the National Institutes of Health's policy for requesting access to controlled-access data maintained in NIH-designated data repositories and the U.S. Census Bureau's website on Federal Statistical Research Data Centers, secure facilities providing authorized access to restricted-use microdata for statistical purposes only. NIH requires researches to be a tenure-track professor, senior

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[828] *Id.* at 106.
[829] 83 Fed. Reg. at 18,771.
[830] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

scientist, or equivalent and go through required procedures prior to gaining access.[831] The U.S. Census Bureau requires researchers to obtain Census Bureau Special Sworn Status, which requires passing a moderate risk background check and swearing to protect respondent confidentiality for life, with significant financial and legal penalties under Title 13 and Title 26 for failure to do so.[832]

It is unclear how these policies are informing EPA's proposal. EPA's proposal would require data to be made "publicly available," and these forms of restricted access specifically do not make data publicly available. They require significant resources and infrastructure and careful thought about who will be permitted to access such data and under what conditions—none of which EPA has provided any discussion of in the Proposal.

Footnote 22: These recommendations are consistent with those of Lutter and Zorn (2016). https:// www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.we re.

EPA cites to a working paper by Randall Lutter and David Zorn as supporting the proposition that "EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective and may also include: Requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements."[833]

Lutter and Zorn reference these strategies as ones agencies could use to minimize the risks to personally identifiable information when agencies make data publicly available.[834] However, EPA's proposed regulations do not discuss or propose implementation of any of these strategies. The Proposal would result in a rule that mandates only that data be made "publicly available" without any possibility for more restricted release. As the comments discuss, EPA has further not consulted with other federal agencies on this Proposal.

Lutter and Zorn additionally do not argue that agencies should immediately disregard studies where data cannot be made publicly available, and provide alternative procedures agencies should utilize in those cases when still relying on studies.[835] In a separate statement on the HONEST Act, which contains similar requirements as the Proposal, Lutter and Zorn stated that the legislation "should also allow agencies to regulate in instances where they do not possess data."[836] While these additional procedures they recommend agencies follow could still be overly

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[831] NIH, *Requesting Access to Controlled-Access Data Maintained in NIH-Designated Data Repositories (e.g., dbGaP)*, https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/ (last accessed Aug. 10, 2018).
[832] U.S. Census Bureau, *Secure Research Environment*, https://www.census.gov/about/adrm/fsrdc/about/secure_rdc.html (last accessed Aug. 10, 2018).
[833] 83 Fed. Reg. at 18,771.
[834] Randall Lutter & David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper 31 (Sept. 2016).
[835] *Id.* at 32-33.
[836] Randall Lutter and David Zorn, *The Data That Our Government Uses Must be Transparent*, SmartRegs (Mar. 13, 2017), https://smartregs.org/the-data-that-our-government-uses-must-be-transparent-caa16b3dc19d.

burdensome and barriers to EPA promulgating important safeguards, it is important to note that even they see the dangers in a rule that would force the agency to disregard studies when underlying data could not be made public.

Footnote 23: https://www.nap.edu/catalog/11434/ expanding-access-to-research-data-reconciling-risks-and-opportunities.

The Proposal claims "The benefits EPA ensuring that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation are that it will improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets."[837] EPA cites to a National Academies report. This report does speak to many benefits of making data available to researchers, including helping to maintain and improve data quality;[838] promoting new research and exploration of new questions using existing data;[839] and allowing for verification, refutation, or refinement of original results.[840]

However, the report simply considers the benefits of making data publicly available in a broad sense, it does not consider the issue in the Proposal—which is that new data is not necessarily being made publicly available that was not before, and at the same time EPA's consideration of scientific research is being limited. Thus, it does not consider the costs to government policy-making that come from EPA's refusing to consider scientific research where underlying data is not publicly available. Since it is questionable whether the Proposal will result in any new data being made available to the public, and certain that it will result in EPA's ignoring valid scientific findings, it is unlikely that this Proposal will "improve the data and scientific quality of the Agency's actions" as EPA claims.

Footnote 24: https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.

EPA cites to a paper by Randall Lutter and David Zorn for its analysis that ''an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available."[841] However, there are important limitation to this analysis that seriously call this conclusion into question.

First, the statement that EPA cites to is taken out of context. The entire sentence is: "More specifically, we can calculate an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available."[842] This statement is *not* a conclusion that the benefits of making publicly

[837] 83 Fed. Reg. at 18,772.
[838] The National Academies, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, National Academies Press 48 (2005).
[839] *Id.* at 38.
[840] *Id.* at 39.
[841] Randall Lutter & David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper (Sept. 2016).
[842] *Id.* at 27.

available data underlying research that federal agencies use to promulgate significant public polices would outweigh the costs. It is describing the figure that Lutter and Zorn go on to calculate—the threshold level of increase in net benefits required by this policy to equal the costs of implementation. They find that "an improvement in net benefits of 0.02 to 2.08 percent would imply that the net benefits of requiring data access are positive."[843] They themselves note that this estimate "fall[s] short of proving that the benefits outweigh the associated costs."[844]

Their analysis itself is suspect because it differs greatly from the cost estimate provided by the Congressional Budget Office for H.R. 1430, Honest and Open New EPA Science Treatment Act of 2017. The CBO estimated that, if the agency were to choose to rely only on studies that met the Act's requirements from the outset, implementing this legislation would cost about $5 million from 2018-2022.[845] They assumed it would cost $10,000 per study to make data available to enable use of studies.[846] They estimated costs of at least $100 million per year if EPA were to continue to rely on as many studies to support its actions as it has done in recent years.[847] An older cost estimate from CBO on a prior version of the HONEST Act estimated that it would cost "about $250 million a year for the next few years."[848] This assumed that EPA would spend from $10,000 to $30,000 per study to make the data available and that EPA would reduce the number of studies it relies on by about one-half.[849]

Zutter and Lorn calculated an alternative amount for the costs to EPA of this legislation. They find that "the total cost to the EPA for data collection and public accessibility would be $2,558 per study, or about 26 percent of the $10,000 per study cost estimated by CBO."[850] They used estimates that EPA reported under the Paperwork Reduction Act for time that entities in the chemical industry would need to spend to comply with EPA's Health and Safety Data Reporting Rule (40 C.F.R. 716).[851] While they purport that the requirements of that rule are similar to the activities that EPA would undertake to comply with the HONEST Act and similar legislation, they provide no further basis for this.[852] Given the great discrepancy between their and CBO's estimates, it is unclear that their estimate sufficiently accounts for the numerous costs associated with EPA locating underlying research data not currently in its possession and upgrading it to enable it to be made publicly available.

