NRDC

August 15, 2018

Acting Administrator Andrew Wheeler
& Office of the Science Advisor
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460
Via Regulations.gov to docket EPA-HQ-OA-2018-0259

Tom Sinks
Office of the Science Advisor
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460
Via email to staff_osa@epa.gov

RE: Comments of Natural Resources Defense Council on "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18,768 (April 30, 2018), Docket ID No. EPA-HQ-OA-2018-0259

I. Introduction

Natural Resources Defense Council (NRDC) is a national, not-for-profit public-health and environmental advocacy organization whose purpose is to safeguard the Earth: its people, its plants and animals, and the natural systems on which all life depends. NRDC has hundreds of thousands of members, all of whom depend on the U.S. Environmental Protection Agency (EPA) to protect them from the harms of pollution. EPA's proposed rule, "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18,768 (Apr. 30, 2018) (the "Proposal") would harm these members by limiting the types of science that EPA could use to protect the environment and public health. As described in detail below, the Proposal is an attack on science and violates the law. EPA should withdraw it immediately.

The Proposal would bar EPA from considering science based on dose response data and models that could not be made "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773. EPA asserts that "[e]nhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions." 83 Fed. Reg. at 18,769. Notably, as described in detail below, neither the Proposal nor docket contains any factual, scientific, technical, logical, or legal support for the suggestion that science and data that are "publicly available in a manner sufficient for independent validation" are necessary elements for the "validity," "reliability," or "transparency" of scientific information. *Id.* EPA provides no basis for its assumption that science or studies for which data are publicly available yield more valid or reliable results than the best available, peer-reviewed, independent, credible science, for

which the underlying data are not publicly available. Similarly, the Proposal arbitrarily fails to address, much less explain, why prior EPA regulatory actions that relied upon studies, data, or other information did not reflect the "best available science" or why they were otherwise unreliable, despite failing to meet the Proposal's standards.

To the contrary, EPA, other federal agencies, EPA scientific advisory bodies, the National Academy of Science (NAS), and EPA's Science Advisory Board (SAB) have repeatedly and consistently relied upon the best available, peer-reviewed, independent, credible scientific studies—for which the underlying data are not publicly available—and found that science to be valid, reliable, trustworthy, and a reflection of the "best available science" that EPA claims as its concern in the Proposal. The Proposal arbitrarily excludes prior research, studies, and data that do not meet its applicability criteria based on concerns that were never announced to researchers or the public, or deemed necessary by any government agency, at the time the research, studies, or data-gathering were undertaken. The Proposal is strikingly at odds with those scientific practices and their history, with *nothing* in the rulemaking docket to support casting aspersions on the practices or history sufficient to prohibit EPA from considering such science.

EPA has unsurprisingly failed to cite a single statute that provides any basis for the Proposal. What statutes EPA does cite conflict with the Proposal, because they require EPA either to consider the best available science (which may be based on data that cannot be made public) or to regulate to protect public health and the environment (which cannot be done if critical science is ignored simply because the underlying data cannot be made public). Similarly, none of the other sources EPA cites provide legal or logical support for the Proposal.

The Proposal also suffers from a host of other problems: its definitions are vague; it is an unexplained reversal from prior agency policy; it handles confidential business information in a capricious manner; it treats other types of agency actions inconsistently; it applies retroactively to studies completed before the rule goes into effect; it fails to analyze the disproportionate effect of the rule on people of color, low-income people, and children; and it contains a cryptic peer review provision.

As explained throughout these comments, EPA's agenda, as reflected in the Proposal, is not greater public trust or understanding; rather, the Proposal's goal is censorship of science and studies whose underlying data are not publicly available and may not be made publicly available as a matter of law or other agreement. The Proposal should be withdrawn.

II. The Proposal is a flawed solution in search of a problem

The Proposal represents an unworkable, ill-explained, unjustified, and thoroughly unlawful approach to address a problem that does not exist. EPA does not explain why the data sharing requirements outlined in the Proposal are suddenly so urgent. This missing argument is especially significant given the decades of peer-reviewed data and models that EPA has justifiably relied on for regulatory actions. There is no "crisis in replicability" for the types of data and models that the Proposal purports to address; as an indication of this, EPA has not cited *any* sources for its assumptions presented in the Proposal.

ED_002389_00015391-00002

The governing, harmful conceit of the Proposal—to censor the best available, peer-reviewed health science that EPA may consider, in order to prevent adoption of protective health and environmental safeguards—is a thinly disguised version of anti-science legislation that Republican members of Congress have introduced, repeatedly, but have been unable to enact into federal law, repeatedly.[1] NRDC opposed those bills strongly, and still does. We raised many of the identical objections to those bills that we raise to the Proposal in these comments.[2] Indeed, it is striking that one of the primary EPA co-authors of the Proposal was a Committee staff person for the leading congressional co-sponsor of the legislation in question when the failed bill was being shepherded through the House of Representatives.[3]

Members of Congress understood that new legislation was required to censor EPA consideration of high quality, peer-reviewed science, and yet EPA barreled ahead with a Proposal based on the same legislative approach while pretending, suddenly, that multiple federal laws have authorized that approach, magically, all along. For the reasons discussed in these comments, the Proposal is not authorized by any federal laws. Moreover, the Proposal violates numerous federal laws entrusted to EPA, in addition to being arbitrary and capricious and an abuse of EPA's discretion.

A leading medical researcher notes that, if the Proposal is approved, "science will be practically eliminated from all decision-making processes" at the agency because so few studies meet (or could be expected to meet, on time scales appropriate for regulatory actions and associated public comment periods) the Proposal's requirements for data availability.[4] Instead of restricting the pool of available science by instituting an unworkable requirement for a broad category of scientific inquiry, EPA should focus on identifying particular weaknesses in the available evidence and targeting future investigations towards addressing specific deficiencies.

Moreover, assessing whether any particular study is reliable is not contingent on whether thy underlying data can be made public, a fundamental point made clear in a report that EPA itself cited in the Proposal.[5] The assessment of study credibility depends on a number of factors, including "how large and rigorous studies are, how well researchers have contained conflicts of interest (financial or other), and how successfully the study design and analysis have limited bias, properly accounting for the complexity inherent in each scientific question."[6]

---

[1] *See, e.g.*, H.R. 4012, "Secret Science Reform Act of 2014," 113th Congress, 2d Session, https://www.congress.gov/113/bills/hr4012/BILLS-113hr4012rfs.pdf.
[2] *See* Letter from John Walke, NRDC, to Honorable Lamar Smith, Chairman, Committee on Science, Space, and Technology, *et al.* (Feb. 11, 2014), *available at* https://www.nrdc.org/sites/default/files/air_14021101a.pdf.
[3] Scott Waldman, "Meet the man helping Pruitt reshape science," *Climatewire*, (May 23, 2018), https://www.eenews.net/stories/1060082467.
[4] Ioannidis, J. P., "All science should inform policy and regulation," *PLoS Medicine* 15(5) (May 3, 2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576. (Hereinafter "All Science")
[5] 83 Fed. Reg. at 18,769, n.6 (citing 67 Fed. Reg. 8452, 8453, Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (February 22, 2002), *available at* https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-andmaximizing-the-quality-objectivity-utility-andintegrity-of-information. (Hereinafter "OMB Guidance")).
[6] *See* All Science, *supra,* n. 4.

With respect to one area of dose response data and models considered by EPA, decades of quantitative, peer-reviewed investigation into the premature mortality risks caused by $PM_{2.5}$ have replicated study findings across different geographic settings and time periods. EPA's own 2009 Integrated Science Assessment (ISA) for $PM_{2.5}$ considered many scientific studies that do not meet the data transparency requirements of the proposed rule. The ISA concluded, based on a wealth of epidemiologic evidence, that a causal relationship exists between short-term $PM_{2.5}$ exposures and cardiovascular effects and mortality, and is likely to exist for respiratory effects. The ISA also found that the scientific evidence is sufficient to conclude that the relationship between long-term $PM_{2.5}$ exposure and respiratory effects is likely to be causal, and is causal for mortality. The Agency has not explained why the scientific evidence underlying these determinations is now insufficient for regulatory decision making. Its proposal to exclude scientific data based on questionable transparency requirements is arbitrary and in direct contradiction with prior Agency determinations.

As the ISA demonstrates, no Agency regulatory action is predicated on the results of any single scientific study; rather, the continual accumulation of quantitative evidence with respect to the dose-response relationships for particular environmental contaminants informs decision making. The causal criteria outlined in the ISA demonstrate the iterative process by which dose-response relationships are assessed over time as evidence is gathered and published in peer-reviewed journals. In assessing the reliability of scientific findings, "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."[7]

A. According to information cited in the Proposal, publicly available data is not needed to ensure reproducibility

Importantly, one of the documents that EPA relies upon in the Proposal in footnote 6 fatally undermines the Proposal's pretense that underlying data protected by confidentiality concerns must be made publicly available in order to be considered valid and reliable, and meet the "reproducibility standard." 83 Fed. Reg. at 18,769. A 2002 Office of Management and Budget report, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," (OMB Guidance)[8] notes that data need not be publicly available in order to meet the reproducibility standard:

> Even in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard. For example, a qualified party, operating under the same confidentiality protections as the original analysts, may be asked to use the same data, computer model or statistical methods to replicate the analytic results reported in the original study.[9]

---

[7] *Id.*
[8] *See supra,* n. 5, OMB Guidance.
[9] *Id.* (citing Krewski, D., Burnett, R. T., Goldberg, M. S., Hoover, K., Siemiatycki, J., Abrahamowicz, M., & White, W. H., Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air

ED_002389_00015391-00004

The OMB Guidance directly undermines the notion that the only way for research to meet the reproducibility standard is by making all underlying data available for public inspection. As the document further notes,

> [t]he primary benefit of public transparency is not necessarily that errors in analytic results will be detected, although error correction is clearly valuable. The more important benefit of transparency is that the public will be able to assess how much an agency's analytic result hinges on the specific analytic choices made by the agency. Concreteness about analytic choices allows, for example, the implications of alternative technical choices to be readily assessed. This type of sensitivity analysis is widely regarded as an essential feature of high quality analysis, yet sensitivity analysis cannot be undertaken by outside parties unless a high degree of transparency is achieved. The OMB guidelines do not compel such sensitivity analysis as a necessary dimension of quality, but the transparency achieved by reproducibility will allow the public to undertake sensitivity studies of interest.[10]

Lastly, the OMB Guidance indicates that publicly accessible data is an unworkable requirement in some situations due to sensitive data that cannot be legally or ethically released to the public: "We acknowledge that confidentiality concerns will sometimes preclude public access as an approach to reproducibility."[11]

The Proposal is arbitrary and capricious and an abuse of EPA discretion by creating a framework in which it is very clear its real concerns are not "actual verification" of studies and data or "best available science," but prohibiting EPA from considering and basing protective regulations on relevant, peer-reviewed science whose underlying data or elements *may not* be made publicly available, due to various legal obligations such as confidentiality agreements, laws, or regulations. The Proposal's real aims are not verification or "best available science"; instead, its aims are censoring science and obstructing evidence of the need for greater health and environmental safeguards.

B. Independent validation is already occurring

The Proposal does not require that any information *actually* be *independently validated* before EPA may consider it or base regulatory decisions on such verification. Accordingly, there is an irrational disconnect between EPA's insistence that information be "publicly available for independent validation" and the Proposal's claim that this ensures EPA will consider and use the "best available science." *See* 83 Fed. Reg. at 18,769. EPA itself has not outlined a process by which "dose response data and models" would be validated, and the Proposal does not seriously consider the methodological complications of partial redaction of underlying study data.

Pollution and Mortality,'' A Special Report of the Health Effects Institute's Particle Epidemiology Reanalysis Project, Cambridge, MA, Health Effects Institute (2000). (Hereinafter "Reanalysis of Harvard Six Cities Study")).

[10] *Id.* at 8456.

[11] *Id.*

ED_002389_00015391-00005

The Proposal claims that its data release requirements are vital for "independent validation," but the truth is that independent validation is happening now. As an example, consider the independent validation of the Harvard Six Cities study by the Health Effects Institute (HEI), which is characteristic of the types of complex epidemiologic investigations that could be subject to the unworkable provisions of this Proposal.[12] The Clean Air Act requires EPA to consider the best available evidence in setting and revising the National Ambient Air Quality Standards (NAAQS) to protect health within an adequate margin of safety. 42 U.S.C. § 7409(b)(1). Fine particulate matter, an air pollution category encompassing solid particles and condensed liquid droplets with a diameter of 2.5 microns or smaller ($PM_{2.5}$), is by far the most dangerous type of air pollution because it can penetrate deep into the lung and enter the bloodstream.[13] The 1993 Harvard Six Cities Study, a groundbreaking study into the link between air pollution exposures and health, examined the health effects of $PM_{2.5}$ air pollution over 16 years on more than 8,000 adults and 14,000 children relying on private medical records and air pollution monitors deployed near study volunteers.[14] The study found a significant relationship between air pollution exposure and risk of early death, but the raw data could not be released publicly because researchers were obligated to ensure study participant confidentiality.

Still, relying on that data, more than 100 peer-reviewed studies have confirmed the basic results of that initial study. Because the study and others like it advanced through the rigorous peer-review process characteristic of the world's leading scientific journals (whose editors have rejected the proposed rule[15]), EPA relied on the results of this study and others in 1997 when it promulgated the first-ever NAAQS for fine particulate matter.[16] Since then, hundreds of additional studies into the health effects of air pollution (conducted across the country[17] and internationally,[18] for both short-[19] and long-term[20] impacts of exposure) and independent re-analyses of existing datasets have affirmed the air pollution-mortality and morbidity links with increasing precision. In 2000, the Health Effects Institute published

---

[12] *See supra,* n. 9.

[13] World Health Organization. *Air Quality Guidelines: Global Update 2005. Particulate Matter, Ozone, Nitrogen Dioxide and Sulfur Dioxide.* World Health Organization (2006).

[14] Dockery, D. W., Pope, C. A., Xu, X., Spengler, J. D., Ware, J. H., Fay, M. E., ... & Speizer, F. E. (1993). An association between air pollution and mortality in six US cities. *New England journal of medicine*, *329*(24), 1753–59 (Hereinafter "Harvard Six Cities Study").

[15] Jeremey Berg, et al., Letter, "Joint statement on EPA proposed rule and public availability of data," *Science,* Vol. 360, Issue 6388, 4 May 2018, *available at* http://science.sciencemag.org/content/360/6388/eaau0116.

[16] 62 Fed. Reg 38,652 *et seq.*, "National Ambient Air Quality Standards for Particulate Matter": Final Rule (July 18, 1997), *available at* https://www.epa.gov/pm-pollution/table-historical-particulate-matter-pm-national-ambient-air-quality-standards-naaqs.

[17] Hoek, G., Krishnan, R. M., Beelen, R., Peters, A., Ostro, B., Brunekreef, B., & Kaufman, J. D. (2013). Long-term air pollution exposure and cardio-respiratory mortality: a review. Environmental Health, 12(1), 43.

[18] Katsouyanni, K., Samet, J. M., Anderson, H. R., Atkinson, R., Le, A. T., Medina, S., ... & Ramsay, T. (2009). Air pollution and health: a European and North American approach (APHENA). Research report (Health Effects Institute), (142), 5–90.

[19] Brook, R. D., Brook, J. R., Urch, B., Vincent, R., Rajagopalan, S., & Silverman, F. (2002). Inhalation of fine particulate air pollution and ozone causes acute arterial vasoconstriction in healthy adults. Circulation, 105(13), 1534–36.

[20] Pope, C. A., Burnett, R. T., Thurston, G. D., Thun, M. J., Calle, E. E., Krewski, D., & Godleski, J. J. (2004). Cardiovascular mortality and long-term exposure to particulate air pollution: epidemiological evidence of general pathophysiological pathways of disease. Circulation, 109(1), 71–77.

ED_002389_00015391-00006

its independent re-analysis[21] of the Harvard Six Cities study, which confirmed the original findings. When HEI was tasked with re-analyzing the study data in February 1997, it required a major investment of time and analytical resources on a scale far beyond that envisioned by the Proposal. In fact, the HEI re-analysis, which validated the original study findings, took three years to complete.[22] The fact that the original Six Cities study stood up strongly to the scrutiny of independent researchers and sensitivity analyses speaks to the methodological rigor that the peer-review system demands. Indeed, the field of air pollution epidemiology in particular already has a high reproducibility standard.[23]

Clearly, the Proposal arbitrarily ignores the significant amounts of time, effort and expense associated with "independent verification" of studies and data, especially given the wide scope of peer-reviewed science that would be subject to data sharing requirements. 83 Fed. Reg. at 18,774.[24] Given how long it took a team of researchers to independently re-analyze a single study, and the relatively short public comment periods associated with EPA regulatory actions,[25] the Proposal is doubly arbitrary: it ignores the significant amounts of time, effort and expense associated with "independent verification" of studies and data. Moreover, it is possible (even likely) that studies or data submitted by the public during comment periods would need to be independently assessed before consideration by EPA. Against the backdrop of EPA rulemakings with public comment periods and open rulemaking time periods and the voluminous amounts of data that would need to be de-identified, shared, and re-analyzed, it would be impossible to achieve independent verification of relevant dose-response information.

EPA has rightly continued to rely on the robust peer-reviewed literature to inform the air quality standard-setting process year after year, incorporating the best available scientific evidence in epidemiology, toxicology, and exposure assessment to set the outdoor air quality standards at levels that protect public health and the environment. It has also (until recently) agreed with leading scientists who have spent their careers studying air pollution and health that no safe threshold of fine particulate air pollution exists. The National Ambient Air Quality Standards and Clean Air Act's designations process have helped to clean up our nation's air in

---

[21] Reanalysis of Harvard Six Cities Study, *supra* n.9.

[22] Elaine Appleton Grant, "Prevailing Winds: A decades-long fight to bring clean air standards in line with environmental health science offers lessons for today," Harvard Public Health Magazine, Fall 2012 *available at* https://www.hsph.harvard.edu/news/magazine/f12-six-cities-environmental-health-air-pollution/. (Hereinafter "Prevailing Winds").

[23] *See* All Science, *supra,* n. 4.

[24] Regarding proposed § 30.7, the Proposal states that "EPA shall conduct independent peer review on *all* pivotal regulatory science used to justify regulatory decisions . . . ." (emphasis added). EPA, in its Proposal and accompanying administrative record, does not begin to grapple with the impossible, burdensome obligation the Proposal creates to conduct new and independent peer review of "all pivotal regulatory science," especially against the backdrop of the real-world experience with the three-year, costly, resource-intensive HEI re-analysis of just *one* study. *See supra,* Prevailing Winds, at n. 22.

[25] Environmental statutes and the Administrative Procedure Act sometimes allow public comment periods to be as short as 30 days. This period of time is wildly out of sync with the Proposal's conceits that making data or models underlying regulatory science publicly available will allow for independent validation. *See, e.g.*, 83 Fed. Reg. at 18,773 (proposed § 30.1). EPA has no response to this disconnect in the Proposal or the administrative record accompanying the Proposal.

ED_002389_00015391-00007

substantial ways since 1970, and have protected millions of Americans, young and old, from breathing polluted air that would harm their health.

When analyzing the HONEST Act, the previously introduced legislation aimed at achieving the same end as the Proposal, the Congressional Budget Office predicted that the yearly tab could top $100 million to upgrade the format and availability of those studies' data to the level required if EPA continues to rely on the same volume of scientific research as in the recent past.[26] In part, the money would go toward obtaining all of the underlying data for specific studies, formatting the information for public use, and providing access to the needed computer codes and models, the analysis said.

The Proposal also fundamentally ignores the real-world constraints, as well as moral barriers in some cases, to replicating studies due to the impossibility or offensiveness of reproducing conditions that underlay the studies. For example, researchers cannot replicate the poor air quality conditions experienced in the past and, correspondingly, the peer-reviewed investigations of the health effects cannot be reproduced. As one leading researcher notes, "researchers cannot ethically randomize people to harmful exposures in order to tackle confounding, nor violate informed consent agreements that prohibit open sharing of private data from past studies."[27]

Finally, the EPA chemical assessment program, called the Integration Risk Information System (IRIS) already uses credible transparent methods to provide the public with reliable, transparent, credible chemical hazard assessments and toxicity values. The program received high praise from its last two reviews by the National Academies of Sciences (NAS 2014 and NAS 2018), as well as from the Scientific Advisory Board (SAB 2017) for its continuous improvements and successes in its methods for evaluating and integrating scientific evidence from various streams including human studies, animal studies, and mechanistic studies. This Proposal would undermine decades of expert work to advance successful data evaluation methods described in the systematic review approach now underway in the EPA IRIS program.

C. Health Insurance Portability and Accountability Act

Many of the studies that EPA has relied on to set and revise the NAAQS are epidemiological prospective cohort investigations encompassing thousands of individuals over several decades. The Proposal's provisions concerning the public sharing of underlying data from these studies directly contradict both the legal protections for private medical data under the Health Insurance Portability and Accountability Act (HIPAA)[28] and the requirements researchers adhere to under the purview of Institutional Review Boards (IRBs),[29] which typically require

---

[26] Congressional Budget Office, Cost Estimate, Honest and Open New EPA Science Treatment Act of 2017, March 29, 2017 *available at* https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.
[27] *See* All Science, *supra,* n. 4.
[28] U.S. Department of Health & Human Services, "The HIPAA Privacy Rule"," *available at* https://www.hhs.gov/hipaa/for-professionals/privacy/index.html.
[29] National Institute of Environmental Health Science, "Institutional Review Board," *available at* https://www.niehs.nih.gov/about/boards/irb/index.cfm.

ED_002389_00015391-00008

investigators to ensure study participant confidentiality and data security. The foundational research in air pollution epidemiology demonstrating a causal link between pollution exposures and adverse health outcomes (including early death,[30] heart disease,[31] lung cancer,[32] stroke,[33] and asthma exacerbations[34]) would be put at risk if the Proposal were finalized. Underlying sensitive health data cannot be released without obtaining individual patient consent, or consent from the next responsible party[35] for study participants who have died.

Importantly, the Proposal does not consider the negative effects it would have on recruitment for future epidemiological studies if members of the public had to permit access to sensitive personal and health information as a condition for study participation. Many of the peer-reviewed studies EPA uses to set and revise National Ambient Air Quality Standards through the Clean Air Act analyze the relationship between exposure to polluted air over many years and a range of adverse health effects. These comprehensive studies have enrolled thousands of American volunteers over periods ranging from several years to decades, in order to understand exactly how pollution harms us. The Proposal would have a chilling effect on the study recruitment process because of the onerous data release requirements. EPA's actual creation of these harmful consequences, and failure to consider and account for these harmful consequences, render the Proposal arbitrary and capricious and an abuse of agency discretion.