They also rely on questionable assumptions in their calculation. They assume that "given modern technology, by the time research has been published, almost all relevant underlying data

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[843] *Id*.
[844] *Id.* at 29.
[845] Congressional Budget Office, *Cost Estimate: H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017* (Mar. 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.
[846] *Id.* at 3.
[847] *Id.* at 3.
[848] Congressional Budget Office, *Cost Estimate: H.R. 1030 Secret Science Reform Act of 2015* (Mar. 11, 2015), https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf.
[849] *Id.* at 3.
[850] Randall Lutter & David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper 23 (Sept. 2016).
[851] *Id.* at 21.
[852] *Id*.

and computer code and models will be in electronic format" so time spend photocopying studies will be reduced.[853] This does not consider that EPA may want to rely on older studies where all relevant information is not available in electronic, easily accessible formats. They provide unsupported estimates for activities that EPA would need to undertake to comply with HONEST Act-like legislation that has no corresponding requirement in EPA's Health and Safety Data Reporting Rule—such as estimating 10 hours for EPA to format unformatted data for public access.[854]

They additionally produce their own estimate for the number of studies that EPA relies on each year, looking at materials posted in dockets on regulations.gov and coming to a total of 18,000 pieces of scientific research per year.[855] CBO estimated 50,000 scientific studies per year.[856] Assuming that EPA continued to rely on all 18,000 studies per year, Zutter and Lorn came to total implementation costs of about $46 million per year, far below the estimate by CBO assuming EPA still relied on at least half of the studies it does currently. Thus, one should view this cost estimate with suspicion, and there is no reason it should be relied on over CBO's cost estimates and does not suffice for EPA providing its own cost benefit analysis.

May 25, 2018 Memorandum

On May 25, 2018, EPA provided a memorandum that provided additional hyperlinks for some of the sources cited in the footnotes.[857]

Footnote 9

- **National Science Foundation: https://www.nsf.gov/bfa/dias/policy/dmp.jsp**
- **National Institute of Science and Technology: https://www.nist.gov/open**
- **National Institutes of Health: https://grants.nih.gov/policy/sharing.htm**

The hyperlinks that EPA provides fail to point to any relevant policies that support EPA's Proposal. First, EPA links to the National Science Foundation's policies requiring investigators who receive NSF grants to share research data with other researchers.[858] Importantly, they are only to release privileged or confidential information "in a form that protects the privacy of individuals and subjects involved" and NSF may make adjustments or exceptions when needed

[853] *Id.* at 22.
[854] *Id.*
[855] *Id.* at 24.
[856] Congressional Budget Office Cost Estimate: H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (Mar. 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf. 3
[857] May 25, 2018 Memorandum Re: Omitted Hyperlinks for Footnotes in the Proposed Rule (Docket ID No. EPA–HQ–OA–2018–0259)
[858] NSF, *Disseminating and Sharing of Research Results*, https://www.nsf.gov/bfa/dias/policy/dmp.jsp (last accessed Aug. 10, 2018).

"to safeguard the rights of individuals and subjects, the validity of results, or the integrity of collections or to accommodate the legitimate interest of investigators."[859]

EPA links to the National Institute of Science and Technology policy on sharing data arising from NIST-funded research.[860] The plan clearly exempts "[p]ersonnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy" from being subject to the data sharing policy.[861]

EPA also cites to The National Institutes of Health. The hyperlink links to a webpage consisting of a number of policies dictating sharing of NIH-funded research with no clarification of which policy EPA is referring to or why it is relevant to the Proposal. While NIH policies do in many cases require data from NIG-funded research to be shared publicly—these policies place protection of personal information at the forefront and thus include controls such as controlled access, de-identification of information, data aggregation and allow exceptions when data cannot be made publicly available.

These examples all deal with policies to share data that the agencies have access to and the ability to share—because they deal with federally-funded research. EPA's Proposal, on the other hand, applies to all data whether or not EPA has the data in its possession or is authorized to release it. They all speak to making data available to increase its utility, not to making data available specifically for the purposes of independent validation of research results, which requires data be available on a more granular level that makes privacy protection more difficult. Further, EPA already has policies in place to make publicly available data that is produced by research it funds. Also, none of these policies address regulating how the agencies themselves rely on or use scientific information. Thus the Proposal in no way "builds upon" the efforts they represent.

Footnote 10

- **Administrative Conference of the United States' Science in the Administrative Process Project: https://www.acus.gov/research-projects/science-administrative-process**
- **Improving Access to and Confidentiality of Research Data: https://www.nap.edu/read/9958**
- **Expanding Access to Research Data: https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities**
- **Access to Research Data in the 21st Century: https://www.nap.edu/catalog/10302/access-to-research-data-in-the-21st-century-an-ongoing**
- **Health Effects Institute: https://www.healtheffects.org/system/files/AppendixD-data-access_3.pdf**

[859] NSF, *Chapter XI - Other Post Award Requirements and Considerations*, https://www.nsf.gov/pubs/policydocs/pappg17_1/pappg_11.jsp#XID4 (Jan. 30, 2017).
[860] NIST, *Public Access to NIST Research*, https://www.nist.gov/open (last accessed Aug. 10, 2018).
[861] NIST, *Managing Public Access to Results of Federally Funded Research Policy* 1-2 (Jun. 26, 2015), https://www.nist.gov/sites/default/files/documents/2018/06/19/final_p_5700.pdf.