The Proposal would stand in stark contrast to the protective, guiding principles of the Health Insurance Portability and Accountability Act,[36] known as HIPAA. HIPAA was enacted nationally in 1996 as Public Law 104-191 and has served as a foundation for the protection of individual patients' privacy in research and in healthcare settings, setting boundaries on the appropriate use and release of health records.

According to the Department of Health and Human Services, HIPAA "establishes appropriate safeguards that health care providers and others must achieve to protect the privacy of health information; . . . holds violators accountable, with civil and criminal penalties that can be imposed if they violate patients' privacy rights; and it strikes a balance when public

---

[30] Pope III, C. A., R. T. Burnett, M. J. Thun, E. E. Calle, D. Krewski, K. Ito, and G. D. Thurston. 2002. "Lung Cancer, Cardiopulmonary Mortality, and Long-Term Exposure to Fine Particulate Air Pollution." JAMA: The Journal of the American Medical Association 287 (9): 1132–1141.

[31] Pope, C. A., Muhlestein, J. B., May, H. T., Renlund, D. G., Anderson, J. L., & Horne, B. D. (2006). Ischemic heart disease events triggered by short-term exposure to fine particulate air pollution. *Circulation*, 114(23), 2443–48.

[32] Turner, M. C., Krewski, D., Pope III, C. A., Chen, Y., Gapstur, S. M., & Thun, M. J. (2011). Long-term ambient fine particulate matter air pollution and lung cancer in a large cohort of never-smokers. *American journal of respiratory and critical care medicine*, 184(12), 1374–81.

[33] Hong, Y. C., Lee, J. T., Kim, H., & Kwon, H. J. (2002). Air pollution: a new risk factor in ischemic stroke mortality. *Stroke*, *33*(9), 2165–69.

[34] Ostro, B., Lipsett, M., Mann, J., Braxton-Owens, H., & White, M. (2001). Air pollution and exacerbation of asthma in African-American children in Los Angeles. *Epidemiology*, 12(2), 200–08.

[35] U.S. Department of Health & Human Services, "Personal Representatives," *available at* https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/personal-representatives/index.html.

[36] U.S. Department of Health & Human Services (HHS). 2013. "Health Information Privacy: What Does the HIPAA Rule Do?," December 19, 2002; *available at* https://www.hhs.gov/hipaa/for-individuals/faq/187/what-does-the-hipaa-privacy-rule-do/index.html.

ED_002389_00015391-00009

responsibility supports disclosure of some forms of data – for example, to protect public health."[37]

With the shift away from paper to electronic medical records in recent decades, "the potential for individuals to access, use, and disclose sensitive personal health data" has increased.[38] While protecting individual patient privacy is a long-standing tradition among health-care and public health practitioners, previous legal protections were afforded by a patchwork of inconsistent and often inadequate laws and regulations. In 2003, pursuant to HIPAA, rules were enacted to expressly protect the privacy of certain individually identifiable health data, or "protected health information" (PHI). The HIPAA Privacy Rule (Standards for Privacy of Individually Identifiable Health Information) offered the first national standards for protecting the privacy of health information.[39]

For researchers at American universities and teaching hospitals, HIPPA and the Privacy Rule are part of life, especially in the health sciences. Any proposed research project must submit a complete description of its planned use, protection, and storage of PHI before the university's Institutional Review Boards (IRB), before any research project may proceed. Each researcher needs to annually renew their familiarity and expertise with the terms of HIPAA and the Privacy Rule, by taking a test to certify compliance. It is eminently obvious to those involved in research that protecting study subjects' personal data is of the utmost importance, from an ethical and a legal viewpoint.

The Proposal, on the other hand, would disallow use of an enormous body of carefully-protected, de-identified health data from epidemiological studies large and small, for which IRBs have approved collection because patient privacy has been protected. The rule would effectively demand that study subjects' private health information be made publicly available, or else not be usable in regulatory efforts. This measure would hamstring the research community's ability to continue to produce foundational, health-protective research. Not only would the rule destroy society's collective ability to benefit from studies of the causes of and potential cures for ill health, it also would veer dangerously toward compromised privacy during an era in which electronic data security is a nationwide crisis. In short, the Proposal flies in the face of decades of statutory, regulatory and institutional progress to simultaneously protect public health and privacy.

D. Anonymization or partial redaction of data is unworkable

Proponents of the Proposal have suggested that privacy concerns surrounding the sharing of health data can be mitigated by anonymizing the individual-level health data that researchers collect. This overlooks the serious problem that anonymizing data (through techniques such as data masking, coding, and de-identification techniques) might not adequately protect confidentiality or privacy. Various studies have documented that de-identification techniques to

---

[37] *Id.*
[38] Thacker SB. "HIPAA Privacy Rule and Public Health: Guidance from CDC and U.S. Department of Health and Human Services." *MMWR* 52:1–12 (April 11, 2003).
[39] *Id.*

ED_002389_00015391-00010

render data anonymous is not "simple," despite what the Proposal suggests, and can lead to the publication of protected confidential or private data. One study explained that "[b]y linking demographics to public records such as voter lists, and mining for names hidden in attached documents, we correctly identified 84 to 97 percent of the profiles for which we provided names."[40] Another explained "87% (216 million of 248 million) of the population in the United States had reported characteristics that likely made them unique based only on [5-digit ZIP, gender, date of birth]."[41] Finally, another explains that "any data that is even minutely useful can never be perfectly anonymous."[42] The Proposal does not acknowledge these issues.

The claim that publicly available dose response data and models would allow for independent validation stands in direct contradiction to the legal privacy protections that apply to key data necessary for re-analysis. The proposed partial redaction of sensitive information poses a cascading set of problems, because the statistical models characteristic of epidemiologic investigations rely on the inclusion of potentially confounding variables (*e.g.*, age, sex, home address, health status, diet and alcohol consumption, smoking history) in order to properly isolate the pollution-health relationship with precision.[43] To understand the dose-response connection, these studies analyze detailed health, demographic, spatial, and behavioral information from thousands of people. This information is extremely sensitive and collected at the individual level. As such, our nation's health privacy laws and Institutional Review Board (IRB) protocols require researchers to keep the data secure and confidential to prevent misuse. Collectively, these data points help researchers understand and isolate the cause-effect relationship between exposure to air pollution and risks for various health problems. It would be extremely difficult if not impossible for anyone using partially-redacted data sets derived from epidemiologic cohort studies to "validate" the results of the original studies, because such investigators would not be working with complete data sets.

As further demonstration, the 2009 Integrated Science Assessment for $PM_{2.5}$ notes that "[a]ppropriate statistical adjustment for confounders requires identifying and measuring all reasonably expected confounders."[44] Therefore, exclusion of some potentially sensitive confounding variables from an underlying dataset likely would lead a different team of investigators to a different result. Causing this wrongheaded and indefensible outcome results from the core approach and conceit in the Proposal, revealing it to be yet again, arbitrary and capricious and an abuse of EPA discretion. Put another way, the quantitative findings of dose-response relationships would almost certainly differ—not as a result of any true difference in the quantitative exposure-effect relationship, but because the original work relied on complete data

---

[40] Sweeney, L., Abu, A., & Winn, J. Identifying Participants in the Personal Genome Project by Name, Harvard University, Data Privacy Lab White Paper at 1, Cambridge 2013, *available at* https://dataprivacylab.org/projects/pgp/1021-1.pdf.

[41] Sweeney, L., Simple Demographics Often Identify People Uniquely, Carnegie Mellon University, Data Privacy Working Paper 3 at 2. Pittsburgh 2000, *available at* https://dataprivacylab.org/projects/identifiability/paper1.pdf.

[42] Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. Rev. 1701, 1755 (2010).

[43] For example, see confounding variable adjustment in Pope III, C. A., Burnett, R. T., Thun, M. J., Calle, E. E., Krewski, D., Ito, K., & Thurston, G. D. (2002). Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution. *Jama*, *287*(9), 1132–41.

[44] U.S. EPA, Integrated Science Assessment (ISA) for Particulate Matter (Final Report, Dec 2009), 1–16, Washington, DC, EPA/600/R-08/139F, 2009.

ED_002389_00015391-00011

sets and the new analyses would not—due to the Proposal. The resulting discrepancies in quantitative findings could serve as motivation to call the original study results into question due to faulty and incomplete re-analyses.

In any case, such an undertaking would be immensely costly, complicated, and slow—and deliver no net benefit to EPA or the American public. The cost projections are staggering: when EPA staffers in 2017 considered the potential effects of the failed HONEST Act[45] that mirrors the approach of the Proposal, they calculated[46] that efforts to anonymize health data and confidential business information could top $250 million annually[47] (and potentially up to $1 million **per study**) for the already strained agency workforce—huge amounts of taxpayer money and staff time that would be much better spent on implementing our nation's environmental laws.

Despite this significant cost estimate, EPA does not confront the financial dimensions or the need for financial incentives to support the unprecedented data release requirements in the rule.[48] It also does not consider the fact that scientists do not typically receive funding to make the data underlying peer-reviewed studies available for public inspection. The Proposal would likely "significantly reduce" the evidence base that the EPA considers for air quality/health analyses (according to a Congressional Budget Office evaluation of the HONEST Act[49]), a dramatic reduction that excludes the best available scientific studies that the agency has relied on for more than 20 years to set and revise the NAAQS.

Under the Proposal, EPA would not be able to rely on the best available science for its Integrated Science Assessments of air pollution that inform the NAAQS-setting process. Meanwhile, industry-funded research calling into question the air pollution-health link would not be subject to similar data release requirements, or even peer-review and independent reevaluation. This approach is asymmetric and favors selective, opaque, and questionable research methods over the consensus of robust peer-reviewed scientific investigation. Transparency in scientific data is an important topic, but one that needs to be balanced against the privacy concerns of study participants and legal and ethical restrictions on the sharing of sensitive data.

EPA identifies no indication under federal laws that Congress intended to create or authorize a lose-lose dynamic, in which EPA could exercise its authority either by excluding the best available, peer-reviewed science to inform health and environmental protections, *or* force researchers or ordinary Americans to cast aside privacy concerns, as well as legal and ethical

---

[45] H.R. 1430, "Honest and Open New EPA Science Treatment Act of 2017," 115th Congress, *available at* https://www.congress.gov/bill/115th-congress/house-bill/1430.
[46] EPA Internal Analysis of HONEST Act (2017), *available at* https://www.scribd.com/document/344731162/EPA-analysis-of-Honest-Act-to-CBO.
[47] *Id.*; *see also* Union of Concerned Scientists, Administrator Pruitt Ignores EPA Staff Analysis of HONEST Act Costs, *available at* https://www.ucsusa.org/center-science-and-democracy/attacks-on-science/administrator-pruitt-ignores-epa-staff-analysis#.W3I-_dJKjIW.
[48] *See* All Science, *supra,* n. 4.
[49] Congressional Budget Office, Cost Estimate, Honest and Open New EPA Science Treatment Act of 2017, March 29, 2017 *available at* https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.

ED_002389_00015391-00012

restrictions on the sharing of sensitive data. That false choice is entirely a creation of the agency's misguided policy preferences in the Proposal. The rule is arbitrary and capricious and an abuse of EPA discretion, with its selective application of data release requirements and disregard for the quantitative complexities of epidemiologic research.

E. EPA misrepresents data sharing policies at scientific journals

The Proposal identifies data sharing policies at a number of peer-reviewed scientific journals and claims that these policies support the Proposal's underlying public access requirements for dose response data and models. This is false. In fact, these various journal policies are more flexible in their terms for data sharing and nuanced in their practical approaches than what EPA fundamentally misrepresents in the Proposal. *See, e.g.*, 83 Fed. Reg. at 18,771/1, nn.20–22. An examination of these sources indicates, in fact, that the language of the Proposal is not consistent with best practices and is unworkable in practice.

The Proposal is not, as it claims, "consistent with requirements for many scientific journals." 83 Fed. Reg. at 18,771. Specifically, the Taylor and Frances journal policy for data transparency[50] is much more nuanced than EPA claims and offers a range of options for data submission, demonstrating the need for flexibility and discipline-specific concerns with respect to the public sharing of sensitive data. The Springer Nature Research Data Policy[51] cited in the proposed rule is similarly flexible, describing requirements across a spectrum for four types of underlying research data. For only one of four types of research data is data sharing required as a condition for publication. The frequently asked questions document for the Springer Nature Data Policy[52] notes that "[t]he policies apply to all research that support publications but *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*."[53] The Proposal's categorical exclusion and prohibition are thus flatly inconsistent with the Springer Nature Research Data policy cited in the Proposal. *See* 83 Fed. Reg. at 18,771/1, n.20.

Furthermore, Elsevier's corresponding policy[54] is optional for authors, and states that the journal: "will . . . [e]ncourage and support researchers to share research data *where appropriate* and at the earliest opportunity, for example by enhancing our submission processes to make this easier."[55] A frequently asked questions page further explaining this policy says that the "policy is clear in that *we encourage and support authors to share their research data rather than mandating them to do so* and provide tools and services to enable them to do this effectively.

---

[50] Taylor & Frances Group, "Author Services: Data Sharing Policies," *available at* http://authorservices.taylorandfrancis.com/wp-content/uploads/2018/01/Data-sharing-policies.pdf.
[51] Springer Nature, "Research Data: Research Data Policy Types," *available at* https://www.springernature.com/gp/authors/research-data-policy/data-policy-types/12327096.
[52] Springer Nature, "Research Data: Research Data Policies FAQ," *available at* https://www.springernature.com/gp/authors/research-data-policy/faqs/12327154 (and see Question 5: "5. Do the policies apply to sensitive or personal data and data subject to third party restrictions?").
[53] *Id.* (emphasis added).
[54] Elsevier, "Research Data," *available at* https://www.elsevier.com/about/our-business/policies/research-data.
[55] *Id.* (emphasis added); *see also* Elsevier, "Research Data FAQs," *available at* https://www.elsevier.com/about/policies/research-data/research-data-faqs.

ED_002389_00015391-00013

Where there is community support for (often discipline-specific) mandates regarding data deposit, submission and sharing, some of our journals may reflect this with their own mandatory data sharing policies."[56] This same supporting frequently asked questions resource from Elsevier says that Elsevier "respect[s] authors who need to keep research data under embargo."[57] The Proposal, by contrast, does not allow researchers to keep their research data under embargo. Nor does the Proposal offer such discipline-specific flexibility and, as a result, is neither practically workable nor consistent with the policies of the world's leading scientific journals.

The Elsevier policy does not apply strict data release requirements to include publicly accessible information. It says that "[r]esearch data should be made available free of charge to all researchers *wherever possible* and with minimal reuse restrictions."[58] It further states that "[r]esearchers should remain in control of how and when their research data is accessed and used, and should be recognised and valued for the investments they make in creating their research data and making it available."[59] Under the Proposal, researchers retain no such control over their data; the Proposal ignores these harmful ramifications.

The PLOS Data Availability policy notes that, for studies involving human participants, "data must be handled so as to not compromise study participants' privacy."[60] The PLOS Policy itself links to the National Institutes of Health Data Sharing Workbook, which states that:

> It is rarely sufficient to simply remove names, addresses, telephone numbers, Social Security Numbers, and the like. Deductive disclosure of individual subjects becomes more likely when there are unusual characteristics or the joint occurrence of several unusual variables. Samples drawn from small geographic areas, rare populations, and linked datasets can present particular challenges to the protection of subjects' identities.[61]

Similarly, the NIH Data Sharing Workbook specifies that "[s]ome investigators withhold parts of the sample; others block access to specific variables, especially items with low prevalence rates that make it easier to identify participants with unusual characteristics."[62] Within this policy, the "measures used to minimize the risk of breaching the confidentiality of data" are unworkable given the depth and breadth of peer-reviewed research that would fall under the rule.[63] The Proposal identifies no plan for EPA to manage mandatory agreements to maintain confidentiality, data encryption, electronic firewalls and locked storage facilities, password authentication of users, audit trails, disaster prevention and recovery plans, or security measures for backup tapes.

---

[56] *Id.* (*See* "Is it compulsory to share my research data?") (emphasis added).
[57] *Id.* (*See* "Do I have to my share research data straight away?").
[58] *See supra,* n. 54, Elsevier, "Research Data," (emphasis added).
[59] *Id.*
[60] PLOS One, "Data Availability," *available at* http://journals.plos.org/plosone/s/data-availability.
[61] National Institutes of Health, "Data Sharing Workbook," Feb. 13, 2004, *available at* https://grants.nih.gov/grants/policy/data_sharing/data_sharing_workbook.pdf.
[62] *Id.*
[63] *Id.*

ED_002389_00015391-00014

To the extent data availability, even broadly defined, is contemplated in the Proposal, it is done so prospectively, not retroactively. Unlike the Proposal, the PLOS policy does not apply retroactively to all relevant studies: "[t]he data policy was implemented on March 3, 2014. Any paper submitted before that date will not have a data availability statement. However, for all manuscripts submitted or published before this date, data must be available upon reasonable request."[64] Similarly, the Springer Nature polices began during the first quarter of 2016 but did not apply retroactively, as the Proposal would.[65]

The NIH policy cited in footnote 21 of the Proposal also states that "[t]he investigator must be a tenure-track professor, senior scientist, or equivalent, to be able to submit" a data access request.[66] This fatally undermines the notion in the Proposal that data must be available to all members of the public in order to meet the reproducibility threshold. Furthermore, the Census Bureau resource,[67] also cited in footnote 21 of the Proposal, describes the Federal Research Data Centers. These centers restrict access to certain individuals, who "must obtain Census Bureau Special Sworn Status – passing a moderate risk background check and swearing to protect respondent confidentiality for life, facing significant financial and legal penalties under Title 13 and Title 26 for failure to do so."[68] Again, this fatally undermines the notion in the Proposal that data must be available to all members of the public. While the Proposal simply says that members of the "public" can access these centers, the reality is that access to such controlled spaces is carefully restricted and *not* accessible to all members of the public. EPA does not seriously confront the significant challenges involved in enabling access.

Finally, there is no evidence in the record that the Federal Statistical Research Data Centers have the capacity to handle the substantial amounts of data that would be required to be submitted under the Proposal. But the massive increase in data-handling responsibilities propelled by the Proposal indicates strongly that EPA must first investigate and document what those resource capacities are, and whether the Centers believe they can handle increased responsibilities. If EPA fails to undertake such investigations and fails to demonstrate adequate resources and data-handling capacities, finalizing any rule based on the Proposal would be arbitrary and capricious and an abuse of EPA discretion.

The report cited in footnote 22 of the Proposal[69] suggests that strategies for data transparency "should be cost-effective," yet no consideration of the cost repercussions of the Proposal is given in the Proposal or accompanying administrative record. This is extraordinary,

---

[64] *See supra,* n. 60.
[65] *See supra,* n. 52, Question 7: "Is data sharing mandatory for every article?"
[66] National Institutes of Health, Office of Science Policy, "Requesting Access to Controlled-Access Data Maintained in NIH-Designated Data Repositories," *available at* https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/.
[67] United States Census Bureau, "Federal Statistical Research Data Centers," *available at* https://www.census.gov/fsrdc.
[68] United States Census Bureau, "Federal Statistical Research Data Centers; Secure Data Environment," *available at* https://www.census.gov/about/adrm/fsrdc/about/secure_rdc.html.
[69] Randall Lutter and David Zorn, "On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making," Mercatus Working Paper, Mercatus Center, George Mason University, September 2016, *available at* https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.

ED_002389_00015391-00015

and independent evidence that the Proposal and supporting materials are arbitrary and capricious and an abuse of EPA discretion. As just one example of the costs associated with data transparency requirements of this nature, the report cited by EPA itself quantified cost of compliance at $46 million.[70] This amount represents more than two-thirds of the *entire* annual budget of the EPA office responsible for writing all clean air safeguards and standards under the Clean Air Act, the Office of Air Quality Planning and Standards.[71] This amount equals over 90% of the budgeted amount for *every* EPA employee working in OAQPS.[72] Neither the Proposal nor the accompanying administrative record remotely addresses, much less explains, how these data transparency compliance costs will be met. Moreover, the options for data sharing listed within footnote 22 are more expansive than those listed in the Proposal. They 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.

F. The Proposal will not enhance public understanding

The Proposal claims that it "will help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand." 83 Fed. Reg. at 18,769/1. This is false and unsupported in multiple respects. As these comments explain, the Proposal would prohibit EPA from considering information that will be the best available, peer-reviewed, independent, credible science—on the arbitrary and irrelevant grounds that underlying data are not publicly available. In this fashion, as these comments discuss, the Proposal would obstruct and thwart EPA from its mission and responsibility to protect public health and the environment.

Moreover, the Proposal would do so in a manner that the public cannot and would not trust and understand: the Proposal utterly fails to demonstrate or even support the claim that its approach ensures the information relied upon by EPA would be more trustworthy. EPA establishes no logical nexus or evidence-based link between the Proposal and its insinuations that studies or information lacking publicly available data are unreliable, invalid, irrelevant or untrustworthy. Additionally, the Proposal utterly fails to demonstrate or even support the claim that its approach ensures the information relied upon by EPA would be more understandable to the public.

First, EPA fails to establish or even support the premise of its wrongheaded belief: that the best available, peer-reviewed, independent, credible science is not understandable already to the public, or the informed, knowledgeable members of the public versed in the scientific, technical, legal, economic or policy matters relevant to EPA's regulations, actions and mission.

---

[70] *Id.* at 25.
[71] U.S. EPA, Fiscal Year 2019: Justification of Appropriation Estimates for the Committee on Appropriations, 837, *available at* https://www.epa.gov/sites/production/files/2018-02/documents/fy-2019-congressional-justification-all-tabs.pdf.
[72] *Id.*

ED_002389_00015391-00016

Second, the Proposal's claim about enhanced public understanding suffers from a fundamental internal contradiction and logical failing inherent to its approach: nothing in the Proposal requires that (1) publicly available data be actually considered, addressed, verified or replicated by EPA prior to the agency being allowed to consider the study based on that data; (2) publicly available data be actually considered, addressed, verified or replicated by any other person or party prior to EPA being allowed to consider the study based on that data; and (3) publicly available data be actually considered, addressed, verified or replicated by EPA, any person, or any party *ever*, before or after EPA is allowed to consider the study based on that data. Accordingly, it is false and unsupported to suggest that the Proposal ensures greater public "understanding" than the longstanding regulatory landscape where the Proposal's prescriptions and proscriptions do not exist.

III. The Proposal would devastate EPA's ability to protect people from hazardous substances with well-known harmful effects

A. Lead in drinking water, soil, and paint

The damaging effects of early childhood lead exposure can last a lifetime, so prevention is the only effective and meaningful solution. Lead-contaminated soil, food, drinking water, and dust from leaded paint can all be inhaled or ingested by children, and from there be circulated through the bloodstream into all the organs, bones, and brain. Adverse effects include brain damage, kidney damage and disease, infertility in men and women, elevated blood pressure and strokes in adults, and neurological damage that can cause pain in the muscles and joints.[73] Exposures during pre-natal and early life development are especially devastating.

The lead regulations and reduction measures resulting from the implementation of science-based EPA regulations are essential for reducing lead poisoning effects in the U.S. population. Since 2001, life-saving EPA standards under the Toxic Substances Control Act (TSCA) have protected children and families from exposure to lead in paint, dust, and soil, in and around homes and childcare facilities.[74] This regulation supports existing regulations regarding worker training and certification, lead hazard disclosure in real estate transactions, requirements for lead cleanup under state authorities, and lead hazard evaluation and control in Federally-owned housing. In addition, it establishes authority under TSCA to set residential lead dust cleanup levels.

The EPA Lead and Copper Rule (LCR) of 1991 established drinking water protections by requiring tap water monitoring and triggering a public alert and some protective action such as corrosion prevention measures or service line replacement if lead levels exceed 15 ppb. 40 C.F.R. Part 141 Subpart I. Revisions to the LCR in the 2007 rule update requirements for monitoring, treatment, and customer notification.[75] The LCR rule applies to water utilities, and

---

[73] U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Toxicological profile for lead, August 2007, *available at* https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf.
[74] *Lead; Identification of Dangerous Levels of Lead*, 66 Fed. Reg. 1206 (Jan. 5, 2001).
[75] U.S. EPA, Economic and Supporting Analyses: Short-Term Regulatory Changes to the Lead and Copper Rule, Office of Water, 2007, EPA-815-R0-7022.

ED_002389_00015391-00017

the companion Reduction of Lead in Drinking Water Act sets standards for pipes, solder, and other plumbing fittings.

The lead rules are based on risk analyses conducted by EPA using epidemiology studies published in the 1990s that correlate childhood blood lead levels with impaired brain function and adverse behavioral effects.[76] Many of the published studies are longitudinal cohort studies that include measurements of lead in blood from children decades ago, and then follow them out over time to observe lasting effects. Thanks to important EPA regulations and effective lead-reduction measures in gasoline and paint, overall blood lead levels have been reduced in many people. This makes it impossible to replicate the exposure conditions at the time the original children in the study cohort had their blood lead levels measured, such as the Port Pirie cohort study population living near a lead smelter in the 1980s.[77] Studies like these—longitudinal cohort studies, particularly those that capture exposures that may no longer occur—are not reproducible.

B. Vinyl chloride

Vinyl chloride (VC) is an industrial chemical that is manufactured as a monomer, and then polymerized into polyvinyl chloride (PVC) plastic, used in a wide variety of industrial and consumer plastic products including home siding, pipes, wire and cable coatings, packaging, furniture, household products, and automotive parts.[78] The VC monomer was first reported to cause cancer in 1969 based on animal laboratory studies.[79] This was followed almost immediately by evidence in VC workers of cancer. In addition, workplace epidemiology studies identified a link between VC exposure and a very rare degenerative bone disease called acroosteolysis that was cripplingly painful; it was not identified in the rodent studies.[80, 81]

Vinyl chloride is regulated in workplaces, and in drinking water, food, and air:[82]

- OSHA issued workplace regulations in 1974, forcing a reduction in the allowable level of the VC monomer by 500-times, from 500 ppm to 1 ppm averaged over an 8-hour workday.[83] Despite predictions of dire job losses, virtually all U.S. manufacturing

---

[76] Needleman HL, Gunnoe C, Leviton A, Reed R, Peresie H, Maher C, Barrett P. Deficits in psychologic and classroom performance of children with elevated dentine lead levels. N Engl J Med. 1979 Mar 29;300(13):689–95. Erratum in: N Engl J Med. 1994 Sep 1;331(9):616–7.
[77] Baghurst PA, Robertson EF, McMichael AJ, Vimpani GV, Wigg NR, Roberts RR. The Port Pirie Cohort Study: lead effects on pregnancy outcome and early childhood development. Neurotoxicology. 1987 Fall;8(3):395–401.
[78] U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, Toxicological profile for Vinyl Chloride, 2006, Atlanta, GA, *available at* https://www.atsdr.cdc.gov/ToxProfiles/tp20.pdf (Hereinafter "Vinyl Chloride").
[79] Viola PL, Bigotti A, Caputo A. Oncogenic response of rat skin, lungs, and bones to vinyl chloride. Cancer Res. 1971 May;31(5):516–22.
[80] Creech JL Jr, Johnson MN. Angiosarcoma of liver in the manufacture of polyvinyl chloride. J Occup Med. 1974 Mar;16(3):150–51.
[81] *Supra* n.78.
[82] *Id.*
[83] United States Department of Labor, Occupational Safety and Health Administration, Regulations for Vinyl Chloride, *available at*

ED_002389_00015391-00018

facilities met the new standard within a few years while reducing costs, largely through better containment of the unpolymerized monomer and improved exposure monitoring.[84]

- EPA regulates VC pollution under the Safe Drinking Water Act (MCL=0.02 mg/L based on increased risk of cancer), and under EPA's Ambient Water Quality Criteria (0.025 ug/L).[85, 86]

- FDA regulations limit vinyl chloride in food contact materials and packaging.[87]

The studies that support these EPA safeguards, and particularly the identification of diseases in workers like acroosteolysis that were not identified in rodent studies, are critical to protecting human health and preventing adverse environmental impacts. Thanks to effective health-protective regulatory actions by EPA, OSHA and other federal agencies the elevated exposure conditions suffered by industrial workers in the 1970s and earlier are no longer the industry norm. Thus, these studies cannot meet the standards of transparency and replicability set out in the Proposal.

C. Pyrethroids

Pyrethroids are a class of insecticides that includes deltamethrin and permethrin, used on food crops including vegetables, fruit, and corn.[88] Permethrin is also used as a spray in homes and public spaces like hotels, theaters, restaurants, and hospitals.[89] It is also used to impregnate clothing, shoes, bed nets, and camping gear advertised to repel mosquitoes and ticks.[90] Pyrethroid pesticides are classified by EPA as a "likely human carcinogen," and is linked in

---

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10021; 29 C.F.R. 1910.1017 *et seq.*

[84] Sass JB, Castleman B, Wallinga D. Vinyl Chloride: A Case Study of Data Suppression and Misrepresentation. *Environmental Health Perspectives*. 2005;113(7):809-812. doi:10.1289/ehp.7716.

[85] U.S. EPA, "National Primary Drinking Water Regulations," *available at* https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations.

[86] *Supra* n.78.

[87] *Id.*

[88] U.S. Geological Survey, Pesticide National Synthesis Project: Estimated Annual Agricultural Pesticide Use, Pesticide Use Maps – Permethrin, 2015, *available at* https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2015&map=PERMETHRIN&hilo=L&disp=Permethrin (Hereinafter "Pesticide Maps).

[89] U.S. EPA, Office of Pesticide Programs' Review of the Status of Six PBPK Models in Preparation for the FIFRA SAP for the October 24-27, 2017 Physiologically Based Pharmacokinetic Modeling to Address Pharmacokinetic Differences Between and Within Species, August 3, 2017 *available at* https://www.epa.gov/sites/production/files/2017-08/documents/epa_opp_review_of_status_of_pbpk_models.pdf (Hereinafter "Review of Six PBPK Models")

[90] Interlandi, Jeneen, Consumer Reports, "Can Permethrin Treated Clothing Help You Avoid Mosquito Bites? We tested L.L.Bean and ExOfficio insect-repellent clothing," (May 26, 2016) *available at* https://www.consumerreports.org/insect-repellents/permethrin-treated-clothing-mosquito-bites/.

ED_002389_00015391-00019

published studies to Parkinson's Disease and adverse behavioral problems in prenatally exposed children.[91, 92]

EPA convened a FIFRA Scientific Advisory Panel in October 2017 to assess its use of a Physiologically Based Pharmacokinetic Model (PBPK) used in its risk assessment for the pyrethroid pesticides. The PBPK model was sponsored and submitted to EPA by the Council for the Advancement of Pyrethroid Human Risk Assessment, L.L.C. (CAPHRA).[93] CAPHRA identifies its participating parties as chemical and agrochemical manufacturers.[94, 95] CAPHRA describes its intentions as follows: "The general area of CAPHRA's planned activity is to generate and submit to the [U.S. EPA] studies necessary to address EPA's concerns for the potential for age-dependent sensitivity to Pyrethroids."[96]

Despite the central role of the pyrethroid PBPK model in EPA's regulatory approval for pyrethroid pesticides, it appears that scientific peer reviewers on the FIFRA Scientific Advisory Panel were unable to obtain the raw data necessary to provide a robust peer review of the model. SAP Panelist Dr. Dale Hattis requested these data from EPA on September 6 and September 12 without receiving them, including "key data" for "evaluating the uncertainty in the modeling" and "data needed for assessment of the calibration of the PBPK models."[97]

At this point, the EPA Scientific Advisory Panel meeting is postponed indefinitely.[98] The stated reason is "due to the unavailability of experts," but the more likely reason is to bias the

---

[91] *See supra,* n.88, Pesticide Maps.
[92] Furlong MA, Barr DB, Wolff MS, Engel SM. Prenatal exposure to pyrethroid pesticides and childhood behavior and executive functioning. Neurotoxicology. 2017 Sep;62:231–38; Viel JF, Rouget F, Warembourg C, Monfort C, Limon G, Cordier S, Chevrier C. Behavioural disorders in 6-year-old children and pyrethroid insecticide exposure: the PELAGIE mother-child cohort. Occup Environ Med. 2017 Mar;74(4):275–81.
[93] *See supra,* n.89; U.S. EPA, Background materials on the Physiologically Based Pharmacokinetic (PBPK) models on deltamethrin and cis-permethrin to the Panel for the October 24-27, 2017 session of the FIFRA Scientific Advisory Panel (FIFRA SAP) reviewing PBPK modeling to address pharmacokinetic differences between and within species. July 25, 2017. EPA-HQ-OPP-2017-0180-0009; U.S. EPA, Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held on "Research to Evaluate the Potential for Juvenile Sensitivity to Pyrethroids." ID: EPA-HQ-OPP-2015-0130-0019.
[94] Including AMVAC Chemical Corporation, Commerce, CA; BASF Corporation, Durham, NC; Bayer Animal Science, Pittsburgh, PA; Bayer CropScience, Research Triangle Park, NC; Botanical Resources Australia, Sandy Bay, Tasmania, Australia; Cheminova Inc., Arlington, VA; DuPont Crop Protection, Newark, DE; FMC Corporation, Philadelphia, PA; LG Life Sciences, Ltd., Clifton, VA; McLaughlin Gormley King Company, Minneapolis, MN; Meghmani, c/o Chemical Consultants International, Inc., Stilwell, KS; S.C. Johnson & Son, Inc., Racine, WI; Sumitomo Chemical Co., Ltd., Tokyo, Japan; Syngenta Crop Protection, LLC, Greensboro, NC; Valent BioSciences Corporation, Libertyville, IL; and Wellmark International (Central Life Sciences), Schaumburg, IL.
[95] 76 Fed. Reg. 60,530, et seq, Notice Pursuant to the National Cooperative Research and Production Act of 1993; Council for the Advancement of Pyrethroid Human Risk Assessment, L.L.C. (Sept. 29, 2011) *available at* https://www.federalregister.gov/documents/2011/09/29/2011-24874/notice-pursuant-to-the-national-cooperative-research-and-production-act-of-1993-council-for-the.
[96] *Id.*
[97] *See* Attachment 27: Email from D. Hattis to EPA DFO M. King, Sept 6, 2017; Email from D. Hattis to EPA DFO M. King, Sept 12, 2017; Email from D. Hattis to SAP Chair J McManaman, Oct 3, 2017.
[98] U.S. EPA, Meeting Materials for the October 24-27, 2017 Scientific Advisory Panel. Physiologically-based Pharmacokinetic Modeling, *available at* https://www.epa.gov/sap/meeting-materials-october-24-27-2017-scientific-advisory-panel.

ED_002389_00015391-00020

panel with the addition of industry experts, as EPA has done recently with its Scientific Advisory Boards.[99] A model that underestimates exposures and health risks will lead to regulations that fail to protect Americans from harmful exposures to pyrethroid pesticides.

D. Organophosphates, including chlorpyrifos

Congress recognized that pesticides are designed to be poisonous, and thus requires them to be registered by EPA, under the Federal Insecticide, Fungicide, and Rodenticide Act. FIFRA requires that when used according to the label, a pesticide will not cause unreasonable adverse effects on the environment or human health, which is commonly referred to as FIFRA's safety standard. FIFRA was amended by the Food Quality Protection Act, which passed Congress unanimously in 1996. Under FQPA, the agency must prohibit any pesticide use for which the registrant has failed to demonstrate that there is a reasonable certainty of no harm to vulnerable populations including infants and children from cumulative and aggregate exposure (from the diet and all other sources).

Organophosphate pesticides like chlorpyrifos are widely used in agriculture, with over 5 million pounds of the insecticide applied annually across the U.S. to a variety of crops including apples, oranges, broccoli, and berries.[100] Symptoms of acute poisoning include nausea and vomiting, headaches, dizziness, seizures, paralysis, and, in extreme cases, even death.

Due to risks to children's health, in 2000 EPA banned household use of chlorpyrifos and most other organophosphate pesticides.[101] Residential uses prior to the ban were causing very high exposures to pregnant women and young children. Scientists have since learned that even much lower levels may be harmful to children.

However, scientists have since shown in longitudinal cohort epidemiologic studies, that even low levels of exposure—too low to poison a pregnant mother—can disrupt brain development in their prenatally exposed children, leading to developmental delays, lower IQ, learning disabilities, and ADHD-like behaviors.[102]

To protect these children, in October 2015, the Obama Administration EPA proposed to ban chlorpyrifos because agency scientists found contamination of drinking water. A year later, EPA found that chlorpyrifos residues on food, including fruits and vegetables, are unsafe for

---

[99] EPA unveils new industry-friendlier science advisory boards. Science magazine. By Sean Reilly, E&E News, Kevin Bogardus, E&E News, Nov. 3, 2017, *available at* http://www.sciencemag.org/news/2017/11/epa-unveils-new-industry-friendlier-science-advisory-boards.

[100] U.S. EPA, Ingredients Used in Pesticide Products: Chlorpyrifos, *available at* https://www.epa.gov/ingredients-used-pesticide-products/chlorpyrifos.

[101] *Id.*

[102] Rauh VA, Garfinkel R, Perera FP, Andrews HF, Hoepner L, Barr DB, Whitehead R, Tang D, Whyatt RW. Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children. Pediatrics. 2006 Dec;118(6):e1845–59. Epub 2006 Nov 20; Bouchard MF, Chevrier J, Harley KG, et al. Prenatal Exposure to Organophosphate Pesticides and IQ in 7-Year Old Children. Environ Health Perspect. 2011;1003185(April); Rauh VA, Garcia WE, Whyatt RM, Horton MK, Barr DB, Louis ED. Prenatal exposure to the organophosphate pesticide chlorpyrifos and childhood tremor. Neurotoxicology. 2015;51:80–86.

ED_002389_00015391-00021

pregnant women and children; residue levels were far above their target risk level—in some cases, by up to 140 times.[103]

These epidemiologic studies can no longer be reproduced because—thanks to FQPA and the ban on residential uses—pregnant women and young children are no longer poisoned by indoor use of organophosphate pesticides at such high levels. Banning the use of chlorpyrifos would reduce human risk, leading to a healthier future for our children.

E. Mercury

Mercury is a powerful neurotoxic agent capable of adversely affecting fetus and childhood development in low concentrations. EPA maintains a series of web pages describing the health effects of mercury.[104] EPA has also summarized the health and environmental effects of mercury in previous TSCA rulemakings.[105] Mercury is a highly neurotoxic contaminant that is most toxic when methylated. Biological processes in the watershed convert the mercury to methylmercury which accumulates in the food chain resulting in elevated levels in fish, other wildlife, and ultimately in humans.[106] Commonly consumed fish may have methylmercury levels 100,000 times that of the ambient water.[107] Mercury contamination of fish stocks is widespread in the United States.[108, 109] Studies of mercury levels in fish in rivers, lakes, and streams across the United States found mercury levels exceeding the level for human health concern for a significant portion of the sites sampled.[110]

Newly deposited mercury has been shown to be more bioavailable and more rapidly converted to methylmercury and represents a greater fraction of the methylmercury which is

---

[103] U.S. EPA, Memorandum: Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review, Nov. 3, 2016, Docket ID No. EPA-HQ-OPP-2015-0653-0454.
[104] U.S. EPA, Health Effects of Exposures to Mercury, *available at* https://www.epa.gov/mercury/health-effects-exposures-mercury.
[105] *See, e.g.*, 71 Fed. Reg. 39,035 *et seq.*, Mercury Switches in Motor Vehicles; Proposed Significant New Use Rule, at 39,040–41, (July 11, 2006).
[106] U.S. EPA, How People are Exposed to Mercury, *available at* https://www.epa.gov/mercury/how-people-are-exposed-mercury.
[107] 79 Fed. Reg. 63,258 *et seq.*, Effluent Limitations Guidelines and Standards for the Dental Category, at 63,277, (Oct. 22, 2014).
[108] U.S. Geological Survey, Recent Findings from the National Water-Quality Assessment (NAWQA) and Toxic Substances Hydrology Programs (as presented to the NAWQA National Liaison Committee, Aug. 21, 2009).
[109] U.S. EPA, 2017 EPA-FDA Advice about Eating Fish and Shellfish, *available at* https://www.epa.gov/fish-tech/2017-epa-fda-advice-about-eating-fish-and-shellfish.
[110] Scudder, B.C., Chasar, L.C., Wentz, D.A., Bauch, N.J., Brigham, M.E., Moran, P.W., and Krabbenhoft, D.P., 2009, Mercury in fish, bed sediment, and water from streams across the United States, 1998–2005: U.S. Geological Survey Scientific Investigations Report 2009–5109, *available at* https://pubs.usgs.gov/sir/2009/5109/pdf/sir20095109.pdf (Hereinafter "Mercury in streams"); Wathen, J. B., Lazorchak, J. M., Olsen, A. R., & Batt, A. (2015). A national statistical survey assessment of mercury concentrations in fillets of fish collected in the US EPA national rivers and streams assessment of the continental USA. *Chemosphere, 122*, 52–61., *abstract available at* http://www.sciencedirect.com/science/article/pii/S0045653514012636.

ED_002389_00015391-00022

incorporated into food chains and ultimately into fish.[111] Local sources have been implicated in elevated levels of mercury measured in ambient air,[112] precipitation,[113, 114] soils,[115] and methylmercury levels in biota, including fish.[116] Reductions in local mercury emissions levels have been tied to decreasing levels measured in the environment and biota.[117, 118, 119] Therefore, to achieve the National Academy of Sciences' public-health goal of reducing mercury concentrations in fish,[120] current mercury emissions should be ratcheted down, thereby decreasing the amount of mercury cycling through aquatic systems and reducing contamination of fish and people.

Some populations may face even greater risks: Asians, Pacific Islanders, and Native Americans are all more likely to have elevated blood mercury levels, as are women living in the Northeast and other coastal areas, or consuming a lot of fish.[121, 122] A 2011 study of 1,465 newborns in Minnesota's Lake Superior Basin found eight percent of the newborns had blood mercury levels above 5.8 μg/l.[123]

---

[111] Hintelmann H, Harris R, Heyes A, Hurley JP, Kelly CA, Krabbenhoft DP, Lindberg S, Rudd JW, Scott KJ, St Louis VL. Reactivity and mobility of new and old mercury deposition in a boreal forest ecosystem during the first year of the METAALICUS study. Mercury Experiment to Assess Atmospheric Loading In Canada and the US. *Environmental Science & Technology*, 2002 Dec 1;36(23):5034–40.

[112] Manolopoulos H, Snyder DC, Schauer JJ, Hill JS, Turner JR, Olson ML, Krabbenhoft DP, Sources of speciated atmospheric mercury at a residential neighborhood impacted by industrial sources, *Environmental Science & Technology*, 2007 Aug. 15;41(16):5626–33.

[113] Dvonch, J. T., Graney, J. R., Keeler, G. J., & Stevens, R. K. (1999). Use of elemental tracers to source apportion mercury in south Florida precipitation. *Environmental Science & Technology*, *33*(24), 4522–27.

[114] White, E. M., Keeler, G. J., & Landis, M. S. (2009). Spatial variability of mercury wet deposition in eastern Ohio: summertime meteorological case study analysis of local source influences. *Environmental Science & Technology*, *43*(13), 4946–53.

[115] Biester, H., Müller, G., & Schöler, H. F. (2002). Estimating distribution and retention of mercury in three different soils contaminated by emissions from chlor-alkali plants: part I. *Science of the Total Environment*, *284*(1), 177–89.

[116] Evers, D. C., Han, Y. J., Driscoll, C. T., Kamman, N. C., Goodale, M. W., Lambert, K. F., Holsen, T.M., Chen, C.Y., Clair, T.A., & Butler, T. (2007). Biological mercury hotspots in the northeastern United States and southeastern Canada. *Bioscience*, *57*(1), 29–43.

[117] Frederick, P. C., Hylton, B., Heath, J. A., & Spalding, M. G. (2004). A historical record of mercury contamination in southern Florida (USA) as inferred from avian feather tissue: Contribution R-09888 of the Journal Series, Florida Agricultural Experiment Station. *Environmental Toxicology and Chemistry*,*23*(6), 1474–78.

[118] Driscoll, C. T., Han, Y. J., Chen, C. Y., Evers, D. C., Lambert, K. F., Holsen, T. M., Kamman, N.C., & Munson, R. K. (2007). Mercury contamination in forest and freshwater ecosystems in the northeastern United States. *BioScience, 57*(1), 17–28, a*vailable at* https://surface.syr.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1003&context=cie.

[119] *See supra* n.110, Mercury in Streams.

[120] National Research Council. 2000. Toxicological Effects of Methylmercury. Washington, DC: The National Academies Press, *available at* https://doi.org/10.17226/9899.

[121] Hightower, J. M., O'Hare, A., & Hernandez, G. T. (2006). Blood mercury reporting in NHANES: identifying Asian, Pacific Islander, Native American, and multiracial groups. *Environmental Health Perspectives*, *114*(2),173–75.

[122] Mahaffey KR, Clickner RP, Jeffries RA. Adult women's blood mercury concentrations vary regionally in the United States: association with patterns of fish consumption (NHANES 1999-2004). Environ Health Perspect. 2009 Jan;117(1):47–53. doi: 10.1289/ehp.11674.

[123] Patricia McCann, Minnesota Department of Health, Mercury Levels in Blood from Newborns in the Lake Superior Basin, GLNPO ID 2007-942, Final Report, November 30, 2011.