- **Center for Open Science: https://osf.io/x2w9h/?_ga=2.15543670.1160736397.1518527893-776332106.1518527893**
- **Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology: http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf**
- **Bipartisan Policy Center's Science for Policy Project: http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf**

I. The Health Effects Institute, https://www.healtheffects.org/system/files/AppendixD-data-access_3.pdf

EPA provides a link to the HEI Policy On The Provision Of Access To Data Underlying HEI funded Studies. This policy is "to provide access expeditiously to data for studies that it has funded and to provide that data in a manner that facilitates review and verification of the work but also protects the confidentiality of any volunteers who may have participated in the study and respects the intellectual interests of the original investigator of the work."[862] It is written to be consistent with OMB Circular A-110, which requires agencies to respond to FOIA requests for data underlying federally supported research used to develop federal agency actions with the force and effect of law. EPA already has policies in place to make public the data underlying research that it funds, and already must comply with OMB Circular A-110, thus, it is unclear how this Proposal builds upon this policy.

Furthermore, the policy specifically excludes "personal and medical information and similar information that is personally identifiable, and the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study" and requires the requestor to pay reasonable costs. In this manner, it further deviates from the Proposal.[863]

II. Center for Open Science, https://osf.io/x2w9h/?_ga=2.15543670.1160736397.1518527893-776332106.1518527893

EPA links to the Center for Open Science's 2017-2020 Strategic Plan.[864] While the strategic plan outlines COS's own mission to "increase openness, integrity, and reproducibility of scholarly research" and to meets its goal of creating "a future scholarly community in which the process, content, and outcomes of research are openly accessible by default" nothing in this

[862] HEI, *APPENDIX D: HEI POLICY ON THE PROVISION OF ACCESS TO DATA UNDERLYING HEIFUNDED STUDIES*, https://www.healtheffects.org/system/files/AppendixD-data-access_3.pdf (last accessed Aug. 10, 2018).
[863] *Id.*
[864] Center for Open Science, *Strategic Plan*, https://osf.io/x2w9h/?_ga=2.15543670.1160736397.1518527893-776332106.1518527893.

strategic plan suggests anything like EPA's Proposal.[865] It does not discuss barring use of studies or ensuring access to underlying data—and thus is completely irrelevant to the Proposal.

III. Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology: http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf

EPA links to a survey conducted by the Center for Media and Public Affairs and Center for Health and Risk Communication at George Mason University.[866] They surveyed members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology. However, the survey thus does not represent any official recommendation or policy position from these professional organizations, and represent only the views of the members who chose to participate in the survey.

Thus, while the survey found 69 % of those surveyed "regard it as "very important" for assessors to have access to underlying raw data for the most critical studies in order to independently analyze their results," this should be viewed in the rightful context.[867] The survey did not ask whether agencies should continue to rely on scientific studies where the underlying data cannot be made public or independently analyzed. The survey question further appears to have only asked whether researchers assessing studies should have access to underlying data to independently analyze results, not whether underlying data should be made *publicly available*.

Further, the Dose Response Section of the Society for Risk Analysis has since submitted a comment to EPA that states this footnote and the claim that EPA makes that the Proposal took into consideration these recommendations and policies is "inaccurate" and that "the 'Dose-Response Section [sic] of the Society for Risk Analysis' has never adopted any 'policies or recommendations' on this or any other topic."[868] They have asked that EPA remove all references to the organization and make clear in the comment response for this rule that "'third party Organizations' whose policies and recommendations were considered do not include the Society for Risk Analysis or the Dose-Response Specialty Section."

The Society for Toxicology similarly have said this survey does not constitute support from the Specialty Section or the SOT as a whole, and requesting "that any and all references to "members of the Risk Assessment Specialty Section of the Society of Toxicology" be removed

[865] *Id.* at 6.
[866] George Mason University, *Expert Opinion on Regulatory Risk Assessment* (Dec. 6, 2013), http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf.
[867] Id. at 2-3.
[868] Comment from Weihsueh A. Chiu, Chair, Dose-Response Specialty Group, Society for Risk Analysis, Docket ID No. EPA–HQ–OA–2018–0259 (May 24, 2018).

from the Final Rule."[869] They also specifically comment that "invalidating data solely on the basis of public availability is inappropriate."[870]

IV. Bipartisan Policy Center's Science for Policy Project, http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf

EPA provides a hyperlink to the Final Report of the Science for Policy Project *Improving the Use of Science in Regulatory Policy*.[871] This report makes a number of recommendations, none of which endorse the Proposal. In relevant part, Recommendation Three suggests "Agencies and their scientific advisory committees should cast a wide net in reviewing studies relevant to regulatory policy, and should make their methods for filtering and evaluating those studies more transparent."[872] They urge agencies to increase availability of data and information on research studies and subject all studies relied on in the formulation of regulation to be subject to the requirements of the Shelby Amendment and OMB Circular A-110 regardless of who funded the study.[873] Importantly, those requirements contain important exception for confidentiality and privacy concerns—and thus do not support the Proposal.

This recommendation is also aimed at *increasing* use of science in regulatory policy, and does not suggest that agencies not rely on studies where those data access requirements cannot be met because of other concerns. It also highlights that the use of CBI to prevent access to data appears to be overused and urges agencies to make procedures more stringent to allow only for legitimate claims of CBI—which EPA does not address in its Proposal.[874]

Recommendation Four states: "The federal government, universities, scientific journals and scientists themselves can help improve the use of science in the regulatory process by strengthening peer review, expanding the information available about scientific studies, and setting and enforcing clear standards governing conflict of interest."[875] As part of this recommendation, the report "Federal agencies, universities and journals should encourage or require on-line publication of the methods and data underlying published scientific studies."[876] However, it once again does not say that agencies should not consider research studies where this is not possible due to privacy or other compelling reasons.