ED_002389_00015391-00023

Researchers have estimated that in the United States methylmercury toxicity is associated with between 376 and 14,293 excess cases per year of a level of cognitive impairment that would be considered mental retardation. The cost of caring for these children has been estimated between $500 million and $17.9 billion annually, and this cost will be incurred every year until mercury emissions are reduced.[124, 125] Mercury releases associated with mercury uses in products and processes contribute "significantly" to this mercury pollution.[126]

EPA's activities to protect from and minimize exposure to mercury begins with its fish advisories, since the consumption of fish is the largest exposure pathway for the general population.[127] EPA also promotes state and local fish advisories. As of 2011, all 50 states have fish advisories for mercury, and mercury accounted for 81% of all state and local fish advisories, in whole or in part.[128]

This concern about mercury exposure has led EPA to restrict intentional uses of mercury in products. For example, EPA promulgated a Significant New Use Rule (SNUR) under TSCA section 5(a) for elemental mercury used in certain "convenience light switches, anti-lock braking system (ABS) switches, and active ride control system switches."[129] Similarly, EPA promulgated a SNUR covering mercury-added flow meters, natural gas manometers, and pyrometers, because of the risk of human exposure to mercury during the products' manufacture, use, and disposal at the products' end of life.[130] About two years later, EPA promulgated a SNUR covering mercury-added barometers, manometers, hygrometers, and psychrometers, essentially for the same reasons.[131]

EPA also regulates mercury dischargers to surface waters under the Clean Water Act. This Administration recently finalized effluent guidelines for dental offices.[132] In addition to the Clean Water Act, other environmental laws that limit mercury exposures include the Clean Air Act (CAA), Safe Drinking Water Act (SDWA), Resource Conservation and Recovery Act (RCRA), and the Emergency Planning and Community Right to Know Act (EPCRA).[133]

---

[124] Trasande, L., Schechter, C. B., Haynes, K. A., & Landrigan, P. J. (2006). Mental retardation and prenatal methylmercury toxicity. *American Journal of Industrial Medicine*, *49*(3), 153–58.
[125] Trasande, L., Schechter, C., Haynes, K. A., & Landrigan, P. J. (2006). Applying cost analyses to drive policy that protects children: mercury as a case study. *Annals of the New York Academy of Sciences, 1076*: 911–923, *abstract available at* http://www.ncbi.nlm.nih.gov/pubmed/17119266.
[126] Great Lakes Regional Collaboration, *Mercury in Products Phase-Down Strategy* 1 (June 2008).
[127] U.S. EPA, Guidelines for Eating Fish that Contain Mercury, *available at* https://www.epa.gov/mercury/guidelines-eating-fish-contain-mercury.
[128] U.S. EPA, 2011 National Listing of Fish Advisories, (December 2013), EPA-820-F-13-058, *available at* https://www.epa.gov/sites/production/files/2015-06/documents/technical-factsheet-2011.pdf.
[129] 72 Fed. Reg. 56,903 *et seq.*, Mercury Switches in Motor Vehicles; Significant New Use Rule (Nov. 5, 2007).
[130] 75 Fed. Reg. 42,330 *et seq.*, Elemental Mercury Used in Flow Meters, Natural Gas Manometers, and Pyrometers (July 21, 2010).
[131] 77 Fed. Reg. at 31,728 *et seq.,* Elemental Mercury Used in Barometers, Manometers, Hygrometers, and Psychrometers; Significant New Use Rule (May 30, 2012).
[132] 82 Fed. Reg. 27,154 *et seq.,* Effluent Limitations Guidelines and Standards for the Dental Category: Final Rule, (June 14, 2017).
[133] U.S. EPA, Environmental Laws that Apply to Mercury, *available at* https://www.epa.gov/mercury/environmental-laws-apply-mercury.

ED_002389_00015391-00024

EPA very conservatively estimates that more than 75,000 newborns each year may have increased risk of learning disabilities associated with in-utero exposure to methylmercury, based on maternal blood levels exceeding the EPA Reference Dose (RfD) of 5.8 μg/L.[134] Even the EPA RfD likely underestimates the extent of risks to newborns due to bio-concentration of methylmercury across the placenta.[135] Three times more women of childbearing age—7.3%—have blood mercury levels exceeding 3.5 μg/L, indicating that up to 265,000 or more infants are born each year facing cognitive impacts from mercury exposure based on maternal blood levels.[136]

The RfD is based on recommendations of the National Research Council (NRC) of the National Academy of Sciences (NAS), that conducted an extensive analysis and calculations derived from three longitudinal epidemiologic studies: the Seychelles Islands, the Faroe Islands, and the New Zealand studies.[137] The studies measured neuropsychological effects in children that were exposed prenatally to methylmercury as a result of pregnant mother's consuming contaminated seafood. The use of these studies to set EPA exposure limits was the result of a years-long transparent process of expert scrutiny, public engagement, inter-agency cooperation, and publication in scientific journals.

However, the studies can no longer be reproduced, particularly the Faroe Islands study in which the exposure to the community was a result of eating whales, a practice that has since declined due to public alerts about the hazards of eating the mercury-tainted meat particularly for children and pregnant and breastfeeding women. In addition, it would take decades to repeat the studies, which took decades to conduct in the first place.

F. Air pollution

Since the Clean Air Act became law in 1970, it has helped to dramatically improve air quality across the country and deliver substantial, measurable health gains. A peer-reviewed EPA study issued in 2011 found that the Clean Air Act Amendments of 1990 achieved enormous health benefits (including avoidance of 160,000 premature deaths in adults by 2010) that will increase as programs take full effect.[138] In 2009, leading air pollution epidemiologists published

---

[134] Birch RJ, Bigler J, Rogers JW, Zhuang Y, Clickner RP. Trends in blood mercury concentrations and fish consumption among U.S. women of reproductive age, NHANES, 1999-2010. Environ Res. 2014 Aug;133:431–38.
[135] Mahaffey KR, Clickner RP, Jeffries RA. Adult women's blood mercury concentrations vary regionally in the United States: association with patterns of fish consumption (NHANES 1999-2004). Environ Health Perspect. 2009 Jan;117(1):47–53. doi: 10.1289/ehp.11674.
[136] Based on data from the U.S. EPA Trends study of 2013 provided via personal communication to David Lennett, NRDC, from Jeffrey Bigler, USEPA, Bigler.Jeff@epa.gov, January 2014.
[137] Rice DC. The US EPA reference dose for methylmercury: sources of uncertainty. Environ Res. 2004 Jul;95(3):406–13. https://www.ncbi.nlm.nih.gov/pubmed/15220074.
[138] U.S. EPA, Benefits and Costs of the Clean Air Act 1990-2020, the Second Prospective Study, *available at* https://www.epa.gov/clean-air-act-overview/benefits-and-costs-clean-air-act-1990-2020-second-prospective-study.

ED_002389_00015391-00025

a study demonstrating that, from 1980 to 2000, reductions in exposure to $PM_{2.5}$ pollution had increased the average American life span by 1.6 years (more than 19 months).[139]

The Clean Air Act requires EPA to consider the best available evidence in setting and revising the National Ambient Air Quality Standards (NAAQS) to protect health within an adequate margin of safety. 42 U.S.C. § 7409. Fine particulate matter, an air pollution category encompassing solid particles and condensed liquid droplets with a diameter of 2.5 microns or smaller ($PM_{2.5}$), is one of the most dangerous types of air pollution because it can penetrate deep into the lung and enter the bloodstream.[140] Groundbreaking studies into the link between air pollution exposures and health like the 1993 Harvard Six Cities Study[141] examined the health effects of $PM_{2.5}$ air pollution over 16 years on more than 8,000 adults and 14,000 children relying on private medical records and air pollution monitors deployed near study volunteers. The study found a significant relationship between air pollution exposure and risk of early death, but the raw data could not be released publicly because researchers were obligated to ensure study participant confidentiality.

As explained in section II.B., more than 100 peer-reviewed studies have confirmed the basic results of that initial study relying on that data. Because the study and others like it went through the rigorous peer-review process characteristic of the world's leading scientific journals (whose editors have rejected the Proposal[142]), EPA relied on the results of the Harvard Six Cities study and others in 1997 when it promulgated the NAAQS for fine particulate matter.[143] Hundreds of additional studies into the health effects of air pollution have been conducted since then across the country[144] and internationally,[145] for both short-[146] and long-term[147] impacts of exposure, and independent re-analyses of existing datasets have affirmed the air pollution-

---

[139] Pope III, C. A., Ezzati, M., & Dockery, D. W. (2009). Fine-particulate air pollution and life expectancy in the United States. *New England Journal of Medicine*, *360*(4), 376–86.
[140] World Health Organization. *Air Quality Guidelines: Global Update 2005. Particulate Matter, Ozone, Nitrogen Dioxide and Sulfur Dioxide*. World Health Organization (2006).
[141] Dockery, D. W., Pope, C. A., Xu, X., Spengler, J. D., Ware, J. H., Fay, M. E., ... & Speizer, F. E. (1993). An association between air pollution and mortality in six US cities. *New England journal of medicine*, *329*(24), 1753–59.
[142] *See supra* n.15, http://science.sciencemag.org/content/360/6388/eaau0116.
[143] *See* 62 Fed. Reg 38,652 *et seq.*, "National Ambient Air Quality Standards for Particulate Matter": Final Rule (July 18, 1997), *available at* https://www.epa.gov/pm-pollution/table-historical-particulate-matter-pm-national-ambient-air-quality-standards-naaqs.
[144] Hoek, G., Krishnan, R. M., Beelen, R., Peters, A., Ostro, B., Brunekreef, B., & Kaufman, J. D. (2013). Long-term air pollution exposure and cardio-respiratory mortality: a review. *Environmental Health*, *12*(1), 43.
[145] Katsouyanni, K., Samet, J. M., Anderson, H. R., Atkinson, R., Le, A. T., Medina, S., ... & Ramsay, T. (2009). Air pollution and health: a European and North American approach (APHENA). *Research report (Health Effects Institute)*, (142), 5–90.
[146] Brook, R. D., Brook, J. R., Urch, B., Vincent, R., Rajagopalan, S., & Silverman, F. (2002). Inhalation of fine particulate air pollution and ozone causes acute arterial vasoconstriction in healthy adults. *Circulation*, *105*(13), 1534–36.
[147] Pope, C. A., Burnett, R. T., Thurston, G. D., Thun, M. J., Calle, E. E., Krewski, D., & Godleski, J. J. (2004). Cardiovascular mortality and long-term exposure to particulate air pollution: epidemiological evidence of general pathophysiological pathways of disease. *Circulation*, *109*(1), 71–77.

ED_002389_00015391-00026

mortality and morbidity links with increasing precision. In 2000, the Health Effects Institute published its independent re-analysis[148] of the study, which confirmed the original findings.

As explained in section II.C., many of the studies that EPA has relied on to set and revise the NAAQS are epidemiological prospective cohort investigations encompassing thousands of individuals over several decades. The Proposal's requirement for the public sharing of underlying data of these studies contradicts HIPAA's legal protections for private medical data[149] and requirements researchers adhere to under Institutional Review Boards (IRBs),[150] which typically require investigators to ensure participant confidentiality and data security. Underlying sensitive health data cannot be released without obtaining individual patient consent, or consent from the next responsible party for study participants who have died. The foundational research in air pollution epidemiology demonstrating a causal link between pollution exposures and adverse health outcomes—including early death,[151] heart disease,[152] lung cancer,[153] stroke,[154] and asthma exacerbations[155]—is therefore at risk if the Proposal is finalized.

While the NAAQS have strengthened over time, epidemiologic evidence indicates that even greater health gains could be achieved if our nation's air quality standards were stronger.[156] The unprecedented requirements of the Proposal threaten to undermine this progress by allowing EPA to rely on weaker science that could stall or reverse historical strengthening of the NAAQS. Under the Proposal, EPA would not be able to rely on the best available science for its Integrated Science Assessments of air pollution which inform the NAAQS-setting process, while industry-funded research calling into question the air pollution-health link, would not be subject to similar data release requirements, or even peer-review and independent reevaluation. This approach is asymmetric and favors selective, opaque, and questionable research methods over the consensus of robust peer-reviewed scientific investigation. Transparency in scientific data is an important topic, but one that needs to also balance the privacy concerns of study participants and legal and ethical restrictions on the sharing of sensitive data. The rule is arbitrary in its selective

---

[148] *See supra,* n.9, Reanalysis of Harvard Six Cities Study.
[149] U.S. Department of Health and Human Services, The HIPAA Privacy Rule, *available at* https://www.hhs.gov/hipaa/for-professionals/privacy/index.html.
[150] *See*, *e.g.*, National Institute of Environmental Health Sciences: Institutional Review Board, *available at* https://www.niehs.nih.gov/about/boards/irb/index.cfm.
[151] Pope III, C. A., R. T. Burnett, M. J. Thun, E. E. Calle, D. Krewski, K. Ito, and G. D. Thurston. 2002. "Lung Cancer, Cardiopulmonary Mortality, and Long-Term Exposure to Fine Particulate Air Pollution." JAMA: The Journal of the American Medical Association 287 (9): 1132–1141.
[152] Pope, C. A., Muhlestein, J. B., May, H. T., Renlund, D. G., Anderson, J. L., & Horne, B. D. (2006). Ischemic heart disease events triggered by short-term exposure to fine particulate air pollution. *Circulation*, *114*(23), 2443–48.
[153] Turner, M. C., Krewski, D., Pope III, C. A., Chen, Y., Gapstur, S. M., & Thun, M. J. (2011). Long-term ambient fine particulate matter air pollution and lung cancer in a large cohort of never-smokers. *American Journal of Respiratory and Critical Care Medicine*, *184*(12), 1374–81.
[154] Hong, Y. C., Lee, J. T., Kim, H., & Kwon, H. J. (2002). Air pollution: a new risk factor in ischemic stroke mortality. *Stroke*, *33*(9), 2165–69.
[155] Ostro, B., Lipsett, M., Mann, J., Braxton-Owens, H., & White, M. (2001). Air pollution and exacerbation of asthma in African-American children in Los Angeles. *Epidemiology*, *12*(2), 200–08.
[156] Di, Q., Wang, Y., Zanobetti, A., Wang, Y., Koutrakis, P., Choirat, C., ... & Schwartz, J. D. (2017). Air pollution and mortality in the Medicare population. New England Journal of Medicine, 376(26), 2513–22.

ED_002389_00015391-00027

application of data release requirements and disregard for the quantitative complexities of epidemiologic research.

The Proposal also has clear adverse consequences for cost-benefit analyses that consider the substantial costs of health effects caused by exposure to air pollution. This area of work includes efforts to address carbon dioxide (CO_2) pollution and climate change, such as the Clean Power Plan. Health and air quality-related monetized benefits from reducing $PM_{2.5}$ pollution, a co-benefit of CO_2 reductions, would be substantially reduced if EPA is unable to rely on the best available science for pollution-health impacts. In its proposed rule repealing the Clean Power Plan, EPA signaled this approach: the economic health benefits of $PM_{2.5}$ reduction were zeroed-out[157] by EPA after levels reached the current annual NAAQS (12 $\mu g/m^3$) or the lowest measured level (LML) of $PM_{2.5}$ in two key peer-reviewed studies that EPA has historically relied on, including an expanded re-analysis of the Harvard Six Cities data.[158, 159] This approach of using the NAAQS or LML as a safe threshold directly contradicts the best available science[160, 161] and EPA's own stance on the pollution threshold issue as recently as 2012.[162] The Proposal is designed to support the indefensible notion that a safe threshold of air pollution like $PM_{2.5}$ could exist, despite the opinions of the world's leading experts on this issue and emerging evidence indicating that relatively low levels of exposure to air pollution may actually confer *more* risk[163] than even the current EPA dose-response approach for $PM_{2.5}$ exposure assumes.

G. Radiation

1. EPA's Radiation Standards

Three federal agencies have overlapping and differing responsibilities to protect the public from radiation. The Department of Energy (DOE), which among other tasks runs the U.S. nuclear weapons program, has for decades been attempting to clean up dozens of nuclear

---

[157] U.S. EPA, Regulatory Impact Analysis for the Review of the Clean Power Plan: Proposal, Oct. 2017, at 10, *available at* https://www.epa.gov/sites/production/files/2017-10/documents/ria_proposed-cpp-repeal_2017-10.pdf.
[158] Krewski, D., Jerrett, M., Burnett, R. T., Ma, R., Hughes, E., Shi, Y., ... & Thun, M. J. (2009). *Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality* (No. 140). Boston, MA: Health Effects Institute.
[159] Lepeule, J., Laden, F., Dockery, D., & Schwartz, J. (2012). Chronic exposure to fine particles and mortality: an extended follow-up of the Harvard Six Cities study from 1974 to 2009. *Environmental health perspectives*, *120*(7), 965.
[160] U.S. EPA, Summary of Expert Opinions on the Existence of a Threshold in the Concentration-Response Function for PM2.5-related Mortality, Technical Support Document, June 2010, *available at* https://www3.epa.gov/ttnecas1/regdata/Benefits/thresholdstsd.pdf.
[161] Crouse DL, Peters PA, van Donkelaar A, Goldberg MS, Villeneuve PJ, Brion O, et al. (2012). Risk of nonaccidental and cardiovascular mortality in relation to long-term exposure to low concentrations of fine particulate matter: a Canadian national-level cohort study. Environ Health Perspect 120708–714.; 10.1289/ehp.110404.
[162] Letter from Gina McCarthy to the Hon. Fred Upton, Chairman, Committee on Energy and Commerce, U.S. House of Representatives, Feb. 3, 2012, *available at* https://www.nrdc.org/sites/default/files/epa-letter-upton-pm-benefits-20120203.pdf.
[163] Burnett, R. T., Pope III, C. A., Ezzati, M., Olives, C., Lim, S. S., Mehta, S., ... & Anderson, H. R. (2014). An integrated risk function for estimating the global burden of disease attributable to ambient fine particulate matter exposure. *Environmental health perspectives*, *122*(4), 397.

ED_002389_00015391-00028

weapons production sites around the country in an essentially self-regulating fashion (with respect to radioactivity). The Nuclear Regulatory Commission (NRC) regulates the nation's commercial nuclear power industry of approximately 100 commercial nuclear reactors located in 31 states. The NRC implements standards as part of its regulation of civilian sources of nuclear radiation, and it oversees the decommissioning of commercial nuclear facilities. EPA, via authority granted under the Atomic Energy Act, 42 U.S.C. §§ 2011-2296; Reorganization Plan No. 3. of 1970, 5 U.S.C. app. 1; the Nuclear Waste Policy Act of 1982, as amended, 42 U.S.C. §§ 10101-10270; and the Waste Isolation Pilot Plant Land Withdrawal Act, Pub. L. 102-579, 106 Stat. 4777., issues generally applicable radiation standards for protection of the public, as well as standards for nuclear power operations, protection from radon, administering radiation cleanup standards under Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund) which governs aspects of a host of cleanups of federal and nonfederal facilities, health, and environmental standards for uranium and thorium mill tailings, and for the Waste Isolation Pilot Plant in New Mexico and the proposed Yucca Mountain nuclear waste repository in Nevada.

Specifically,

> In forming EPA, the authors of Reorganization Plan No. 3 created a new national approach for protecting the general public from the harmful exposure to radiation. Two key radiation protection functions would now be housed in a single agency – the promulgation of generally applicable environmental standards to limit man-made radioactive materials in the environment, and the development of national radiation protection guidance for Federal and State agencies to follow in the development of their radiation protection programs and regulations. Along with these responsibilities, EPA was provided extensive research and surveillance capabilities to support the development of national guidance and standards, as well as the authority to provide technical assistance to the States.[164]

Essentially, the radiation standard-setting functions for protection of the general public (not at the weapons production sites) of the Atomic Energy Commission, administered through its Division of Radiation Protection Standards, were transferred to EPA to the extent that such functions "consist of establishing generally applicable environmental standards for the protection of the general environment from radioactive material."[165] Under the authority of the Atomic Energy Act, these standards were defined as "limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material."[166]

And as is generally understood, EPA's and NRC's authorities are overlapping and, theoretically, work together to meet an objective of protecting the general public and radiation

---

[164] *Radiation Protection at EPA, The First 30 Years*, U.S. EPA, Office of Radiation and Indoor Air, EPA 402-B-00-001, August 2000, http://www2.epa.gov/sites/production/files/2015-05/documents/402-b-00-001.pdf.
[165] Reorganization Plan No. 3 of 1970 (July 9, 1970), https://archive.epa.gov/epa/aboutepa/reorganization-plan-no-3-1970.html.
[166] *Id.*

workers from exposures to ionizing radiation, EPA sets regulatory limits and guidelines on radionuclide concentration in air, water, and soil. *See* 40 C.F.R. §§ 190-197, *Subchapter F – Radiation Protection Programs* (*cf.*, EPA sets standards for "radiation doses received by members of the public in the general environment and to radioactive materials introduced into the general environment as the result of operations which are part of a nuclear fuel cycle." 40 C.F.R. § 190.01.). NRC's regulatory structures are supposed to be consistent with those set by EPA. Indeed, NRC rules, when addressing dose limits for individual members of the public, state that "[i]n addition to the requirements of this part, a licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 C.F.R. part 190 shall comply with those standards." 10 C.F.R. § 20.1301(e).

2. The Linear No-Threshold (LNT) dose-response model

As it does in every other instance and under every other environmental statute, EPA relies on independent, authoritative scientific bodies to provide analyses and evaluations of scientific evidence in support of its radiation standard-setting policies. EPA bases its regulatory limits and nonregulatory guidelines for population exposures to low-level ionizing radiation on the linear no-threshold (LNT) dose-response model.[167] EPA's radiation protection standards are based on the premise that any radiation dose carries some risk, and that risk increases directly with dose. This method of estimating risk is called the "linear no-threshold dose-response model (LNT).

This longstanding and well-supported assumption presumes that the risk of cancer due to a low dose exposure is proportional to dose, with no threshold. For over 40 years the LNT dose-response model has been commonly utilized when developing practical and prudent guidance on ways to protect workers and members of the public from the potential for harmful effects from radiation in balance with the commercially justified and optimized uses of radiation. EPA derives the LNT model from reports by authoritative scientific bodies including the U.S. National Academy of Sciences (NAS), the National Council on Radiation Protection and Measurements (NCRP), and the International Commission on Radiological Protection (ICRP). There is strong scientific consistency by these authoritative groups that an LNT model is the best at the current time (and has been for the past half century).[168, 169] Indeed, EPA noted as recently as late 2015, "[o]ver the last half century, numerous authoritative national and international bodies have convened committees of experts to examine the issue of LNT as a tool for radiation regulation and risk assessment . . . Again and again, these bodies have endorsed LNT as a reasonable approach to regulating exposures to low dose radiation."[170]

---

[167] *See, e.g.*, https://www.epa.gov/radiation/radiation-health-effects.
[168] Puskin, Jerome S., "Perspective on the use of LNT for radiation protection and risk assessment by the US Environmental Protection Agency." Dose-Response 7.4 (2009): dose-response.
[169] Valentin, Jack, The 2007 recommendations of the international commission on radiological protection. Oxford: Elsevier, 2007.
[170] *See* https://www.nrc.gov/docs/ML1530/ML15301A820.pdf.