Wendy Wagner, who served on the panel that produced the recommendations has stated: "They don't adopt any of our recommendations, and they go in a direction that's completely

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[869] Comment from Leigh Ann Burns Naas, Society of Toxicology, Docket ID No. EPA–HQ–OA–2018–0259 (May 25, 2018) at 1.
[870] *Id.* at 2
[871] Bipartisan Policy Center, Science for Policy Project, *Improving the Use of Science in Regulatory Policy* (Aug. 5, 2009), http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf.
[872] *Id.* at 41.
[873] *Id.*
[874] *Id.* at 43.
[875] *Id.* at 45.
[876] *Id.* at 46.

opposite, completely different. . . . They don't adopt any of the recommendations of *any* of the sources they cite. I'm not sure why they cited them."[877]

Footnote 11

- **Proceedings of the National Academy of Sciences: http://www.pnas.org/page/authors/journal-policies#xi**
- **PLOS ONE: http://journals.plos.org/plosone/s/data-availability**
- **Science: http://www.sciencemag.org/authors/science-journals-editorial-policies**
- **Nature: http://www.nature.com/authors/policies/data/data-availability-statements-data-citations.pdf**

While EPA links to journal policies that encourage or require, in some instances, sharing data, they contain exceptions when privacy would be compromised.[878] The editors of these journals issued a joint statement opposing the Proposal. They note that some data sets cannot be shared publicly, and that there are still other methods available to verify scientific findings. The statement also strongly condemns the notion of excluding scientific information from consideration when underlying data cannot be made publicly available:

> It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.[879]

Thus, journal policies encouraging the sharing of underlying data do not support a proposal by a regulatory agency to exclude from consideration studies when the underlying data is not publicly available.

Footnote 16:

- **U.S. Department of Health and Human Services: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html**
- **National Institute of Standards and Technology: https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf**
- **U.S. Department of Education: https://studentprivacy.ed.gov/sites/default/files/resource_document/file/data_deidentification_terms.pdf**
- **U.S. Census Bureau: https://www.census.gov/about/adrm/linkage/technical-documentation/processing-de-identification.html**

EPA suggests the examples linked to could address concerns about privacy and confidentiality arising from the Proposal. However, the cited sources provide no assurance that

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[877] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 25, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/.

[878] *See* discussion below on footnote 20.

[879] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

the Proposal could be implemented to expand disclosure of personal data without serious risks to privacy.

I. U.S. Department of Health and Human Services, https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

EPA first points to guidance on de-identification requirements under HIPAA. This guidance provides two methods for de-identifying data: (1) expert determination method, where an expert determines that, after application of statistical and scientific principals and methods, the risk is very small that the information alone or with other available information could be used to identify the subject; and (2) the safe harbor method, requiring that a number of identifiers are removed. The first method requires case-by-case work and EPA has provided no information regarding how EPA could implement it or how much it might cost and thus the feasibility of requiring researchers or EPA to de-identify data this way is questionable. The second method requires removal of much information useful for research that may be necessary to be able to independently validate the research, so it is unclear that it would satisfy the Proposal's demands. Furthermore, the safe harbor method has been shown to provide potentially insufficient privacy protections.[880]

II. National Institute of Standards and Technology, https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf

EPA links to a NIST document entitled *De-Identification of Personal Information* as a potential solution to address concerns about confidentiality and privacy.[881] This document discusses different techniques and issues with de-identification of personal information. However, the document does not discuss de-identification of personal information specifically for the purposes of making research data publicly available for independently validating scientific studies. The document instead notes that:

> The purpose of de-identifying data is to allow some uses of the de-identified data while providing for some privacy protection by shielding the identity of the data subjects. These two goals are antagonistic, in that there is a trade-off between the amount of de-identification and the utility of the resulting data. However, de-identification opens up new uses for the data that were previously prohibited due to privacy concerns. It is thus the role of the data controller, standards bodies, regulators, lawmakers and courts to determine the appropriate level of security, and thereby the acceptable trade-off between de-identification and utility.[882]

EPA completely fails to note this obstacle, that as data is stripped of identifiable material it also loses utility to researchers. EPA cites to broad privacy protection techniques without explaining

[880] Latanya Sweeney, Ji Su Yon, Laura Perovich, Katherine E Boronow, Phil Brown, and Julia Green Brody, *Re-identifcation Risks in HIPAA Safe Harbor Data: A Study of Data From One Environmental Health Study*, Technology Science (August 28, 2017).
[881] Simson L. Garfinkel, *De-Identification of Personal Information* (NISTIR 8053), NIST (Oct. 2015), https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf.
[882] *Id.* at 11-12.

whether they could be applied to protect privacy while still allowing enough utility in the data set to allow for independent validation as required by the Proposal.

The document notes many of the challenges to protecting privacy including that: "de-identification approaches based on suppressing or generalizing specific fields in a database cannot provide absolute privacy guarantees, because there is always a chance that the remaining data can be re-identified using an auxiliary dataset."[883] The harms of data linkages and increasing difficulty to preserve privacy as more and more information about individuals is made available is another challenge that EPA has not addressed.

III. U.S. Department of Education, https://studentprivacy.ed.gov/sites/default/files/resource_document/file/data_deidentification_terms.pdf

EPA links to a document of the Privacy Technical Assistance Center, *Data De-identification: An Overview of Basic Terms*, which provides a high-level overview of key terms and practices to help educational agencies and institutions comply with the Family Educational Rights and Privacy Act (FERPA).[884] EPA has not explained why the requirements of FERPA are applicable here. This document is concerned with data disclosure that occurs "when schools, districts, or states publish reports on student achievement or share students' data with external researchers" not to make information publicly available for independent validation.[885] Thus its unclear that methods used to de-identify but preserve data for those purposes would be adequate in this context.

For example, one of the methods that the U.S. Department of Education uses for disclosure avoidance for tabular data is to not release information for any cell that has a size below some minimum, which essentially means not disclosing information where there are small numbers in a certain cell.[886] This could obviously lead to a loss of information that would prevent a de-identified data set from being used to independently validate research findings.