ED_002389_00015391-00030

3. Studies in support of the LNT dose-response model

The NAS Biological Effects of Ionizing Radiation (BEIR) VII committee has studied and published its report on risk models for estimating the relationship between exposure to low levels of ionizing radiation and harmful health effects.[171] The data used in the BEIR VII study are: atomic bomb survivor studies, medical radiation studies, occupational radiation studies, and environmental radiation studies. The committee judged that the LNT model provided the most reasonable description of the relation between low dose exposure to ionizing radiation and the incidence of solid cancers that are induced by ionizing radiation.

The NCRP published its latest commentary on the LNT issue only months ago, in April 2018.[172] The specific purpose of its commentary is to provide a review of recent epidemiologic data from studies with low doses or low dose rates and the Life Span Study (LSS) of atomic-bomb survivors to determine whether these epidemiologic studies broadly support the LNT dose-response model as a reasonable basis for radiation protection. Epidemiologic studies of humans provide evidence that is critically important in establishing potentially causal associations of environmental factors with the disease. The studies were selected by a consensus of experts who have a broad purview of the recent radiation epidemiology literature, and they ensured that the largest and most important eligible studies were included.

Examples of studies of radiation-exposed populations evaluated are:

1. Japanese atomic-bomb survivors
   The LSS is a research program investigating life-long health effects based on epidemiologic studies. The study being conducted by the Radiation Effects Research Foundation (RERF)[173] is used by standard-setting bodies in establishing a recommendation for radiation protection. The LSS cohort[174] includes both a large proportion of survivors who were within 2.5 km of the hypocenters at the time of the bombings and a similar-sized sample of survivors who were between 3 and 10 km from the hypocenters whose radiation doses were negligible.

   The major objective of the study is to investigate the long-term effects of atomic-bomb radiation on causes of death and incidence of cancer. The atomic-bomb survivors of Hiroshima and Nagasaki are subject to follow-up study[175, 176] for their remaining lives, starting from 1950. The LSS cohort of atomic-bomb survivors has provided important data because it is a large cohort (~87,000 survivors of all ages) with relatively accurate dosimetry,

---

[171] National Research Council. *Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2.* Vol. 7. National Academies Press, 2006.
[172] NCRP Commentary 27. "Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection." NCRP, 2018.
[173] *See* http://rerf.or.jp/en.
[174] National Research Council. *Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2.* Vol. 7. National Academies Press, 2006.
[175] Grant, Eric J., et al. "Solid cancer incidence among the Life Span Study of atomic bomb survivors: 1958–2009." *Radiation research* 187.5 (2017): 513–37.
[176] Ozasa, Kotaro, et al. "Studies of the mortality of atomic bomb survivors, Report 14, 1950–2003: an overview of cancer and noncancer diseases." *Radiation research* 177.3 (2012): 229-243.

ED_002389_00015391-00031

a wide dose range over 60 years of high-quality follow-up for mortality and over 50 years of follow-up for cancer incidence, and nearly 1,000 excess solid-cancer cases, besides excess leukemias. The study provides strong indirect support for the use of an LNT model.

2. Worker exposure studies
   Radiation worker studies assess risks in worker groups exposed largely to many low doses received at a low dose rate, providing direct evidence regarding the validity of the LNT model. INWORKS is an example of these studies.[177] INWORKS is the latest international collaboration for examining the health of workers in more than one country who were exposed occupationally to ionizing radiation. INWORKS included dosimetry for 20 different nuclear sites/organizations in three countries. Dosimetry was based on individual personal dosimeter readings at the start of the workers beginning their radiation work (at earliest, between 1944 and 1952) through 2005. The U.S. cohort of INWORKS consisted of 119,195 nuclear workers at four Department of Energy nuclear weapons facilities (Hanford site, Idaho National Laboratory, Oak Ridge National Laboratory, and Savannah River site) and at the Portsmouth Naval Shipyard. This large study[178] provides one of the strongest pieces of epidemiologic evidence that the LNT quantitative model is useful for radiation protection.

3. Environmental exposure studies
   An example of environmental exposure studies for low doses and low dose rate is the Chernobyl resident cohorts.[179, 180] The 1986 accident at the Chornobyl nuclear power plant in northern Ukraine resulted in the exposure of substantial proportion of Belarus, Ukraine, and the Russian Federation to radioactive fallout. The most notable apparent health consequence of the accident has been the large increase in thyroid cancer among those exposed as children or teenagers starting 4-5 years after the accident. Studies of cohorts of children in Ukraine and Belarus who had thyroid measurements of iodine activity shortly after the Chernobyl accident and systematic thyroid screenings were conducted. The data on exposure to radioactive iodine have added considerable information relative to the dose-response relationship. The thyroid cancer experienced by children in exposed areas of the Ukraine, Belarus, and Russia conforms to the LNT model.

4. Medical exposure studies
   Patients treated with lung collapse for TB in the 1930s to 1960s are one of the few medically exposed populations that provide consistent evidence for dose-response relationships. Patients on average would receive on the order of 100 chest fluoroscopies over several years.

---

[177] Leuraud, Klervi, et al. "Ionising radiation and risk of death from leukaemia and lymphoma in radiation-monitored workers (INWORKS): an international cohort study." *The Lancet Haematology* 2.7 (2015): e276–e281.
[178] Schubauer-Berigan, Mary K., et al. "Cancer mortality through 2005 among a pooled cohort of US nuclear workers exposed to external ionizing radiation." *Radiation research* 183.6 (2015): 620–31.
[179] Brenner, Alina V., et al. "I-131 dose response for incident thyroid cancers in Ukraine related to the Chornobyl accident." *Environmental health perspectives* 119.7 (2011): 933.
[180] Tronko, Mykola D., et al. "A cohort study of thyroid cancer and other thyroid diseases after the Chornobyl accident: thyroid cancer in Ukraine detected during first screening." *Journal of the National Cancer Institute* 98.13 (2006): 897–903.

ED_002389_00015391-00032

Since the 1970s, studies[181] of TB patients who received repeated chest x-ray fluoroscopies to monitor lung collapse have provided valuable information relevant to the LNT hypothesis. The TB fluoroscopy studies provide strong support for the LNT model for breast cancer.

NCRP commentary in conclusion of its epidemiology studies states that, based on current epidemiologic data, the LNT model should continue to be used for radiation protection purposes, and "no alternative dose-response relationship appears more pragmatic or prudent for radiation protection purposes than the LNT model."[182]

4. How the Proposal jeopardizes health protections

Because it does not cite or even note the statutory sources of EPA's radiation standard setting authority, EPA fails to reference to the proper legal authority to address radiation protection standards and the underlying science and dose estimations, and thus fails to present the terms or substance of the proposed action or a description of the subjects and issues involved. Thus, the public has been denied a reasonable and meaningful opportunity to participate in the rulemaking process.[183]

Despite the failure to precisely name radiation standards or cite the EPA's authority under the Atomic Energy Act, the Proposal is susceptible to a reading that EPA intends to attack the underlying science for radiation standards, and the LNT in particular, just as the agency is attacking standards for the air, water, and health protections. Indeed, Dr. Edward J. Calabrese of the University of Massachusetts, longtime promoter of the radiation hormesis idea that low doses of radiation are beneficial for humans, stated in support of this draft rule, "[t]he [P]roposal represents a major scientific step forward by recognizing the widespread occurrence of non-

---

[181] Howe, Geoffrey R. "Lung cancer mortality between 1950 and 1987 after exposure to fractionated moderate-dose-rate ionizing radiation in the Canadian fluoroscopy cohort study and a comparison with lung cancer mortality in the atomic bomb survivors study." *Radiation research* 142.3 (1995): 295–304.

[182] NCRP Commentary 27. "Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection." NCRP, 2018, at 139.

[183] In order to preserve objections in the administrative record, we submit comments directed at any wrongheaded and unlawful attack on an LNT for radiation, notwithstanding EPA's failure to mention radiation—or any other substance or pollutant—in the "non-linearity" section of the Proposal. 83 Fed. Reg. at 18,770. The Proposal's cursory suggestion of "non-linearity in the concentration-response function for specific pollutants and health effects," 83 Fed. Reg. at 18,770/3, fails to provide fair notice or any justification that would allow any final rule to assert "non-linearity in the concentration-response function" for *any* specific pollutants or *any* health effects. There is *no* information, evidence, or regulatory text in the Proposal or regulatory docket supporting or even addressing the suggestion of non-linearity in the concentration-response function for *any* specific pollutants or *any* health effects. Nor is there any discussion or material in the Proposal or accompanying docket supporting or even addressing EPA's cursory suggestion of non-linearity. The Proposal conclusorily references "growing empirical evidence of non-linearity," *id.*, but then fails to identify *any* such empirical evidence in the Proposal or docket. Before EPA may adopt any final rule addressing "non-linearity in the concentration-response function" for *any* specific pollutants or *any* health effects, EPA would be required to re-issue a new proposed rule with actual regulatory text and supporting legal, factual, scientific, and technical information providing fair notice to the public concerning any suggestion of "non-linearity in the concentration-response function" for *any* specific pollutants or *any* health effects.

ED_002389_00015391-00033

linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process."[184]

EPA's Proposal states only that "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." 83 Fed. Reg. at 18,770/3. The Proposal fails to provide a citation or single shred of empirical evidence to support the statement. By contrast, the science in radiation epidemiological studies has repeatedly demonstrated, over decades, *the precise opposite conclusion*—to wit, that the LNT dose-response model provides the most reasonable description of the relation between low dose exposure to ionizing radiation and the incidence of solid cancers that are induced by ionizing radiation.

The epidemiologic science and associated studies that are the basis of adherence to the LNT and decades of protective radiation standards are likely to be expressly excluded from consideration by EPA by the terms of this Proposal. NAS and other studies that EPA has long relied upon in the radiation standards setting process are epidemiological human cohort studies. EPA's Proposal, if implemented, would limit EPA staff from basing regulatory actions on precisely these types of studies by requiring that the underlying data of these studies be publicly shared. This would be a nearly impossible task for the agency. Data for some of the radiation epidemiological studies are accessible to users[185, 186] with a detailed description of how a user can access the information. However, public sharing of personally identifiable information (PII) is restricted because the studies rely on confidential health data. To become an authorized user of the data sets and to reduce misuse of that data, users are barred from linking data from the database with any other source of information that leads to PII of an individual with records in the database.

These are profoundly important studies that have been peer reviewed for decades and the science that has emerged from them has been validated multiple times. But these are not studies where the entirety of the public data can be shared or independently replicated. There are no other radiation epidemiologic studies of health and longevity on a large size population (example: more than 120,000 individuals in the atomic-bomb survivor studies) that have continued for more than 60 years. Thus, replication of the studies is impossible as this data comes from individuals exposed to significant acute and protracted dose of radiation. Implementation of the rule would effectively block the use of such key scientific studies and allow for radiation standards to be either wholly weakened or made functionally meaningless.

Specifically, EPA relied on the LNT dose-response model to develop the following reports and regulations to protect the general public and radiation workers from the potential for harmful effects from radiation:

---

[184] *See* https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations.

[185] *See* https://apps.orau.gov/cedr/#.Wv73Y-4vxEY.

[186] *See* http://rerf.or.jp/en.

ED_002389_00015391-00034

Federal guidance reports (FGRs) for radiation protection that provide technical information and policy recommendations for radiation dose and risk assessment:

- FGR 11 (1988)[187]—Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion
- FGR 12 (1993)[188]—External Exposure to Radionuclides in Air, Water, and Soil
- FGR 13 (1999)[189]—Cancer Risk Coefficients for Environmental Exposure to Radionuclides
- EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population (the "Blue Book")[190]

Nuclear fuel cycle standards and regulations addressing environmental issues for all phases of the uranium fuel cycle, including uranium milling; chemical conversion; fuel fabrication and reprocessing; power plant operations; waste management, storage, and disposal; and site cleanup for milling operations.

- The Uranium Fuel Cycle (40 C.F.R. Part 190)[191]—a standard that sets generally applicable environmental limits for the entire uranium fuel cycle
- Uranium and Thorium Mill Tailings (40 C.F.R. Parts 192)[192]—health and environmental standards for uranium and thorium mill tailings

Examples of areas that might be impacted by this rule include:

1. Maximum allowed concentrations of radionuclides in drinking water
2. Soil cleanup levels for Superfund sites
3. Monitoring around radiation-producing equipment used for medical purposes
4. Radioactive waste disposal
5. The concept of ALARA (As Low As Reasonably Achievable) in radiation protection

Abandoning the LNT dose-response model and replacing it with either a threshold model or a concept that low doses of radiation are safe will have an adverse effect on radiation workers and the general public by allowing radiation protection regulations to be relaxed, reinterpreted and then weakened.

---

[187] Eckerman, Keith F., Anthony B. Wolbarst, and Allan CB Richardson. "Federal Guidance Report No. 11: Limiting values of radionuclide intake and air concentration and dose conversion factors for inhalation, submersion, and ingestion." *Oak Ridge, TN: Oak Ridge National Laboratory* (1988).

[188] Eckerman, Keith F., and J. C. Ryman. "Federal Guidance Report No. 12: External Exposures to Radionuclides in Air, Water, and Soil Exposure-to-Dose Coefficients for General Application," *U.S. Environmental Protection Agency, Washington, DC* (1993).

[189] Eckerman, Keith F., et al. "Cancer risk coefficients for environmental exposure to radionuclides." *Federal Guidance Report* 13 (1999).

[190] *See* https://www.epa.gov/sites/production/files/2015-05/documents/bbfinalversion.pdf.

[191] *See* https://www.epa.gov/radiation/environmental-radiation-protection-standards-nuclear-power-operations-40-cfr-part-190.

[192] *See* https://www.epa.gov/radiation/health-and-environmental-protection-standards-uranium-and-thorium-mill-tailings-40-cfr.

ED_002389_00015391-00035

IV. There is no statutory authority for the Proposal

The law is clear that EPA may adopt rules only if those rules are based on statutory authority delegated by Congress. EPA may not invent statutory authority where none exists, nor adopt regulations lacking statutory authority merely because EPA believes that to be better policy. *See, e.g.*, *Massachusetts v. EPA*, 549 U.S. 497, 535, 127 S. Ct. 1438, 1463 (2007) ("EPA must ground its reasons for action or inaction in the statute."); *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) (stating "agency power to act" is shaped by how "Congress confers power upon it"). Agencies need especially clear congressional delegations of authority to create regulatory exemptions. *See New York v. U.S. EPA*, 413 F.3d 3, 41 (D.C. Cir. 2005) (stating that the agency needs "clear congressional delegation" to support an exemption). EPA identifies no such delegations, certainly not the clear delegations required by law, for the Proposal.

EPA lists seven statutes as the basis for the Proposal. But none of the various statutes cited provides support for the rule's provisions, definitions, requirements, or exemptions. Rather, EPA invents statutory authority where none exists, and creates proposed regulatory text out of thin air. In most cases, EPA simply cites its general authority for rulemaking under the statutes. But that general authority alone cannot provide a basis for the rule, especially when, as explained in section V, the rule would *conflict* with the requirements of each of the statutes. *See New York v. U.S. EPA*, 413 F.3d 3, 40–42 (D.C. Cir. 2005). In other instances, it appears that EPA just searched the statutes for the word "research" and then cited those sections without any further analysis. The cited provisions do not support the proposed rule:

A. Clean Air Act sections 103, 301(a); 42 U.S.C. §§ 7403, 7601(a)

EPA cites 42 U.S.C. § 7601(a) of the Clean Air Act as one basis for the Proposal. But that section merely authorizes the Administrator to "prescribe such regulations as are necessary to carry out his functions under this chapter." The courts have made clear that "EPA cannot rely on its gap-filling authority to supplement the Clean Air Act's provisions when Congress has not left the agency a gap to fill." *NRDC v. EPA.*, 749 F.3d 1055, 1064 (D.C. Cir. 2014); *see also American Petroleum Institute v. EPA*, 52 F.3d 1113, 1119 (D.C. Cir. 1995) ("the general grant of rulemaking power to EPA cannot trump specific portions of the CAA"); *NRDC v. Reilly*, 976 F.2d 36, 41 (D.C. Cir. 1992) (EPA cannot use its general rulemaking authority as justification for adding to a statutorily specified list); *Sierra Club v. EPA*, 719 F.2d 436, 453 (D.C. Cir. 1983) (same); *Gonzales v. Oregon*, 546 U.S. 243, 264–65 (2006) ("It would go . . . against the plain language of the text to treat a delegation for the 'execution' of [the Attorney General's] functions as a further delegation to define other functions well beyond the statute's specific grants of authority."). Here, not only is there no statutory gap to fill, as explained further below, the Proposal is in direct conflict with other provisions of the Act. EPA cannot rely on 42 U.S.C. § 7601(a) to support this rule.

EPA also cites 42 U.S.C. § 7403, which requires the Administrator to establish a national research and development program for air pollution, among other things. EPA does not state specifically which of the many subsections it believes authorizes this proposed rule. Thus, the citation fails to provide sufficient notice for the public to comment on the proposed rule.

ED_002389_00015391-00036

Nothing in the Proposal establishes or even purports to establish the type of national research and development program for air pollution discussed in subsection (a). But that subsection is nonetheless revealing about congressional intent concerning "studies relating to the causes, effects (including health and welfare effects) extent, prevention, and control of air pollution." 42 U.S.C. § 7403(a)(1). There is no indication that Congress intended to allow EPA to ignore or refuse to consider studies on the health and welfare effects of air pollution only if raw data or 'regulatory science underlying EPA's actions [were] publicly available in a manner sufficient for independent validation." *See* 83 Fed. Reg. at 18,773 (proposed §§ 30.1–30.3). Indeed, the absence of any such congressional conditions or criteria makes it all the more obvious that EPA invented and added those criteria and conditions as a matter of its own policy preferences, contrary to the Act. This EPA may not do.

Subsection (b) authorizes EPA to collect and make available information about such research, but nothing in that subsection allows EPA to *restrict* which types of data it considers in regulatory decisions. Nor does subsection (b) draw any distinction between dose-response data and other types of data. Again, the absence of any such congressional distinction makes it all the more obvious that EPA invented and added that distinction as a matter of its own policy preferences, contrary to the Act. This EPA may not do. None of the other subsections in 42 U.S.C. § 7403 address this issue either. There is no support in the Clean Air Act for the Proposal.

B. Clean Water Act sections 104, 501; 33 U.S.C. §§ 1254, 1361

EPA cites sections 104, 33 U.S.C. § 1254, and 501, 33 U.S.C. § 1361, of the Clean Water Act as putative authority for the Proposal. Nothing in these sections authorize the Proposal's limitations on scientific evidence.

With respect to section 104, the Proposal tellingly fails to specify which of its 22 subsections supposedly supports the restrictions EPA has proposed. This deficiency reflects a lack of authority for the Proposal in section 104. And even if EPA thinks that it can cobble together language in section 104 to support the Proposal, the agency's complete failure to identify in the Proposal how section 104 authorizes this rulemaking means that EPA did not provide sufficient notice for the public to comment on the Proposal.

None of the subsections in section 104 states or suggests that, in promulgating regulations under the Clean Water Act, EPA may limit its consideration of "regulatory science underlying its actions" only to studies or analyses "are publicly available in a manner sufficient for independent validation." *See* 83 Fed. Reg. at 18,773 (proposed § 30.5). To the contrary, several subsections indicate that Congress intended EPA to consider available scientific evidence in order to carry out the Act.

First, subsection (b) authorizes EPA to collect and publicize results and information related to studies about water pollution but does not say anything about *limiting* consideration of science simply because data cannot be made public, either as part of rulemakings or otherwise. Nor does it draw any distinction between dose-response data and other types of data.

ED_002389_00015391-00037

Second, subsection (c) directs EPA to "conduct research on, and survey the results of other scientific studies on, the harmful effects on the health or welfare of persons caused by pollutants." It provides no authority whatsoever for *limiting* consideration of studies, models or data, dose-response or otherwise, during rulemakings; indeed, by directing EPA to "survey the *results of other scientific studies*," rather than the publicly-available dose-response data underlying those results, this subsection contradicts the Proposal's limitations and conditions.

Third, subsection (*l*)(1) indicates that EPA should be inclusive with respect to considering evidence, as it directs EPA to "develop and issue to the States for the purpose of carrying out this Act *the latest scientific knowledge available* in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water in varying quantities. He shall revise and add to such information whenever necessary to reflect developing scientific knowledge."

Fourth, subsection (n) directs EPA to cooperate with various entities to "conduct and promote, encourage contributions to, continuing comprehensive studies of the effects of pollution, including sedimentation, in the estuaries and estuarine zones of the United States on fish and wildlife, on sport and commercial fishing, on recreation, on water supply and water power, and on other beneficial purposes." Importantly, subsection (n)(2) reveals Congress's intention that EPA will consider information broadly, by instructing the agency to "assemble, coordinate, and organize *all existing pertinent information* on the Nation's estuaries and estuarine zones . . . ."

EPA also cites 33 U.S.C. § 1361 as a basis for the Proposal, but it does not provide the agency with the authority it desires. Subsection (a) merely states that the "Administrator is authorized to prescribe such regulations as are necessary to carry out his functions under this chapter." As explained above, that general grant of authority cannot support the rule, especially when the rule conflicts with the Act. Moreover, EPA casually invokes this provision, but does not make any effort to justify the proposed restrictions as necessary to any particular CWA statutory function, so it has not made the case that this provision provides authority to adopt the Proposal's limits.

Finally, the Act contains other indications that Congress intended EPA's consideration of science to be inclusive. In particular, section 304(a)(1) of the Act states:

> The Administrator, after consultation with appropriate Federal and State agencies and other interested persons, shall develop and publish, within one year after the date of enactment of this title (and from time to time thereafter revise) criteria for water quality *accurately reflecting the latest scientific knowledge* (A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, including ground water; (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes; and (C) on the effects of pollutants on biological community diversity, productivity, and stability, including information on the

ED_002389_00015391-00038

factors affecting rates of eutrophication and rates of organic and inorganic sedimentation for varying types of receiving waters.

Although water quality criteria EPA develops are not issued as regulations, such that the Proposal as written would likely not apply to them, the salient point—illustrated by the italicized language above—is that Congress refused to limit EPA's consideration of available evidence in discharging one of its core functions aimed at protecting the nation's waters. EPA provides no reason in the Proposal why the regulations the Proposal targets should be any different.