IV. U.S. Census Bureau, https://www.census.gov/about/adrm/linkage/technical-documentation/processing-de-identification.html

EPA provides a link to a website titled *Data Ingest and Linkage* that details the U.S. Census Bureau's approach to linking data across many records held by the Bureau, permitting more detailed information to be linked back to one individual to allow for analysis and research. The website links to a working paper that describes the method by which the Bureau assigns a unique person identifier to records it holds that enables it to link records together to create the

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[883] *Id.* at 5.
[884] U.S. Department of Education, Privacy Technical Assistance Center, *Data De-identification: An Overview of Basic Terms* (Oct. 2012), https://studentprivacy.ed.gov/sites/default/files/resource_document/file/data_deidentification_terms.pdf.
[885] *Id.*
[886] *Id.* at 4.

final file.[887] It is totally unclear how this process on linking together records is a solution that EPA could implement to protect privacy of individuals when disclosing data as it concerns how to identify data to specific people—not how to make data available while protecting their privacy.

Footnote 20:

- Taylor & Francis: https://authorservices.taylorandfrancis.com/data-repositories/
- Elsevier: https://www.elsevier.com/authors/author-services/research-data
- PLOS: http://journals.plos.org/plosone/s/data-availability
- Springer Nature: https://www.springernature.com/gp/authors/research-data-policy/repositories

EPA cites to "policies or recommendation" of several journals that require data be deposited in public data repositories as an example of the Proposal's requirement of data availability.[888] While these journals have policies that encourage authors to deposit data in public data repositories, they all have important exceptions in cases where this is not feasible or ethical.

The hyperlink for Taylor & Francis links to a page that provides information about how to find public data repositories to submit date to in order to comply with journal sharing policies. However, Taylor & Francis' basic data sharing policy "which applies across many of [their] journals" does not *require* data be submitted to a public data repository, but "encourages authors to share and make data open where this does not violate protection of human subjects or other valid subject privacy concerns."[889] Thus, this policy is flexible and allows exceptions for when privacy concerns are at stake.

The hyperlink for Elsevier links to a page providing general information about data sharing. While the web page notes that researchers "are increasingly encouraged, or even mandated, to make. . . research data available, accessible, discoverable and usable," it also provides important qualifications.[890] It notes, "there are times when the data is simply not available to post or there are good reasons why it shouldn't be shared."[891] In these cases, authors are encouraged to provide a data statement explaining why the data cannot be shared.

The hyperlink for PLOS links to a page describing PLOS's data availability policies. It explains, "PLOS journals require authors to make all data underlying the findings described in their manuscript fully available without restriction, with rare exception."[892] The policy recommends deposition of the data into a public repository, however, it recognizes that there are

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[887] Deborah Wagner & Mary Layne, *The Person Identification Validation System (PVS): Applying the Center for Administrative Records Research and Applications' (CARRA) Record Linkage Software, CARRA Working Paper Series*, Working Paper # 2014-01, U.S. Census Bureau (July 1, 2014).
[888] 83 Fed. Reg. at 18,771.
[889] Taylor & Francis Author Services, *Understanding our data sharing policies*, https://authorservices.taylorandfrancis.com/understanding-our-data-sharing-policies/ (last accessed Aug. 10, 2018).
[890] Elsevier, *Sharing research data*, https://www.elsevier.com/authors/author-services/research-data (last accessed Aug. 10, 2018).
[891] *Id.*
[892] PLOS One, *Data Availability*, http://journals.plos.org/plosone/s/data-availability (last accessed Aug. 10, 2018).

instances when this may not be ethical or legal, for instance because the "underlying data pose privacy or legal concerns e.g., where data might reveal the identity or location of participants."[893] In these instances, it allows an exception to this policy.

The hyperlink for Springer Nature links to a page listing recommended repositories. While Springer Nature's data policies support data sharing via public data repositories, it notes, "reasonable restrictions on data availability are permitted to protect human privacy, biosafety or respect reasonable terms of use for data obtained under license from third parties."[894]

[893] *Id.*

[894] Springer Nature, *Research Data Policies FAQs*, https://www.springernature.com/gp/authors/research-data-policy/faqs/12327154 (last accessed Aug. 10, 2018).

Appendix B. Provisions of Federal Environmental Statutes Requiring EPA to Consult With Other Federal Agencies in Implementing Key Programs

Consultation Provisions in Clean Air Act

Section	Section Title	Consultation Requirement
§118(c)	President's Air Quality Advisory Board and Advisory Committees	(c) Prior to- (1) issuing criteria for an air pollutant under section 108(a)(2) (2) publishing any list under section 111(b)(1)(A) or 112(b)(1)(A), (3) publishing any standard under section 111 or section 112, or (4) publishing any regulation under section 202(a), The administrator shall, to the maximum extent practicable within the time provided, consult with appropriate advisory committees, independent experts, and Federal departments and agencies.
§103	Research, Investigation, Training, and other Activities	Consult with other Federal agencies to coordinate research and avoid duplication of activities
§108(a)	Air Quality Criteria and Control Techniques	Consult with Federal agencies to issue information on air pollution control techniques
§108(c)	Air Quality Criteria and Control Techniques	"[A]fter consultation with the Secretary of Transportation…update the June 1978 Transportation-Air Quality Planning Guidelines and publish guidance on the development and implementation of transportation and other measures necessary to demonstrate and maintain attainment of national ambient air quality standards."
§108(f)(1)	Air Quality Criteria and Control Techniques	Consult with Secretary of Transportation to provide information "regarding the formulation and emission reduction potential of transportation control measures related to criteria pollutants and their precursors."
§112(d)(9)	Hazardous Air Pollutants	Allows Administrator not to list radionuclide emissions if Administrator determines, after consultation with Nuclear Regulatory Commission (NRC), that NRC regulations already provide an adequate margin of safety.
§122	Listing of Certain Unregulated Pollutants	Consult with NRC before listing any nuclear or nuclear by-product material
§169A	Visibility Protections for Federal Class 1 Areas	Consultation with Department of Interior and Federal Land Managers for regional haze determinations
§231(a)(2)(B)(i)	Aircraft Emission Standards	Consult with Federal Aviation Administration on aircraft engine emission standards
§250 (d)	General Provisions	Consult with Department of Energy (DOE) and Department of Transportation (DOT) in carrying out Administrator's duties under the this part (Clean Fuel Vehicles)
§404(f)(1)(A)	Energy Conservation and Renewable Energy	Consult with Secretary of Energy to determine Qualified Energy Conservation Measure

§507(b)(3)(A)	Small Business Stationary Source Technical and Environmental Compliance Assistance Program	Consult with SBA Administrator to determine which category of small business sources could be exempted

Consultation Provisions in Clean Water Act

Section	Section Title	Text
§304(c)	Information and Guidelines	Consult with appropriate Federal and State agencies to issue information on pollution-reducing procedures and operating methods to implement standards of performance under §306.
§304(d)(1)-(2)	Information and Guidelines	Consult with appropriate Federal and State agencies to publish the amount of reduction attainable through secondary treatment and information on alternative waste treatment management techniques.
§304(e)	Information and Guidelines	Consult with appropriate Federal and State agencies to publish supplemental regulations to control plant site runoff, leaks/spillage, sludge/waste disposal, and drainage
§304(f)	Information and Guidelines	Consult with Federal and State agencies to issue guidelines for evaluating nonpoint sources and methods to control pollution from those sources.
§307(a)(7)	Toxic Pretreatment Effluent Standards	Consult with Federal departments and agencies prior to publishing regulations pursuant to this section
§404(d)(1)	Disposal of Sewage Sludge	Administrator must consult with Federal agencies on regulations providing guidelines for the disposal of sludge and the utilization of sludge for various purposes.
§118(a)	Lake Tahoe Study	Coordinate with Secretary of Agriculture and other Federal agencies regarding adequacy and need for extending Federal oversight of Lake Tahoe
§311(d)(2)(M)	Oil and Hazardous Substance Liability	Consultation with FWS and NOAA for a fish and wildlife response plan
§312(e)	Marine Sanitation Devices	"Before the standards and regulations under this section are promulgated, the Administrator and the Secretary of the department in which the Coast Guard is operating shall consult with the Secretary of State; the Secretary of Health, Education, and Welfare; the Secretary of Defense; the Secretary of the Treasury; the Secretary of Commerce; other interested Federal agencies…."

Consultation Provisions in Federal Insecticide, Fungicide, and Rodenticide Act

Section	Section Title	Text
136w(a)(2)(A)	Authority of the Administrator: Procedure: Proposed regulations	**(A) Proposed Regulations:** **At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation.** If the Secretary comments in writing to

		the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.
136w(a)(2)(B)	Authority of the Administrator: Final Regulations	**At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation.** If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect
136w(a)(3)	Authority of the Administrator: Procedure: Congressional Committees	At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.
136w(a)(4)	Authority of the Administrator	Simultaneously with the promulgation of any rule or regulation under this subchapter, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

136w-3	Identification of Pests; cooperation with Department of Agriculture	The Administrator, in coordination with the Secretary of Agriculture, shall identify those pests that must be brought under control. The Administrator shall also coordinate and cooperate with the Secretary of Agriculture's research and implementation programs to develop and improve the safe use and effectiveness of chemical, biological, and alternative methods to combat and control pests that reduce the quality and economical production and distribution of agricultural products to domestic and foreign consumers.
136(r)(a)	Research and Monitoring: Research	The Administrator shall undertake research including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this subchapter, and **the Administrator shall conduct research into integrated pest management in coordination with the Secretary of Agriculture.** The Administrator shall also take care to ensure that such research does not duplicate research being undertaken by any other Federal agency.
136a-1(n)(2)-(3)	Reregistration of registered pesticides: Authorization of funds to develop public health data	**(2)** Consultation. In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary [of Health and Human Services] prior to taking final action to suspend registration under section 3(c)(2)(B)(iv) or cancel a registration under section 4, 6(e), or 6(f). In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section. **(3)** Benefits to support family. The Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section or reregistration under section 4
7 USCS 136(ll)(2)	Definitions: Minor Use	(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and--

136i(a)(1)	Use of restricted use pesticides; applicators	Requires the Administrator to consult with Governor of each state to conduct a program for the certification of use of specific pesticides.
136a(c)(1)(F)(ii)	Registration of Pesticides: Procedure for registration	The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause [enacted Aug. 3, 1996] and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in **consultation** with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that--(I) there are insufficient efficacious alternative registered pesticides available for the use; (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health; (III) the minor use pesticide plays or will play a significant part in managing pest resistance; or (IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.
136t(b)	Delegation and Cooperation	**(b)** Cooperation. The Administrator shall cooperate with the Department of Agriculture, any other Federal agency, and any appropriate agency of any State or any political subdivision thereof, in carrying out the provisions of this Act and in securing uniformity of regulations.
136o(e)	Imports and Exports	Secretary of the Treasury shall prescribe regulations for this section in consultation with the Administrator.
136p	Exemption of Federal and State Agencies	The Administrator may, at the Administrator's discretion, exempt any Federal or State agency from any provision of this Act if the Administrator determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.
136w-7	Department of Agriculture Minor Use Program	**(A)** Grant authority. The Secretary, in consultation with the Administrator, shall establish a program to make grants for the development of data to support minor use pesticide registrations and reregistrations. The amount of any such grant shall not exceed 1/2 of the cost of the project for which the grant is made.
136i-1(a)(1)	Pesticide Recordkeeping	The Secretary of Agriculture, in consultation with the Administrator of the Environmental Protection Agency, shall require certified applicators of restricted use pesticides
136i-2(c)	Collection of Pesticide Use Information	Coordination. The Secretary of Agriculture shall, as appropriate, coordinate with the Administrator of the Environmental Protection Agency in the design of the

		surveys and make available to the Administrator the aggregate results of the surveys to assist the Administrator.