Accordingly, the Clean Water Act does not authorize the Proposal.

C. Safe Drinking Water Act sections 1442, 1450(a)(1); 42 U.S.C. §§ 300j–1, 300j–9(a)(1)

EPA cites 42 U.S.C. § 300j–1 of the Safe Drinking Water Act as authority for the rule. Subsection (a) of that section allows EPA to conduct some types of research on drinking water contamination and requires it to conduct other studies. But it says nothing about which types of studies EPA may consider in rulemakings and does not distinguish between dose-response studies and other types of studies. The absence of any such congressional distinction or restriction makes it all the more obvious that EPA invented and added the distinction and restrictions in the Proposal as a matter of its own policy preferences, contrary to the Act. This EPA may not do. The remainder of the subsections have nothing to do with data or research. At any rate, EPA does not state specifically which of the subsections in 42 U.S.C. § 300j–1 it believes authorizes this proposed rule. Thus, the citation fails to provide sufficient notice for the public to comment on the proposed rule.

EPA also cites 42 U.S.C. § 300j–9(a)(1), but that says only that the "Administrator is authorized to prescribe such regulations as are necessary or appropriate to carry out his functions under this subchapter." As explained above, that general grant of authority cannot support the rule, especially when the rule conflicts with the Act. The Safe Water Drinking Act does not authorize the proposed rule.

D. Resource Conservation and Recovery Act sections 2002(a)(1), 7009; 42 U.S.C. §§ 6912(a)(1), 6979

EPA also claims that 42 U.S.C. § 6912(a)(1) of the Resource Conservation and Recovery Act provides authority for the rule. But 42 U.S.C. § 6912(a)(1) merely states that the Administrator is authorized to "prescribe, in consultation with Federal, State, and regional authorities, such regulations as are necessary to carry out his functions under this chapter." As explained above, that general grant of authority cannot support the rule, especially when the rule conflicts with the Act. There is no support in RCRA for the Proposal.

It appears that EPA's citation to 42 U.S.C. § 6979 is a mistake. That section deals with labor standards for construction and says nothing about research, data, or science. At any rate, EPA does not state specifically which provision of 42 U.S.C. § 6979 it believes authorizes the

ED_002389_00015391-00039

Proposal. Thus, the citation fails to provide sufficient notice for the public to comment on the proposed rule.

E. Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311; 42 U.S.C. §§ 9616, 9660

Under the Comprehensive Environmental Response, Compensation, and Liability Act, EPA cites 42 U.S.C. § 9616 as authority, but that section merely provides a schedule for the assessment and remediation of Superfund sites. It is entirely unclear what this has to do with the subject matter of the Proposal. EPA does not state specifically which provision of 42 U.S.C. § 9616 it believes authorizes the Proposal, nor does the Proposal even explain the reference. Thus, the citation fails to provide sufficient notice for the public to comment on the proposed rule.

EPA also cites 42 U.S.C. § 9660, which has many subsections. This broad citation also fails to provide sufficient notice for the public to comment on the proposed rule. Subsections (a), (b), and (c) require the Secretary of Health and Human Services and the Administrator of EPA to establish research programs on the effects of hazardous substances on human health. But nothing in those sections limits EPA's consideration of studies in which the data can be made public or draws a line between dose-response data and other types of data. The absence of any such congressional distinction or restriction makes it all the more obvious that EPA invented and added the distinction and restrictions in the Proposal as a matter of its own policy preferences, contrary to the Act. This EPA may not do. CERCLA does not authorize the Proposal.

F. Emergency Planning and Community Right-To-Know Act section 328; 42 U.S.C. § 11048

The only authority EPA cites under the Emergency Planning and Community Right-To-Know Act is 42 U.S.C. § 11048, which states that the "Administrator may prescribe such regulations as may be necessary to carry out this chapter." The citation fails to provide sufficient notice for the public to comment on the Proposal. EPA does not identify any statutory authority for why the proposed rule is necessary to carry out the chapter. As explained above, that general grant of authority cannot support the rule, especially when the rule conflicts with the Act. EPCRA does not authorize the proposed rule.

G. Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a); 7 U.S.C. §§ 136r(a), 136w

Under the Federal Insecticide, Fungicide, and Rodenticide Act, EPA cites 7 U.S.C. § 136r(a), which authorizes the Administrator to "undertake research." That section does not allow the *restriction* of what types of research EPA may consider in rulemakings or otherwise. Nor does it draw any distinction between dose-response data and other types of data. The absence of any such congressional distinction or restriction makes it all the more obvious that EPA invented and added the distinction and restrictions in the Proposal as a matter of its own policy preferences, contrary to the Act. This EPA may not do.

ED_002389_00015391-00040

EPA also cites 7 U.S.C. § 136w, which is the general rulemaking authority that allows the Administrator to carry out the provisions of FIFRA. As explained above, that general grant of authority cannot support the rule, especially when the rule conflicts with the Act. Moreover, the citation fails to provide sufficient notice for the public to comment on the Proposal. FIFRA does not authorize the proposed rule.

H. Toxic Substances Control Act, as amended, section 10; 15 U.S.C. § 2609

EPA cites 15 U.S.C. § 2609 under the Toxic Substances Control Act as support for this rule. But that section states only that 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 chapter." It does not allow EPA to *limit* the type of data considered in regulatory decisions, nor does it draw a distinction between dose-response data and other types of data. TSCA does not support the proposed rule. The absence of any such congressional distinction or restriction makes it all the more obvious that EPA invented and added the distinction and restrictions in the Proposal as a matter of its own policy preferences, contrary to the Act. This EPA may not do.

I. No other federal statute supports the Proposal

As EPA is aware, when an agency drafts a proposed rule pursuant to congressionally delegated authority, the exercise of that authority is governed by the informal rulemaking procedures outlined in the Administrative Procedure Act (APA), 5 U.S.C. § 553.5. EPA is required to provide the public with adequate notice of a proposed rule, followed by a meaningful opportunity to comment on the rule's content. 5 U.S.C. § 553 (b)-(c).

The requirement under § 553 to provide the public with adequate notice of a proposed rule is generally achieved through the publication of a notice of proposed rulemaking in the Federal Register, and the APA requires that the notice of proposed rulemaking include "(1) the time, place, and nature of public rulemaking proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)1-3. Generally speaking, the notice requirement of § 553 is satisfied when the agency "affords interested persons a reasonable and meaningful opportunity to participate in the rulemaking process." *Forester v. Consumer Prod. Safety Comm'n*, 559 F.2d 774, 787 (D.C. Cir. 1977).

The Proposal fails to reference any other legal authority to support its adoption. The agency claims its Proposal is "consistent with" Administrative Procedure Act provisions to ensure public participation in the rulemaking process, 83 Fed. Reg. at 18,769/2, but this faint "consistent with" falls far short of any legal authority for the Proposal, or even any claim of such authority. The Administrative Procedure Act provides no authority for the Proposal and, tellingly, EPA does not and cannot identify any authority therein. Even were this "consistent with" claim an attempt by EPA to claim any legal authority for the Proposal, the throw-away

ED_002389_00015391-00041

statement fails to provide sufficient notice for the public to comment on the proposed rule or any asserted legal authority in the APA.

Finally, the Proposal's solicitation of comment—"on whether additional or alternative sources of authority are appropriate bases for this proposed regulation"—does not and cannot itself provide any justification for EPA finalizing a rule based on additional or alternative sources of legal authority. This fails to provide sufficient notice for the public to comment on the proposed rule or any other possible legal authorities. For all these reasons, EPA lacks any basis to finalize a rule invoking any other legal authorities to support its adoption.

J. No case law supports the Proposal

The Proposal "directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773. However, the Proposal fails to identify a single court decision supporting an agency's decision to bar itself from considering relevant studies or information on the grounds that underlying data are not "publicly available in a manner sufficient for independent validation," where such a requirement is not statutorily imposed. Indeed, EPA in the entire Proposal only cites two cases related to this question, and EPA admits, as it must, that *both* cases "upheld EPA's use (sic) non-public data in support of its regulatory actions." *Id.* at 18,769 n.3 (citing *Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010) & *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002)).

Footnote 3 in the Proposal contains two noteworthy, albeit unintended, indictments of the approach proposed by EPA. First, footnote 3 states that "[h]istorically, EPA has not consistently observed the policies underlying this proposal." Tellingly, EPA does not and cannot identify even *one* example in which EPA *has observed* the policies underlying the Proposal. Our research, to the contrary, has identified no instance in which EPA has followed the policies underlying the Proposal, to bar EPA from considering relevant studies or science submitted by the public or gathered by EPA, on the grounds that the underlying data are not "publicly available in a manner sufficient for independent validation."

Second, footnote 3 implies that there are instances where EPA's use of non-public data in support of its regulatory actions was rejected by a court. *See id.* ("courts have *at times* upheld EPA's use (sic) non-public data in support of its regulatory actions.") (emphasis added). Again, the Proposal does not and cannot cite a *single* court decision that failed to uphold use of non-public, relevant science or studies relied on by EPA or any other federal or state agency in support of its regulatory actions. *Id.* Our research also failed to identify a single instance in which a court failed to uphold an agency's use of non-public, relevant science or studies by an agency, after that practice was challenged by commenters or petitioners in court.

Of course, in both the cases that the Proposal cites in footnote 3, the D.C. Circuit Court of Appeals refused to prohibit EPA from considering non-public data. In *American Trucking*, the court declined to "impose a general requirement that EPA obtain and publicize the data underlying published studies on which the Agency relies," holding that the "Clean Air Act

imposes no such obligation." 283 F.3d at 372.[193] The court agreed with EPA that "requiring agencies to obtain and publicize the data underlying all studies on which they rely would be impractical and unnecessary." *Id.* (quoting EPA in Particulate Matter NAAQS, 62 Fed. Reg. at 38,689).

The D.C. Circuit reaffirmed this holding in its 2010 decision, *Coalition of Battery Recyclers*, in which the court reiterated that requiring publication of all data underlying studies would be impractical and unnecessary, and was not required by the Clean Air Act. 604 F.3d at 623. EPA in the Proposal utterly fails to explain or demonstrate why its proposed, self-imposed restriction would be any less impractical or unnecessary than those it previously opposed on these grounds. This failure to explain, failure to offer any convincing counter-proof, and failure to explain the agency's reversal of its positions in *American Trucking* and *Coal. Of Battery Recyclers Ass'n* provide independent grounds for finding EPA's Proposal arbitrary and capricious and an abuse of discretion.

Similarly, the Proposal does not identify *any* case law supporting EPA's claimed ability to "exercise its discretionary authority to establish a policy that would preclude it from using such [non-public] data in future regulatory actions." 83 Fed. Reg. at 18,769 n.3. Our research failed to identify any case in which the courts allowed an agency to categorically bind itself from considering relevant, peer-reviewed science, or otherwise valid studies or evidence, because the underlying data was not made publicly available. *Cf., e.g.*, *Southwest Airlines Co. v. Tr. Sec. Admin.*, 554 F.3d 1065, 1074 (D.C. Cir. 2009) (holding TSA was not required to disclose to airline companies the underlying data file used in a GAO report that informed TSA's calculation of security fees given the nature of the decision—which was industry-wide rather than an adjudicative decision—and the deference given to agency denials of discovery); *Pharm. Research and Mfrs. v. FTC*, 790 F.3d 198, 210–11 (D.C. Cir. 2015) (holding the FTC was not required to disclose the 66 individual filings underlying its decision to target only the pharmaceutical industry in a new rule because the filings were confidential, were used as a general source of background in the rulemaking process, and were exempted from disclosure by statute); *State Corp. Comm'n of Kan. v. FERC*, 876 F.3d 332, 335–36 (D.C. Cir. 2017) (holding FERC was justified in relying on a study used by the agency to assess the benefits of a power facilities merger, even though the study was objected to by Kansas on the grounds that the study was performed by a third party and its results could not be verified by Kansas. The court rejected Kansas's objections to the study because Kansas had access to a redacted electronic version of the study, though not the underlying data; Kansas did not pinpoint a specific reason to question the study, and the study's assumptions and results had been reviewed for reasonability.)

Under some circumstances, the D.C. Circuit has upheld an agency's decision to exclude an individual piece of evidence from the decision-making process. In *API v. EPA*, the D.C. Circuit upheld the EPA's decision to discount a published meta-analysis that ran counter to the rule ultimately adopted. 684 F.3d 1342, 1350 (D.C. Cir. 2012). There, EPA considered the study

---

[193] As we discuss elsewhere in these comments, *infra* sections IV.A. & V.A., the Clean Air Act also contains no *authorization* for EPA to refuse to consider published studies submitted by commenters, or gathered by the agency, unless the data underlying the studies have been published and made available. Certainly, there is no suggestion of any such authorization in the *American Trucking* decision or any other court opinion.

ED_002389_00015391-00043

but discounted its results after "[finding] its methodology wanting." The court found the EPA decision to *discount* the study was not arbitrary and capricious because EPA had not "entirely failed to consider an important aspect of the problem [or] offered an explanation for its decision that runs counter to the evidence before the agency." *Id.* (quoting *North Carolina v. EPA*, 531 F.3d 896, 906 (D.C. Cir. 2008)). Critically, EPA *did* consider the study (unlike the censorship approach in the instant Proposal). Moreover, following consideration, the agency offered specific reasons for not relying on the study, including its disagreements with the methodology. *Id.*

Likewise, the D.C. Circuit found in *Intercollegiate Broadcasting System v. Copyright Royalty Board*, that the Copyright Royalty Board had "properly excluded" from evidence a reference to a survey because the survey itself was not entered into evidence and could not be verified. 796 F.3d 111, 129 (D.C. Cir. 2015). In both cases, the court yielded to an agency's discretion to exclude a particular piece of information where the agency had made an individualized determination about the source. None of these cases support the Proposal's categorical ban on EPA considering relevant data, science, or studies (where data are not "publicly available in a manner sufficient for independent validation"), that have been submitted to the agency and that have not been the subject of any individualized determination that the studies or information are flawed or erroneous.

In its Proposal, EPA proposed to *categorically* ignore and exclude all peer-reviewed research with non-public underlying data, without individually considering each study or offering specific reasons for not relying on that study. The Proposal, by barring consideration of foundational scientific research premised upon non-public data, would result in EPA "fail[ing] to consider an important aspect of the problem." *API*, 684 F.3d at 1350. There is no evidence of a court supporting an agency's decision to exclude entire categories of evidence, or studies or information based on categorical prohibitions like the ones in the Proposal, without considering the source and offering specific reasons for not relying on the study. Instead, both EPA and the Courts have indicated already in *API* and *Coalition of Battery Recyclers*, that a rule like the one EPA is currently proposing is not required by the Clean Air Act and would be both impractical and unnecessary. This Proposal runs counter to the D.C. Circuit's decision in *API* and would render EPA's regulatory actions based on the Proposal arbitrary and capricious and an abuse of EPA's discretion. The Proposal's blanket rule would represent a significant and unlawful departure from D.C. Circuit rulings on agencies' limited discretion to choose the sources it will consider and ignore.

V. The Proposal conflicts with the statutes that EPA administers

The Proposal unlawfully restricts EPA's consideration and use of "dose response data and models that underlie" what the Proposal calls "pivotal regulatory science." 83 Fed. Reg. at 18,770/2. The Proposal goes on to state:

> "Pivotal regulatory science" is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based.

Id. By restricting EPA's implementation of its federal organic statutes and the Administrative Procedures Act in this fashion, and by defining "pivotal regulatory science" in this manner, the Proposal violates federal laws. The Proposal does so by requiring EPA to implement federal laws based on the Proposal's criteria and conception of "pivotal regulatory science," rather than on the congressional criteria and requirements in federal statutes that contradict, disallow, or fail to include those criteria and concepts in the Proposal.

A. Clean Air Act

1. Clean Air Act section 101

In Clean Air Act section 101(b), Congress directs EPA "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population." 42 U.S.C. § 7401(b). The Proposal prevents EPA from doing so by blocking the agency from considering information that also is the best available, peer-reviewed, independent, credible science that could persuade or cause the agency to better protect the "public health and welfare and the productive capacity of [the Nation's] population." In this way, the Proposal thwarts the leading purpose of the Clean Air Act. Clean Air Act section 101 shows the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

2. Clean Air Act section 103

Clean Air Act section 103(a)(1) directs EPA to "conduct, and promote the coordination and acceleration of, research, investigations, experiments, demonstrations, surveys, and studies relating to the causes, effects (including health and welfare effects), extent, prevention, and control of air pollution." 42 U.S.C. § 7403(a)(1). There is nothing in these congressional directives restricting these tasks ("research, investigations, experiments, demonstrations, surveys, and studies") to materials based only on data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). Nor is there any authorization in these congressional directives to distinguish between "research, investigations, experiments, demonstrations, surveys, and studies" that involves "dose response data and models," and science that does not, for imposing regulatory restrictions on what science EPA must consider. The absence of any such congressional restrictions, authorizations or distinctions makes it clear that EPA invented and added the Proposal's limitations and conditions as a matter of its own policy preferences, contrary to the Act. This EPA may not do. Clean Air Act section 103(a)(1) shows that the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

Clean Air Act subsection 103(a)(4) directs EPA to "establish technical advisory committees composed of recognized experts in various aspects of air pollution to assist in the examination and evaluation of research progress and proposals and to avoid duplication of research." 42 U.S.C. § 7403(a)(4). Clean Air Act section 103(a)(5) directs EPA to "conduct and promote coordination and acceleration of training for individuals relating to the causes, effects, extent, prevention, and control of air pollution." *Id.* § 7403(a)(5). There is nothing in these congressional directives restricting these tasks to materials based only on data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). Nor is there any authorization in these congressional directives to distinguish between

research or science that involves "dose response data and models" on the one hand, and science that does not, on the other hand, for imposing regulatory restrictions on what science EPA must consider. The absence of any such congressional restrictions, authorizations, or distinctions makes it clear that EPA invented and added the Proposal's limitations and conditions as a matter of its own policy preferences, contrary to the Act. This EPA may not do. Clean Air Act subsections 103(a)(4) & (5) show that the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

Clean Air Act section 103(b) is significantly titled "*Authorized* Activities of Administrator in Establishing Research and Development Program." 42 U.S.C. § 7403(b) (emphasis added). It states that:

> In carrying out the provisions of the preceding subsection the Administrator is authorized to—
>
> (1)
> collect and make available, through publications and other appropriate <u>means</u>, the results of and other information, including appropriate recommendations by him in connection therewith, <u>pertaining to</u> such research and other activities;
> (2)
> cooperate with other Federal departments and agencies, with air pollution control agencies, with other public and private agencies, institutions, and organizations, and with any industries involved, in the preparation and conduct of such research and other activities;
> (3)
> make grants to air pollution control agencies, to other public or nonprofit private agencies, institutions, and organizations, and to individuals, for purposes stated in subsection (a)(1) of this section;
> (4)
> contract with public or private agencies, institutions, and organizations, and with individuals, without regard to section 3324(a) and (b) of title 31 and section 6101 of title 41;
> (5)
> establish and maintain research fellowships, in the Environmental Protection Agency and at public or nonprofit private educational institutions or research organizations;
> (6)
> collect and disseminate, in cooperation with other Federal departments and agencies, and with other public or private agencies, institutions, and organizations having related responsibilities, basic data on chemical, physical, and biological effects of varying air quality and other information pertaining to air pollution and the prevention and control thereof;
> (7)
> develop effective and practical processes, methods, and prototype devices for the prevention or control of air pollution; and
> (8)

> construct facilities, provide equipment, and employ staff as necessary to carry out this chapter.

Id. There is nothing in these congressional directives restricting these tasks, research or data to materials based only on data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). Nor is there any authorization in these congressional directives to distinguish between research, science, data, or models that involves "dose response data and models" on the one hand, and science that does not, on the other hand, for imposing regulatory restrictions on what science EPA must consider. The absence of any such congressional restrictions, authorizations or distinctions makes it clear that EPA invented and added the Proposal's limitations and conditions as a matter of its own policy preferences, contrary to the Act. This EPA may not do. Clean Air Act subsections 103(b) shows that the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

Clean Air Act section 103(d) addresses Environmental Health Effects Research:

> **(1)** The Administrator, in consultation with the Secretary of Health and Human Services, shall conduct a research program on the short-term and long-term effects of air pollutants, including wood smoke, on human health. In conducting such research program the Administrator—
> **(A)**
> shall conduct studies, including epidemiological, clinical, and laboratory and field studies, as necessary to identify and evaluate exposure to and effects of air pollutants on human health;
> **(B)**
> may utilize, on a reimbursable basis, the facilities of existing Federal scientific laboratories and research centers; and
> **(C)**
> shall consult with other Federal agencies to ensure that similar research being conducted in other agencies is coordinated to avoid duplication.

42 U.S.C. § 7403(d). There is nothing in these congressional directives restricting these tasks, research, studies or data to materials based only on data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). Nor is there any authorization in these congressional directives to distinguish between research, science, data or models that involves "dose response data and models" on the one hand, and science that does not, on the other hand, for imposing regulatory restrictions on what science EPA must consider. The absence of any such congressional restrictions, authorizations, or distinctions makes it clear that EPA invented and added the Proposal's limitations and conditions as a matter of its own policy preferences, contrary to the Act. This EPA may not do. Clean Air Act subsection 103(d) shows that the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

Clean Air Act subsection 103(d)(2) directs "[i]n conducting the research program under this subsection, the Administrator shall develop methods and techniques necessary to identify and assess the risks to human health from both routine and accidental exposures to individual air pollutants and combinations thereof." 42 U.S.C. § 7403(d)(2). Subsection 103(d)(2) then says,

"such research program shall include the following elements," listing subsections (A)-(C). *Id.* Subsection 103(d)(2)(B) & (C) are especially relevant and revealing:

> (B) An evaluation, within 12 months after November 15, 1990, of each of the hazardous air pollutants listed under section 7412(b) of this title, to decide, *on the basis of available information*, their relative priority for preparation of environmental health assessments pursuant to subparagraph (C). The evaluation *shall be based on reasonably anticipated toxicity to humans and exposure factors* such as frequency of occurrence as an air pollutant and volume of emissions in populated areas. Such evaluation shall be reviewed by the Interagency Task Force established pursuant to subparagraph (A).
>
> (C) Preparation of environmental health assessments for each of the hazardous air pollutants referred to in subparagraph (B), beginning 6 months after the first meeting of the Interagency Task Force and to be completed within 96 months thereafter. *No fewer than 24 assessments shall be completed and published annually.* The assessments shall be prepared in accordance with guidelines developed by the Administrator in consultation with the Interagency Task Force and the Science Advisory Board of the Environmental Protection Agency. Each such assessment shall include—
>
> (i) an examination, summary, and evaluation of *available toxicological and epidemiological information for the pollutant to ascertain the levels of human exposure which pose a significant threat to human health and the associated acute, subacute, and chronic adverse health effects*;
> (ii) a determination of gaps in *available information related to human health effects and exposure levels*; and
> (iii) where appropriate, an identification of additional activities, including toxicological and inhalation testing, needed to identify the types or levels of exposure which may present significant risk of adverse health effects in humans.