Consultation provisions under the Toxic Substances Control Act

Section	Title	Text
2609(a)	Research, Development, collection, dissemination, and utilization of data	**(a)** Authority. **The Administrator shall, in consultation and cooperation with the Secretary of Health and Human Services and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act**. The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection. Contracts may be entered into under this subsection without regard to sections 3648 and 3709 of the Revised Statutes
2609(b)(1), (2)	Research, development, collection, dissemination, and utilization of information: Information Systems	Administrator shall Consult and cooperate with Secretary of HHS and other heads of appropriate departments and agencies, to establish an efficient system for retrieval of toxicological and other scientific information which could be useful
2609(c)	Research, development, collection, dissemination, and utilization of information: Screening Techniques	Administrator shall coordinate with Assistant Secretary for HHS to develop screening techniques
2609(d)	Research, development, collection, dissemination, and utilization of information: Monitoring	Administrator shall, in consultation and cooperation with the Secretary of Health and Human Services, establish and be responsible for research aimed at the development, in cooperation with local, State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions
2609(e)	Research, development, collection, dissemination, and utilization of information: Basic Research	The Administrator shall, in consultation and cooperation with the Secretary of Health and Human Services, establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d), the bounds of the reliability of such techniques, and the opportunities for their improvement.
2609(g)	Research, development, collection, dissemination, and utilization of information: Exchange of research and development results	The Administrator shall, in consultation with the Secretary of Health and Human Services and other heads of appropriate departments and agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard information format and analysis and consistent testing procedures.

2608(d)	Coordination	"Coordination. In administering this Act [15 USCS §§ 2601 et seq.], the Administrator shall consult and coordinate with the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act . . ."
2608(e)	Exposure Information	If the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.
2604(f)(5)	Manufacturing and Processing Notices: Protection Against Unreasonable Risks	Consult with Assistant Secretary of Labor prior to adopting any restriction of chemical substance for workplace exposures
2604(h)(2)(B)(ii)	Manufacturing and Processing Notices: Exemptions	Consult with AG of the Federal Trade Commission about exempting persons from information requirements.

Consultation Provisions in the Safe Drinking Water Act

Section	Title	Text
300g-1 (b)(1)(D)	Standards: Listing of Contaminants for Consideration, Urgent Threats to Public Health	The Administrator may promulgate an interim national primary drinking water regulation for a contaminant without making a determination for the contaminant under paragraph (4)(C), or completing the analysis under paragraph (3)(C), to address an urgent threat to public health as determined by the Administrator after consultation with and written response to any comments provided by the Secretary of Health and Human Services, acting through the director of the Centers for Disease Control and Prevention or the director of the National Institutes of Health.
300g-1(d)	Regulations:	Regulations; public hearings; administrative consultations. Regulations under this section shall be prescribed in accordance with section 553 of title 5, United States Code (relating to rule-making), except that the Administrator shall provide opportunity for public hearing prior to promulgation of such regulations. In proposing and promulgating regulations under this section, the Administrator shall consult with the Secretary and the National Drinking Water Advisory Council.
300j-12(i)(2)	Funds: Indian Tribes: Use of Funds	(2) Use of funds. Funds reserved pursuant to paragraph (1) shall be used to address the most significant threats to public health associated with public water systems that serve Indian Tribes, as determined by the Administrator in consultation with the Director of the Indian Health Service and Indian Tribes.
300j-13(a)(5)	Source Water Quality Assessment	Demonstration project. The Administrator shall, as soon as practicable, conduct a demonstration project, in consultation with other Federal agencies, to demonstrate the most effective and protective means of

		assessing and protecting source waters serving large metropolitan areas and located on Federal lands.
300j-5(b)	National Drinking Water Advisory Council	**(b)** Functions. The Council shall advise, consult with, and make recommendations to, the Administrator on matters relating to activities, functions, and policies of the Agency under this title [42 USCS §§ 300f et seq.].
300j-3d	Water Supply Cost Savings	**(a)** Drinking water technology clearinghouse. The Administrator, in consultation with the Secretary of Agriculture, shall— **(1)** develop a technology clearinghouse for information on the cost-effectiveness of innovative and alternative drinking water delivery systems, including wells and well systems; and **(2)** disseminate such information to the public and to communities and not-for-profit organizations seeking Federal funding for drinking water delivery systems serving 500 or fewer persons.
300i-3(a)	Contaminant Prevention, Detection and Response	In general. The Administrator, in consultation with the Centers for Disease Control and, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall review (or enter into contracts or cooperative agreements to provide for a review of) current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and source water for community water systems, including each of the following:
300j-19(b)(2)(A)	Algal Toxin Risk Assessment and Management	(b) Information coordination. In carrying out this section the Administrator shall-- (2) as appropriate, consult with-- • (A) other Federal agencies that-- o (i) examine or analyze cyanobacteria or algal toxins; or o (ii) address public health concerns related to harmful algal blooms;

Consultation Provisions in the Comprehensive Environmental Response, Compensation, and Liability Act

Section	**Section Title**	**Consultation Requirement**
§311(a)(1)	Research, Development, and Demonstration	The Secretary of Health and Human Services…in consultation with the Administrator, shall establish and support a basic research and training program…consisting of the following (A) Basic research (including epidemiologic and ecologic studies) which may include each of the following: (i) Advanced techniques for the detection, assessment, and evaluation of the effects on human health of hazardous substances. (ii) Methods to assess the risks to human health presented by hazardous substances. (iii) Methods and technologies to detect hazardous substances in the environment and basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances. (B) Training, which may include each of the following:

		(i) Short courses and continuing education for State and local health and environment agency personnel and other personnel engaged in the handling of hazardous substances, in the management of facilities at which hazardous substances are located, and in the evaluation of the hazards to human health presented by such facilities. (ii) Graduate or advanced training in environmental and occupational health and safety and in the public health and engineering aspects of hazardous waste control. (iii) Graduate training in the geosciences, including hydrogeology, geological engineering, geophysics, geochemistry, and related fields necessary to meet professional personnel needs in the public and private (a) sectors and to effectuate the purposes of this Act.
§311(a)(2)	Research, Development, and Demonstration	The Director of the National Institute for Environmental Health Sciences shall cooperate fully with the relevant Federal agencies referred to in subparagraph (A) of paragraph (5) in carrying out the purposes of this section.
§311(a)(5)	Research, Development, and Demonstration	To assist in the implementation of this subsection and to aid in the coordination of research and demonstration and training activities funded from the Fund under this section, the Secretary shall appoint an advisory council (hereinafter in this subsection referred to as the ''Advisory Council'') which shall consist of representatives of the following: (A) The relevant Federal agencies. (B) The chemical industry. (C) The toxic waste management industry. (D) Institutions of higher education. (E) State and local health and environmental agencies. (F) The general public.
§311(a)(6)	Research, Development, and Demonstration	Within nine months after the date of the enactment of this subsection, the Secretary, acting through the Director of the National Institute for Environmental Health Sciences, shall issue a plan for the implementation of paragraph (1). The plan shall include priorities for actions under paragraph (1) and include research and training relevant to scientific and technological issues resulting from site specific hazardous substance response experience. The Secretary shall, to the maximum extent practicable, take appropriate steps to coordinate program activities under this plan with the activities of other Federal agencies in order to avoid duplication of effort. The plan shall be consistent with the need for the development of new technologies for meeting the goals of response actions in accordance with the provisions of this Act. The Advisory Council shall be provided an opportunity to review and comment on the plan and priorities and assist appropriate coordination among the relevant Federal agencies referred to in subparagraph (A) of paragraph (5).
§311(c)	Research, Development, and Demonstration	HAZARDOUS SUBSTANCE RESEARCH.—The Administrator may conduct and support, through grants, cooperative agreements, and contracts, research with respect to the detection, assessment, and evaluation of the effects on and risks to human health of hazardous substances and detection of hazardous substances in the environment. The Administrator shall coordinate such research with the Secretary of Health and Human Services, acting through the advisory council established under this section, in order to avoid duplication of effort.

§104(i)(4)	Response Authorities	The Administrator of the ATSDR shall provide consultations upon request on health issues relating to exposure to hazardous or toxic substances, on the basis of available information, to the Administrator of EPA
§104(i)(5)(A)	Response Authorities	For each hazardous substance listed pursuant to paragraph (2), the Administrator of ATSDR (in consultation with the Administrator of EPA and other agencies and programs of the Public Health Service) shall assess whether adequate information on the health effects of such substance is available. For any such substance for which adequate information is not available (or under development), the Administrator of ATSDR, in cooperation with the Director of the National Toxicology Program, shall assure the initiation of a program of research designed to determine the health effects (and techniques for development of methods to determine such health effects) of such substance.
§104(i)(6)(C)	Response Authorities	In determining the priority in which to conduct health assessments under this subsection, the Administrator of ATSDR, in consultation with the Administrator of EPA, shall give priority to those facilities at which there is documented evidence of the release of hazardous substances, at which the potential risk to human health appears highest, and for which in the judgment of the Administrator of ATSDR existing health assessment data are inadequate to assess the potential risk to human health as provided in subparagraph (F). In determining the priorities for conducting health assessments
§107(c)	Abatement Action	Within one hundred and eighty days after enactment of this Act, the Administrator of the Environmental Protection Agency shall, after consultation with the Attorney General, establish and publish guidelines for using the imminent hazard, enforcement, and emergency response authorities of this section and other existing statutes administered by the Administrator of the Environmental Protection Agency to effectuate the responsibilities and powers created by this Act.
§120(e)(1)	Federal Facilities	Not later than 6 months after the inclusion of any facility on the National Priorities List, the department, agency, or instrumentality which owns or operates such facility shall, in consultation with the Administrator and appropriate State authorities, commence a remedial investigation and feasibility study for such facility.
§120(e)(6)	Federal Facilities	Administrator, after consultation with other departments, may determine that remedial efforts should be done by another potentially responsible party and may enter into a settlement agreement with such party.

Consultation Provisions in the Resource Conservation and Recovery Act

Section	**Section Title**	**Consultation Requirement**
§2002(a)(1)	Authorities of Administrator	In carrying out this Act, the Administrator is authorized to— (1) prescribe, in consultation with Federal, State, and regional authorities, such regulations as are necessary to carry out his functions under this Act;
§1008(a)	Solid Waste Management Information and Guidelines	Administrator shall consult with Federal agencies, among others, to develop and publish guidelines for solid waste management.

§2001	Office of Solid Waste and Interagency Coordinating Committee	Establishing an Interagency Coordinating Committee for RCRA between EPA, Department of Energy, Department of Commerce, and all other Federal agencies. Includes coordinating research and projects.
§2002(a)(2)-(6)	Authorities of Administrator	(2) consult with or exchange information with other Federal agencies undertaking research, development, demonstration projects, studies, or investigations relating to solid waste; … (5) utilize the information, facilities, personnel and other resources of Federal agencies, including the National Bureau of Standards 1 and the National Bureau of the Census, on a reimbursable basis, to perform research and analyses and conduct studies and investigations related to resource recovery and conservation and to otherwise carry out the Administrator's functions under this Act; and (6) to delegate to the Secretary of Transportation the performance of any inspection or enforcement function under this Act relating to the transportation of hazardous waste where such delegation would avoid unnecessary duplication of activity and would carry out the objectives of this Act and of the Hazardous Materials Transportation Act.
§4002(b)	Federal Guidelines for Plans	Not later than 18 months after enactment, Administrator shall consult with appropriate agencies to promulgate guidelines for the development and implementation of State plans. Such guidelines should be reviewed and revised at least every three years.
§8001(a)	Research, Demonstrations, Training, and Other Activities	The Administrator, alone or after consultation with the [Department of Energy], or [FERC], shall conduct, and encourage, cooperate with, and render financial and other assistance to appropriate public (whether Federal, State, interstate, or local) authorities, agencies, and institutions, private agencies and institutions, and individuals in the conduct of, and promote the coordination of, research, investigations, experiments, training, demonstrations, surveys, public education programs, and studies relating to— (1) any adverse health and welfare effects of the release into the environment of material present in solid waste, and methods to eliminate such effects....
§8001(b)(2)(D)	Research, Demonstrations, Training, and Other Activities	any activities undertaken under provisions of sections 8002 and 8003 as related to energy; as related to energy or synthetic fuels recovery from waste; or as related to energy conservation shall be accomplished through coordination and consultation with the [Department of Energy]