42 U.S.C. § 7403(d)(2)(B) & (C) (emphases added).

There is nothing in these congressional directives restricting these tasks, research, studies or data to materials based only on data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). Nor is there any authorization in these congressional directives to distinguish between research, science, data, or models that involves "dose response data and models" on the one hand, and science that does not, on the other hand, for imposing regulatory restrictions on what science EPA must consider. The absence of any such congressional restrictions, authorizations, or distinctions makes it clear that EPA invented and added the Proposal's limitations and conditions as a matter of its own policy preferences, contrary to the Act. This EPA may not do. Clean Air Act subsection 103(d)(2) shows that the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

Equally damning for the Proposal, when Congress directs EPA to evaluate pollutants and their health effects, Congress uses broad and capacious terms:

- "on the basis of available information" (§ 103(d)(2)(B), 42 U.S.C. § 7403(d)(2)(B));

- "available toxicological and epidemiological information for the pollutant to ascertain the levels of human exposure which pose a significant threat to human health and the associated acute, subacute, and chronic adverse health effects" (§ 103(d)(2)(C)(i), 42 U.S.C. § 7403(d)(2)(C)(i)); and
- "available information related to human health effects and exposure levels" (§ 103(d)(2)(C)(ii), 42 U.S.C. § 7403(d)(2)(C)(ii)).

These instructions to EPA are prefaced with the mandatory language, "[s]uch research program *shall include* the following elements." (§ 103(d)(2), 42 U.S.C. § 7403(d)(2)). Congress went out of its way *not* to authorize EPA to ignore "available toxicological and epidemiological information" to ensure that the agency would be "ascertain[ing] the levels of human exposure which pose a significant threat to human health and the associated acute, subacute, and chronic adverse health effects." (§ 103(d)(2)(C)(i), 42 U.S.C. § 7403(d)(2)(C)(i)).

This shows clear congressional concern with all available science related to human health effects from air pollution—not some restricted, politicized subset of science where underlying, confidential data are "publicly available in a manner sufficient for independent validation." Clean Air Act subsection 103(d)(2) shows that the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

When Congress directs EPA to conduct an ecosystem research program in subsection 103(e), Congress says that such program "shall include" "[e]valuation of risks to ecosystems exposed to air pollutants, including characterization of the causes and effects of chronic and episodic exposures to air pollutants and determination of the reversibility of those effects." 42 U.S.C. § 7403(e). Subsections (e)(3)-(e)(6) address other effects on water quality, crops, soils, and other elements of ecosystems.

There is nothing in these congressional directives restricting these tasks, research, studies, or data to materials based only on data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). Nor is there any authorization in these congressional directives to distinguish between research, science, data, or models that involves "dose response data and models" on the one hand, and science that does not, on the other hand, for imposing regulatory restrictions on what science EPA must consider. The absence of any such congressional restrictions, authorizations, or distinctions makes it clear that EPA invented and added the Proposal's limitations and conditions as a matter of its own policy preferences, contrary to the Act. This EPA may not do. Clean Air Act subsection 103(e) shows that the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

3. Clean Air Act section 108

In section 108(a)(2), Congress required air quality criteria for air pollutants to "*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," CAA § 108(a)(2), 42 U.S.C. § 7408(a)(2) (emphases added). In *American Trucking v. Whitman*, 531 U.S. at 457, the Supreme Court said that NAAQS must be based on "published air quality criteria that reflect the latest scientific knowledge."

The Proposal violates these statutory requirements by prohibiting EPA from considering available science to discharge the agency's statutory responsibility to "protect the public health," with "an adequate margin of safety." CAA § 109(b)(1), 42 U.S.C. § 7409(b)(1). The Proposal does this by subverting and supplanting the congressional criteria in CAA § 108(a)(2), 42 U.S.C. § 7408(a)(2) with a restrictive standard driven by whether raw data are "publicly available in a manner sufficient for independent validation," 83 Fed. Reg. at 18,773/2 (proposed § 30.1).

With this unlawful maneuver, the Proposal prevents EPA from adopting air quality criteria that "*accurately reflect* the *latest* scientific knowledge *useful in indicating* the kind and extent of *all identifiable effects* on public health or welfare." CAA § 108(a)(2), 42 U.S.C. § 7408(a)(2) (emphases added). First, the Proposal thwarts the congressional directives for "accurate[] reflection" of the "latest scientific knowledge." It does so by compelling or allowing EPA to ignore the "latest scientific knowledge," and to fail to "accurately reflect" that science, if raw data are not "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1).

Moreover, the Proposal thwarts the congressional directives for science that is "*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." CAA §108(a)(2), 42 U.S.C. § 7408(a)(2) (emphases added). It does so, again, by compelling or allowing EPA to ignore the "latest scientific knowledge," and to fail to accurately reflect that science, if raw data are not "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1).

Further, section 208 contains the mandatory term "shall"—which does not give the agency latitude. It does not matter if that "scientific knowledge" is "publicly available" in the way EPA contemplates in the Proposal, it must simply inform the effects of air pollution on public health or welfare. Further, *American Trucking* considered the requirements of this section and specifically concluded that "the Clean Air Act imposes no" "general requirement that EPA obtain and publicize the data underlying published studies on which the Agency relies." 283 F.3d at 372.

In these statutory provisions, obviously there is no mention of the necessity, or even relevance, of raw data being "publicly available in a manner sufficient for independent validation" before EPA must consider studies based on that data. Equally plain, there is no authorization for EPA to fail to "accurately reflect" that science when issuing air quality criteria.

There is nothing in these congressional directives restricting EPA's responsibilities, or the research, studies, or data it must consider, to materials based only on data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). Nor is there any authorization in these congressional directives to distinguish between research, science, data, or models that involve "dose response data and models" on the one hand, and science that does not, on the other hand, for imposing regulatory restrictions on what science EPA must consider. The absence of any such congressional restrictions, authorizations, or distinctions makes it clear that EPA invented and added the Proposal's limitations and conditions

as a matter of its own policy preferences, contrary to the Act. This EPA may not do. Clean Air Act subsection 108(a) shows that the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

4. Clean Air Act section 109

The Proposal also violates section 109 of the Clean Air Act and contravenes the Supreme Court decision in *American Trucking v. Whitman*. The Proposal's conception of "pivotal regulatory science" turns on, among other things, "analyses that drive the magnitude of the benefit-cost calculation," and "studies, models and analyses" that are "critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based." 83 Fed. Reg. at 18,770/2; *id.* at 18,773/2 (proposed § 30.2 (*dose response data and models*)). Clean Air Act section 109(b)(1) requires EPA to promulgate or revise health-based national ambient air quality standards that are "requisite to protect the public health," "allowing an adequate margin of safety." 42 U.S.C. § 7409(b)(1).

As noted, in *American Trucking v. Whitman*, a unanimous Supreme Court said that NAAQS must be based on "published air quality criteria that reflect the latest scientific knowledge." 531 U.S. at 457. Moreover, the Court held that Clean Air Act section "109(b), interpreted in its statutory and historical context and with appreciation for its importance to the CAA as a whole, unambiguously bars cost considerations from the NAAQS-setting process." 531 U.S. at 471. The Court also squarely rejected arguments appealing to statutory language concerning "adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance" of NAAQS. The justices made clear such language and concerns have "no bearing upon whether cost considerations are to be taken into account in formulating the standards." *Id.*

The Proposal violates Clean Air Act section 109(b)(1) and the governing Supreme Court interpretation in *American Trucking* by purporting to allow the "magnitude of a benefit-cost calculation" and "quantified costs and benefits" to impact or govern (1) EPA's consideration of peer-reviewed science relevant to reviewing, setting or revising health-based NAAQS; and (2) EPA's review, revision or establishment of health-based NAAQS. This is unlawful.

Clean Air Act sections 109(b)(1), (2), & (c) require EPA to protect Americans' "public health" with an adequate margin of safety, and America's "welfare" from "any known or anticipated adverse effect." 42 U.S.C. § 7409(b)(1), (2) & (c). The Proposal prevents EPA from doing so by blocking the agency from considering information that also is the best available, peer-reviewed, independent, credible science that could persuade or cause the agency to better protect Americans' public health and welfare, based on the statutory criteria in section 109. In this way, the Proposal thwarts the central role and fundamental right to health-based air quality standards under the Clean Air Act. Clean Air Act section 109 shows the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

5. Clean Air Act section 111

Clean Air Act section 111(a)(1) defines a standard of performance as:

> a standard for emissions of air pollutants which reflects the degree of emission limitation *achievable* through the application of the *best system of emission reduction* which (taking into account the cost of achieving such reduction and any nonair quality *health and environmental* impact and energy requirements) the Administrator determines has been *adequately demonstrated.*

42 U.S.C. 7411(a)(1) (emphases added). There is nothing in these congressional directives restricting EPA's establishment of "standards of performance," or its determinations of "achievability" or "best system of emission reduction" or "adequate demonstration," to information based only on data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). Nor is there any authorization in these congressional directives to distinguish between research, science, data, or models involving "dose response data and models" on one hand, and science that does not, on the other hand, for imposing regulatory restrictions on what science EPA must consider.

EPA cannot fulfill the congressional directive to establish the "best system of emission reduction" if EPA is artificially and unlawfully restricting its consideration of data and information to those that are "publicly available in a manner sufficient for independent validation." *Id.* Nor may EPA fulfill the "adequately demonstrated" directive if systems of emission reduction that have been adequately demonstrated require EPA to consider data, science, or information that are not "publicly available in a manner sufficient for independent validation." *Id.*

Clean Air Act section 111(b)(1)(A) requires EPA to establish a list of stationary sources to be subject to section 111 standards of performance:

> [The Administrator] shall include a category of sources in such list if in his judgment it causes, or contributes significantly to, air pollution *which may reasonably be anticipated to endanger public health or welfare.*

42 U.S.C. 7411(b)(1)(A) (emphasis added). There is nothing in the Act restricting EPA's consideration of which categories of sources "may reasonably be anticipated to endanger public health or welfare" to information based only on data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). There is no indication of congressional intent that what "may reasonably be anticipated to endanger public health or welfare" may be modified or constrained by ignoring science and data concerning endangerment if that information is not "publicly available in a manner sufficient for independent validation."

The absence of any such congressional restrictions, authorizations, or distinctions concerning what EPA may consider makes it clear that EPA invented and added the Proposal's limitations and conditions as a matter of its own policy preferences, contrary to the Act. This EPA may not do. Clean Air Act subsections 111(a)(1) and 111(b)(1)(A) show that the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

ED_002389_00015391-00052

6. Clean Air Act Section 112

Clean Air Act Section 112(b) provides a list of toxic air pollutants for which industrial sources must limit their emissions. The statute then directs the Administrator to periodically review that list of hazardous air pollutants and, where appropriate, revise this list by rule. In particular, the Administer is directed to add pollutants which:

> present, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects (including, but not limited to, substances which are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise, but not including releases subject to regulation under subsection (r) as a result of emissions to the air.

42 U.S.C. § 7412(b)(2). There is nothing in these congressional directives restricting EPA's establishment of this list nor of the pollutants that should be added to it based only on data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). Nor is there any authorization in these congressional directives to distinguish between research, science, data, or models involving "dose response data and models" on one hand, and science that does not, on the other hand, for imposing regulatory restrictions on what science EPA must consider.

EPA cannot fulfill the congressional directive to establish section 112(b)(2)'s pollutant list if the agency is artificially and unlawfully restricting its consideration of data and information to those that are "publicly available in a manner sufficient for independent validation." *Id.* Nor will EPA be able to fully analyze pollutants for inclusion on this list if determining inclusion would require EPA to consider data, science or information that are not "publicly available in a manner sufficient for independent validation." *Id.*

Similarly, Section 112(b)(3) lays out a petition process to add chemicals to the Section 112 list that similarly require the petitioner to submit to EPA proof that "the substance is an air pollutant and that emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects." 42 U.S.C. § 7412(b)(3)(B). Here, the straightjacket that the Proposal would place on this statutory language would similarly prevent the agency from carrying out its statutory directive.

Section 112(b)(3)(C) provides criteria for *de*listing pollutants from the list. This section would nonetheless be hamstrung if the agency were limited exclusively to data that are "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,773/2 (proposed § 30.1). Nor is there any authorization in the section's congressional directives to distinguish between research, science, data, or models involving "dose response data and models" on one hand, and science that does not, on the other hand, for purposes of listing or delisting pollutants from section 112's hazardous pollutant list.

ED_002389_00015391-00053

Nearly every subsection of Section 112, including standards for major and area sources, reporting requirements, and accidental release provisions, touch on protecting "public health," weighing "risks," or assessing how "hazardous" a "substance" or "pollutant" may be. EPA cannot fulfill the congressional directives of any of these sections if the agency is artificially and unlawfully restricting its consideration of data and information to those that are "publicly available in a manner sufficient for independent validation." *Id.* Nor will EPA be able to fully analyze risks to or impacts on human health and set section 112 standards accordingly if making such determinations would require EPA to consider data, science, or information that are not "publicly available in a manner sufficient for independent validation." *Id.*

The absence of any such congressional restrictions, authorizations, or distinctions concerning what EPA may consider makes it clear that EPA invented and added the Proposal's limitations and conditions as a matter of its own policy preferences, contrary to the Act. This EPA may not do. Clean Air Act section 112 makes exceedingly clear that the Proposal is arbitrary and capricious and an abuse of EPA's discretion.

The sections listed above merely represent a sampling of some examples in Title 1 of the Act that exemplify the extent to which the Proposal is arbitrary, capricious, an abuse of EPA's discretion, and a violation of clear congressional directives. The Act's five other Titles are no different, and the list provided here is not exhaustive—the Clean Air Act is rife with examples of statutory language that the Proposal would distort with its adherence to data that are "publicly available in a manner sufficient for independent validation" 83 Fed. Reg. at 18,773/2 (proposed § 30.1) and research, science, data, or models involving "dose response data and models."

B. Clean Water Act

The Proposal, if adopted, would imperil the effective implementation of the Clean Water Act. Several provisions of the Act direct EPA to consider a range of data in promulgating regulations to effectuate its goals, and the development of these regulations would be hamstrung by the Proposal's restrictions on considering valid scientific evidence. As discussed in these comments, identifying and excluding valid scientific evidence is time- and resource-intensive and has not been demonstrated to improve the quality of the science EPA considers or its science-based decisions. Accordingly, applying the proposed limitations to the myriad of regulatory decisions the agency is supposed to make would be a recipe for complete paralysis on multiple fronts under the Clean Water Act. Some examples of the water regulations that could be adversely affected by the far-reaching the Proposal follow.

Under sections 301 and 304, EPA must develop effluent limitation guidelines, setting out nationally-applicable pollution discharge standards for various industries. These ELGs "identify, in terms of amounts of constituents and chemical, physical, and biological characteristics of pollutants, the degree of effluent reduction attainable through the application of [particular levels of pollution control stringency] for classes and categories of point sources . . . ." 33 U.S.C. § 1314(b)(1)(A). EPA is to specify the factors used to determine the controls to be used, including "the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, the cost of achieving such effluent reduction, non-water quality environmental impact (including energy

requirements), and such other factors as the Administrator deems appropriate . . . ." *Id.* § 1314(b)(1)(B). Making these judgments and formulating the proper control levels that industrial dischargers must meet will obviously depend on data collected about the processes used in a given industry, control technology performance, cost, and energy use, among other things.

Under section 303, the Act charges EPA with issuing initial water quality standards for states that fail to submit their own, and with developing such standards if EPA determines submitted standards are not consistent with the Act. *Id.* § 1313(b). Congress required these standards to take account of a wide range of evidence, and the Proposal would therefore curtail EPA's actions pursuant to the Act. Specifically, standards:

> shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this chapter. Such standards shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation.

Id. § 1313(c)(2)(A).

In addition, section 303's water quality standards process illustrates a hypocritical element of the Proposal. When states develop water quality standards, they must submit to EPA "[g]eneral information which will aid the Agency in determining the adequacy of the scientific basis of the standards," 40 C.F.R. § 131.6(f), and EPA's review of such a submission considers "[w]hether the State standards . . . are based upon appropriate technical and scientific data and analyses," *id.* § 131.5(a)(4), such that states can consider a wide range of information in establishing standards and EPA's review of the states' standards looks simply to whether the information on which they are based is "appropriate." By contrast, if EPA were obliged to develop standards for a state (either because of a failure to submit or an inadequate submission), the Proposal would require EPA to consider a much more limited universe of information.

Pursuant to section 307 of the Act, EPA may issue category-wide effluent standards for listed toxic pollutants that go beyond the minimum level of control the Act mandates. These more stringent standards "shall take into account the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms, the nature and extent of the effect of the toxic pollutant on such organisms, and the extent to which effective control is being or may be achieved under other regulatory authority." Further, "[a]ny effluent standard promulgated under this section shall be at that level which the Administrator determines provides an ample margin of safety." 33 U.S.C. § 1317(a)(4). Obviously, it takes a substantial effort for EPA to assess these various factors and determine what level of pollution is acceptable, with an "ample margin of safety," and to do so for numerous categories of dischargers (multiplied by numerous different toxic pollutants). If EPA adopts the Proposal, it would make each element of this analysis that much more cumbersome and difficult, and thus make it harder for EPA to effectively protect the public from toxic pollution.

ED_002389_00015391-00055

Section 311 includes a further example of the kinds of regulatory analyses into which the Proposal would inject confusion and administrative burden. That section charges EPA with issuing "regulations designating as hazardous substances, other than oil as defined in this section, such elements and compounds which, when discharged in any quantity into . . . [various water resources] present an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches." 33 U.S.C. § 1321(b)(2)(A). Indeed, answering these kinds of questions seems particularly likely to be undermined by the Proposal, as data relevant to determining the conditions under which hazardous substances may be an "imminent and substantial danger" could well come from prior accidental releases that could fail the Proposal's "reproducibility" trigger.

The foregoing examples are merely illustrative. The Clean Water Act imposes numerous regulatory duties on EPA, and the Proposal threatens to make carrying out those obligations harder. The Act's foundational purpose—"to restore and maintain the chemical, physical, and biological integrity of the Nation's waters," 33 U.S.C. § 1251(a)—would thus be ill-served by finalizing the Proposal.

C. Safe Drinking Water Act

The Safe Drinking Water Act (SDWA) protects the nation's public drinking water supplies. The Act generally applies to "each public water system in each State," 42 U.S.C. § 300g, and requires EPA to set standards for drinking water contaminants that may have an adverse effect on human health and are known or anticipated to occur in such systems, *id.* § 300g-1(b)(1)(A).

For a given contaminant, the SDWA requires that EPA first establish a Maximum Contaminant Level Goal (MCLG), which is "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." *Id.* § 300g-1(b)(4)(A). EPA must then set a Maximum Contaminant Level (MCL) "as close to the [MCLG] as is feasible." *Id.* § 300g-1(b)(4)(B).

EPA also must, every five years, "publish a list of contaminants" that "are not subject to any proposed or promulgated national primary drinking water regulation, which are known or anticipated to occur in public water systems, and which may require regulation . . . ." *Id.* § 300g-1(b)(1)(B)(i). The SDWA requires EPA to prioritize that list based on vulnerable subpopulations that are at risk and other factors. *Id.* § 300g-1(b)(1)(C). EPA must then decide whether to regulate at least five contaminants on the list based on the "best available public health information." *Id.* § 300g-1(b)(1)(B)(ii).

In making these determinations, the SDWA requires EPA to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices," 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)." *Id.* § 300g-1(b)(3)(A); *see also id.* § 300g-1(b)(12), (13) (similar); *id.* § 300j-19 (referring to best available science standard for risk assessment of algal toxins).

ED_002389_00015391-00056

The Proposal would conflict with the SDWA by prohibiting EPA from using the "best available" science and "data collected by acceptable or best available methods" solely because that data could not be made public. Indeed, courts interpreting these requirements have already rejected this proposed limitation on dose-response studies, making clear that they can indeed be the "best available" science regardless of whether the underlying data are publicly available. In *City of Waukesha v. EPA*, the court approved EPA's use of "studies of Hiroshima and Nagasaki atomic bomb survivors" in setting limits for radium and uranium in drinking water. 320 F.3d 228, 248, 252 (D.C. Cir. 2003). But of course, these and similar studies would likely be excluded under the Proposal because the underlying data are not available.[194] The court also upheld the agency's use of the linear, non-threshold (LNT) model used by EPA for both radium and uranium, *id.* at 249–50, 252, which is precisely the model that EPA now implies—without citing any evidence—is not scientifically justified.

Additionally, in carrying out its obligations to establish drinking water standards, the Act directs the agency to discuss "peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data." 42 U.S.C. § 300g-1(b)(3)(b)(v). Moreover, the agency must identify the "[q]uantifiable and non-quantifiable benefits for which there is a factual basis in the rulemaking record" in establishing a drinking water standard. Thus, under the express provisions of the SDWA, the agency cannot simply ignore peer-reviewed studies or other factual information in the record that the Proposed Rule would disallow from consideration, simply because the underlying data may be unavailable. *Id.* § 300g-1(b)(3)(c)(i).

If Congress had intended for the data targeted by the Proposal to be excluded, it could have said so. Instead, Congress directed EPA to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices," and "data collected by accepted methods or best available methods." 42 U.S.C. § 300g-1(b)(3)(A). EPA cannot ignore these commands to achieve its political goal of rolling back public health protections.

D. Resource Conservation and Recovery Act

Under the Resource Conservation and Recovery Act (RCRA), EPA regulates the generation, transportation, treatment, storage, and disposal of hazardous waste. EPA must develop, and revise from time to time, "criteria for identifying the characteristics of hazardous waste" and "for listing hazardous waste" that should be subject to regulation, "taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics." 42 U.S.C. § 6921(a). EPA also must, in cooperation with Agency for Toxic Substances and Disease Registry (ATSDR) and the National Toxicology Program, "identify or list those hazardous wastes" which must be subject to regulation because they contain "certain constituents (such as identified carcinogens, mutagens, or terat[o]gens) at levels in excess of

---

[194] For a description of the studies, *see* Kotaro Ozasa, *Epidemiological research on radiation-induced cancer in atomic bomb survivors*, Journal of Radiation Research, Volume 57, Issue S1, 1 August 2016, Pages i112–i117, https://academic.oup.com/jrr/article/57/S1/i112/2580473.

ED_002389_00015391-00057

levels which endanger human health." *Id.* § 6921(b)(1). Likewise, EPA must promulgate regulations establishing standards applicable to generators and transporters of hazardous waste, and owners and operators of hazardous waste treatment, storage, and disposal facilities, "as may be necessary to protect human health and the environment." *Id.* §§ 6922(a), 6923(a), 6924(a); *see also id.* § 6924(b), (d), (g).

The Proposal conflicts with RCRA's statutory mandate. RCRA requires EPA to evaluate and regulate hazardous waste based on whether it will endanger human health and the environment, while the Proposal allows EPA to disregard relevant science simply because the underlying data cannot be made public. Under RCRA, EPA cannot ignore studies for that reason. Thus, the Proposal violates RCRA.

E. Comprehensive Environmental Response, Compensation, and Liability Act

Under CERCLA, EPA has power to clean up sites that are contaminated with hazardous substances, and to assure that responsible parties pay for such clean up. CERCLA requires EPA to issue regulations that identify hazardous substances that "present substantial danger to the public health or welfare or the environment," and that specify the quantities of such substances that trigger the Act's notification requirements. 42 U.S.C. § 9602(a). The Proposal contradicts this statutory mandate because it allows EPA to arbitrarily exclude some studies solely because the underlying data cannot be made public. Under the statute, EPA is required to use *all* relevant studies in determining whether a substance presents a substantial danger to people or the environment.

CERCLA also requires the President to promulgate and revise the National Contingency Plan for the removal of hazardous substances. *Id.* § 9605(a), (b). The President has delegated that authority to EPA. Exec. Order No. 12580, 52 Fed. Reg. 2923 (1987); Exec. Order No. 12777, 56 Fed. Reg. 54757. The Plan must include criteria for determining priorities "based upon relative risk or danger to public health or welfare or the environment," taking into account enumerated factors. 42 U.S.C. § 9605(a)(8)(A). The Proposal conflicts with this section because it would direct EPA to disregard relevant studies solely because the underlying data could not be made public, even if those studies shed light on the enumerated factors.

CERCLA's non-rulemaking provisions also show that Congress did not intend for studies to be excluded from consideration simply because the underlying data cannot be made public. For example, CERCLA authorizes the President to address hazardous substance releases that pose an "imminent and substantial danger to the public health or welfare," and to "undertake such investigations, monitoring, surveys, testing, and other information gathering" as necessary to determine "the extent of danger to the public health or welfare or to the environment." *Id.* § 9604(a), (b). This shows that Congress's purpose in enacting CERCLA was to address the serious public health and environmental threats of hazardous substance releases. That purpose would be undermined if EPA could refuse to consider relevant studies only because the underlying data cannot be made public.

EPA also has co-responsibility with the ATSDR to establish a registry of diseases relating to toxic substance exposure, as well as to create a list of hazardous substances found at

ED_002389_00015391-00058

Superfund sites, prepare a toxicological profile of those substances, and determine whether adequate information on the health effects of those substances exists. *Id.* § 9604(i). The statute specifically lists the types of studies and data that should be considered in determining whether adequate information exists and assessing the need for further research. *Id.* § 9604(i)(5); *see also id.* § 9604(i)(13). The statute does not exclude studies whose underlying data cannot be made public. In short, the Proposal contradicts both the statutory language and the purpose of CERCLA.

F. Emergency Planning and Community Right-to-Know Act

EPCRA establishes requirements for state and local emergency planning and reporting on hazardous chemicals. It requires EPA to publish a list of extremely hazardous substances and set, by regulation, a threshold planning quantity for each substance on the list. 42 U.S.C. § 11002(a). "Any revisions to the list shall take into account the toxicity, reactivity, volatility, dispersability, combustability, or flammability of a substance." *Id.* § 11002(a)(4). Notably, in defining the criteria that EPA must consider for the list, EPCRA affirmatively directs EPA to consider the toxicity of the substance, among other things, and says nothing about excluding relevant studies for the reasons stated in the Proposal.

EPCRA also contains reporting requirements for owners or operators who manufacture, process, or use hazardous chemicals. *Id.* § 11023. EPA "may by rule add or delete a chemical from the list" of covered chemicals if there is sufficient evidence that the "chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects" or if the "chemical is known to cause or can reasonably be anticipated to cause in humans . . . cancer or teratogenic effects, or . . serious or irreversible . . . reproductive dysfunctions[,] neurological disorders[,] heritable genetic mutations[,] other chronic health effects." *Id.* § 11023(d). A chemical can also be added if it "is known to cause or can reasonably be anticipated to cause . . . a significant adverse effect on the environment of sufficient seriousness" due to its toxicity. *Id.* Of critical importance here, this determination "shall be based on generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, available to the Administrator." *Id.*

The Proposal directly conflicts with EPCRA's requirement to use "generally accepted scientific principles or laboratory tests," or "appropriately designed and conducted epidemiological or other population studies." *See id.* § 11023(d). As explained throughout these comments, there is no reason the underlying data must be public for these tests and studies to be "generally accepted" or "appropriated designed and conducted." Thus, the Proposal is—on its face—contrary to EPCRA's mandate that EPA use these tests and studies when making determinations under the statute.

G. Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA requires that all pesticides distributed or sold in the United States be registered by EPA. EPA cannot register pesticides that would cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a. Likewise it may "by regulation" limit the distribution, sale or use of a pesticide to prevent "unreasonable adverse effects on the environment," *id.* § 136a(a), and

ED_002389_00015391-00059

must cancel the registration of pesticides that cause such "unreasonable adverse effects." *Id.* § 136d. The term "unreasonable adverse effects on the environment" is defined to include unreasonable risks to human health, and dietary risks that violate the standard for pesticide residues under the Food, Drug and Cosmetic Act. *Id.* § 136(bb). Given that registration decisions often depend heavily on dose-response data and models, EPA must clarify whether the Proposal will apply to registration and registration review decisions. If so, the Proposal conflicts with FIFRA's requirement that EPA determine whether pesticides proposed for registration would have unreasonable adverse effects on the environment. In light of that language, EPA cannot exclude relevant studies bearing on a pesticide's effect on human health or the environment simply because the underlying data cannot be made public.

The potential applicability of the Proposal to exclude consideration of epidemiological studies of the health impacts of pesticides where the underlying data cannot be made public also highlights the logical inconsistency and arbitrary approach in the embodied proposed rule. On the one hand, the Proposal appears to be intended to prohibit consideration of such public health studies, but on the other hand seems to envision that industry-conducted studies and models claimed to include confidential business information would be allowed to be considered. This highlights the arbitrary and one-sided nature of the Proposal, and the clear underlying intent, which is to undermine public health protections for the benefit of industry.

Regardless of whether the Proposal applies to registration decisions, it conflicts with FIFRA in other ways. FIFRA directs EPA, when promulgating rules, to "take into account the difference in concept and usage between various classes of pesticides, including public health pesticides, and differences in environmental risk and the *appropriate data for evaluating such* risk between agricultural, nonagricultural, and public health pesticides." *Id.* § 136w(a) (emphasis added); *see also id.* § 136w(c) (setting forth some examples of rules EPA may promulgate under FIFRA). EPA may not exclude "appropriate data" in these regulatory decisions simply because those data cannot be made public. Thus, the Proposal conflicts with FIFRA.

Finally, EPA has violated FIFRA's procedural requirements. FIFRA requires EPA to provide the Scientific Advisory Panel and the Secretary of Agriculture with a copy of the Proposal at least 60 days before publication in the Federal Register. *Id.* § 136w(a)(2), (d). Any notification to the Secretary must be published in the Federal Register. *Id.* § 136w(a)(2)(D). There is no evidence in the Proposal that EPA followed these procedural requirements. (EPA also must provide the Panel and the Secretary a copy of the final rule 30 days before publication in the Federal Register. *Id.* § 136w(a)(2), (d).) Similarly, EPA must furnish a copy of the proposed and final regulation to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate. *Id.* § 136w(a)(3). Again, there is no evidence this occurred.

H. Toxic Substances Control Act

Under TSCA, EPA has broad authority to protect the public from harm from chemical substances and mixtures. TSCA authorizes EPA to issue regulations designed to gather information on, require testing of, and control exposure to chemical substances and mixtures.

ED_002389_00015391-00060

EPA must restrict or ban any chemical substance that presents an unreasonable risk of injury to human health or the environment. *See, e.g.*, 15 U.S.C. §§ 2603, 2604, 2605.

TSCA contains specific provisions regarding EPA's use and consideration of science in rulemakings. "In carrying out sections 2603, 2604, and 2605," EPA must "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science." *Id.* § 2625(h). EPA must further consider the following:

(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.

Id. After consideration of these matters, EPA must make decisions "based on the weight of the scientific evidence." *Id.*

In short, EPA must examine the reliability of a study on a case-by-case basis by weighing several indicators of scientific validity. Noticeably absent from Congress's enumerated factors in § 2625(h) is whether the underlying data can be made available to the public. While § 2625(h)(4) provides that EPA should take into account "the extent of independent verification or peer review" of scientific information, this language indicates that peer review of a study could provide sufficient assurance of its reliability even without additional verification.

TSCA further directs EPA to make available to the public, among other things, "a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies" and "each designation of a chemical substance . . . along with an identification of the information, analysis, and basis used to make the designations." *Id.* § 2625(i). Again, the statute, despite calling out specific information to be made publicly available, does not state that the *underlying data* for these studies must be made publicly available. Thus, the rule is flatly inconsistent with TSCA.

ED_002389_00015391-00061

Finally, even if it were not already clear from the above provisions that EPA cannot bar consideration of studies as provided in the Proposal, TSCA also states that EPA "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." *Id.* § 2625(k). EPA has defined "reasonably available" to mean "information that EPA possesses or can reasonably generate, obtain and synthesize for use . . . for prioritization and risk evaluation. Information that meets such terms is reasonably available information whether or not the information is confidential business information that is protected from public disclosure under 15 U.S.C. 2613." 40 C.F.R. § 702.3. Thus, if the studies covered by the rule are "reasonably available" to EPA, the agency must consider them, regardless of whether the raw data can be made public. EPA cannot create a double standard where studies withheld from the public as confidential business information must be considered but studies for which the underlying data cannot be made publicly available cannot be considered. *See infra* section X. The Proposal is unlawful under TSCA and cannot be promulgated.

I. Food Quality Protection Act (or Food, Drug, and Cosmetics Act)

The Food Quality Protection Act (also known as the Food, Drug, and Cosmetics Act or FFDCA) governs pesticide tolerances. Section 408 of the FFDCA requires EPA to set tolerances, which are maximum residue limits, for pesticide residues on foods. In setting tolerances, EPA must find that the tolerance is "safe." 21 U.S.C. § 346a. Safe is defined as meaning that there is a "reasonable certainty that no harm will result from aggregate exposure to the pesticide residue." *Id.* § 346a(b)(2)(a)(ii). To make this finding, EPA considers, among other things: the toxicity of the pesticide and its break-down products, aggregate exposure to the pesticide in foods and from other sources of exposure, and any special risks posed to infants and children. *Id.* § 346a(b). For threshold effects, EPA is required to add an additional tenfold margin of safety to protect infants and children, unless the administrator finds based on reliable data that a different safety factor will ensure the pesticide is safe. *Id.* § 346a(b)(2)(C)(ii). The statute contains specific provisions regarding the type and availability of data that must be considered. *Id.* § 346a(b)(2)(D), (E), (F).

The Proposal does not cite to the FFDCA, and apparently EPA never considered whether the Proposal is consistent with the law. It is not. First, the Act defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii). As part of this determination, EPA must "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure." *Id.* § 346a(b)(2)(C). EPA cannot do this if it excludes relevant studies solely because the underlying data cannot be made public.

The FFDCA specifically speaks to how threshold and non-threshold effects shall be considered. *Id.* § 346a(b)(2)(B). The Proposal cannot override the specific Congressional mandates in the FFDCA for how to conduct a tolerance assessment. In determining whether there is a reasonable certainty of no harm to infants and children, EPA must consider "available information" on consumption patterns among infants and children, special susceptibility of infants and children (including for example neurological and in utero effects), cumulative effects on infants and children. *Id.* § 346a(b)(2)(C). Likewise, the Act specifies numerous scientific

factors that must be considered in evaluating safety, including considering "available data" on these factors. *Id.* § 346a(b)(2)(D). The Proposal plainly contradicts these mandates. Obviously, published, peer-reviewed literature is "available" and must be considered. As with studies considered under other statutes, EPA fails to explain the arbitrariness of excluding published peer-reviewed studies while allowing industry studies considered confidential business information to be considered.

Finally, the FFDCA contains certain procedural requirements for "establishing general procedures and requirements to implement this section." *Id.* § 346a(e). Yet EPA failed to cite the FFDCA—either its substantive or procedural requirements—at all in its Proposal.

J. Atomic Energy Act

The AEA, 42 U.S.C. § 2011 *et seq.*, is not a typical environmental law, as the original act established the Atomic Energy Commission (AEC) just after World War II to promote the "utilization of atomic energy for peaceful purposes to the maximum extent consistent with the common defense and security and with the health and safety of the public." The concern found in the final clause of its original organic act, "the health and safety of the public," has at no point disappeared in subsequent iterations of the act and this Proposal runs contrary to its clearly stated intent.

The AEC was abolished in the 1970s, and since that then, most of the functions of the AEA are carried out by the Nuclear Regulatory Commission and the U.S. Department of Energy. However, when EPA was formed in the early 1970s, it assumed the AEC's authority to issue generally applicable environmental radiation standards to protect the health and safety of the public. Other federal and state organizations must follow these standards when developing requirements for their areas of radiation protection. EPA also implements the Federal Radiation Council's authority under the AEA, developing guidance for federal and state agencies containing recommendations for their use in developing radiation protection requirements and working with states that have radiation protection programs.

There are several specific statutory requirements that EPA executes under the AEA, which states that "the purpose of this [Act is] to effectuate the policies set forth above by providing for – (d) a program to encourage widespread participation in the development and utilization of atomic energy for peaceful purposes to the maximum extent consistent with the common defense and security *and with the health and safety of the public*." 42 U.S.C. § 2013(d) (emphasis added).

The following regulations are health-based standards, and as we discuss *supra* section III.G., EPA bases its regulatory limits and nonregulatory guidelines for population exposures to low-level ionizing radiation on the linear no-threshold (LNT) dose-response model, which uses the premise that any radiation dose carries some risk, and that risk increases directly with dose. The viability of each of these longstanding health-based protections will be undercut by promulgation of a final rule that resembles this draft for the reasons discussed *supra* section III.G., and in direct conflict with the AEA's requirement that the utilization of atomic

ED_002389_00015391-00063

energy for peaceful purposes be "to the maximum extent consistent with the common defense and security *and with the health and safety of the public*."

- Environmental Radiation Protection Standards for Nuclear Power Operations (40 C.F.R. Part 190); these standards limit radiation releases and doses to the public from the normal operation (non-emergency) of nuclear power plants and other uranium fuel cycle facilities.
- Environmental Radiation Protection Standards for Management and Disposal of Spent Fuel, High Level and Transuranic Wastes (40 C.F.R. Part 191); this regulation sets environmental standards for the disposal of highly radioactive spent nuclear fuel and certain kinds of highly toxic and radioactive wastes produced from the nuclear weapons program that must ultimately be disposed of in a deep geologic repository.
- Health and Environmental Protection Standards for Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings (40 C.F.R. Part 192); this regulation sets standards for the protection of the public health, safety, and the environment from radiological and non-radiological hazards associated with uranium and thorium ore processing, and disposal of associated wastes. In May of 2015, EPA proposed revisions to 40 C.F.R. 192 that would establish groundwater restoration and monitoring requirements at in-situ recovery facilities, and then in January 2017, EPA re-proposed those revisions. We await final agency action on the matter.
- Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance with the 40 C.F.R. Part 191 Disposal Regulations (40 C.F.R. 194); these criteria apply to the certification and recertification of compliance with the radioactive waste disposal standards at the Waste Isolation Pilot Plant (WIPP) in New Mexico, the world's only deep geologic repository, which is operated by the U.S. Department of Energy (DOE) for permanent disposal of transuranic waste from the nation's nuclear defense program.
- Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada (40 C.F.R. Part 197); these regulations, last promulgated in 2008 (after a Federal Appeals Court found an earlier version unlawful, *see, e.g.*, *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251 (D.C. Cir. 2004)), establish public health and environmental standards for storage and disposal of spent nuclear fuel at the proposed repository at Yucca Mountain, Nevada. The U.S. Nuclear Regulatory Commission would implement these regulations at Yucca Mountain if a repository were to be established there.
- As discussed above, the Clean Air Act requires EPA to regulate airborne emissions of hazardous air pollutants (HAPs) from a specific list of industrial sources called "source categories." Standards known as the "National Emission Standards for Hazardous Air Pollutants" (NESHAPs) dictate specific regulatory limits for source categories that emit radionuclides. In 40 C.F.R. Part 61: the *National Emission Standards For Hazardous Air Pollutants*, EPA sets health based standards in a number of settings, such as Subpart B: *Radon Emissions from Underground Uranium Mines*; Subpart H: *Emissions of Radionuclides Other than Radon from Department of Energy Facilities*; Subpart I: *Radionuclide Emissions from Federal Facilities Other than Nuclear Regulatory Commission Licensees and Not Covered by Subpart H*; Subpart K: *Radionuclide Emissions from Elemental Phosphorus Plants;* Q: *Radon Emissions from Department of Energy Facilities*; R: *Radon Emissions from Phosphogypsum Stacks*; Subpart T: *Radon*

Emissions from the Disposal of Uranium Mill Tailings; and Subpart W: *Radon Emissions from Operating Mill Tailings*.

- And last, under the Safe Drinking Water Act (SDWA), discussed above, EPA sets health-based standards on the levels of certain radionuclides in drinking water. After much litigation, in 2000 EPA revised an outdated set of standards that had been in place since the late 1970s and set new monitoring provisions for community water systems (CWS). The current standards are: Combined radium 226/228 of 5 pCi/L; a gross alpha standard for all alphas of 15 pCi/L (not including radon and uranium); a combined standard of 4 mrem/year for beta emitters; and a the MCL for uranium at 30 μg/L.

In short, the Proposal could seriously damage EPA's ability to administer the AEA and protect the public from radiation. Yet the Proposal fails to cite the statute at all.

VI. The cited sources do not support—and in fact contradict—the Proposal

These comments have discussed the failure of statutory authorities cited by EPA to provide any legal support or authorization whatsoever for the Proposal and its approaches. The Proposal also cites various executive orders, memoranda, reports, guidelines and the like with the suggestion or implication that these materials somehow provide support for the Proposal. They do not, and thus the Proposal violates the law. *See, e.g.*, *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986) (reversing and remanding agency decision to carry out last-minute directive by White House Office of Management and Budget without any apparent justification in the administrative record).

First, of course, EPA's proposed rulemakings must be authorized by federal statutes. Executive orders provide no legal authority for agency rulemakings. Nor may executive orders contradict or alter legal responsibilities an agency has under federal statutes or justify arbitrary and capricious agency action. Equally obvious, memoranda, reports, guidelines and the like provide no legal authority for agency rulemakings, nor may they justify arbitrary and capricious agency action. *See, e.g.*, *Medellin v. Texas*, 552 U.S. 491, 524 (2008) ("The President's authority to act, as with the exercise of any governmental power, 'must stem either from an act of Congress or from the Constitution itself.'" (citation omitted)); *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979) ("The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes."). Second, an agency's proposed rulemaking may not be at odds with federal statutes, may not be creatures of the agency's imagination or policy preferences, and may not be otherwise arbitrary, capricious or inconsistent with law. The Proposal fails on all of these scores.

This section of our comments explains how these additional materials cited by EPA in the Proposal (1) fail to provide any support for the Proposal, on scientific, technical, policy, logical or legal grounds; and (2) actually undermine the Proposal—contradicting its approaches and assumptions, directly or indirectly—and demonstrate further that the Proposal is unsupported, arbitrary, capricious and otherwise inconsistent with law.

ED_002389_00015391-00065

A. Footnote 1

The Proposal states, "The best available science must serve as the foundation of EPA's regulatory actions." 83 Fed. Reg. at 18,769. It cites and quotes from Executive Order 13,563, 76 Fed. Reg. 3,821 (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." 83 Fed. Reg. at 18,769 n.1.

The executive order, issued by President Obama, not only does not support the Proposal, it directly undermines the Proposal. There is no suggestion in the cited Obama Executive Order, or in any contemporaneous or subsequent actions by Obama administration federal agencies, that "best available science" means or meant that science underlying an agency's actions must be publicly available in a manner sufficient for independent validation, nor that "pivotal regulatory science" has any meaning akin to the proposed uses in proposed § 30.3 *See* 83 Fed. Reg. at 18,773 ("dose response data and models" and "pivotal regulatory science").

To the contrary, no previous administration has conditioned any notion of "best available science" on the public availability of underlying data, or on the concepts behind the invented term, "pivotal regulatory science." EPA previously routinely used and considered science and studies for which the underlying data was not publicly available as examples of the "best available science." EPA did so for proposed and final regulations, along with other final agency actions, reports, studies and the like. EPA's use and consideration of such science was validated by EPA's science advisory bodies, the National Academy of Science, the Science Advisory Board, and other scientific organizations. *See supra* II.B. And explained in section IX, the Proposal does not provide sufficient explanation for its departure from this past practice.

Moreover, the Executive Order also says that "before issuing a notice of proposed rulemaking," the "agency shall seek the views of those who are likely to be affected." 76 Fed. Reg. 3,821. This Proposal failed to do so, despite its wide-reaching effect. A May 12, 2018, Memorandum to Members of the Chartered Science Advisory Board (SAB) and SAB Liaisons from the Chair of SAB Work Group explains: "The proposed rule deals with issues of scientific practice and proposes constraints that the agency may apply to the use of scientific studies in particular contexts. As such, this rule deals with a myriad of scientific issues for which the Agency should seek expert advice from the Science Advisory Board." *Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN* (2080-AA14), May 12, 2018.[195] The Memorandum further explains that "the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community."[196] This is contrary to Executive Order 13,563.

---

[195] Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14), May 12, 2018, https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.
[196] *Id.* at 3.

ED_002389_00015391-00066

A June 28, 2018, letter from the Chair of the SAB Board, Dr. Michael Honeycutt, on behalf of the SAB, furthers this point.[197] That letter explains that on May 31, 2018, "the full SAB agreed with the Work Group that the proposed rule merits review by the Board and discussed the scientific issues that should be considered."[198] The letter reiterates 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."[199] This letter underscores that the Proposal is inconsistent with Executive Order 13,563.

B. Footnote 2

The Proposal cites the 2009 Presidential Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity in support of the proposition that "[e]nhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions. By better informing the public, the Agency is enhancing the public's ability to understand and meaningfully participate in the regulatory process." 83 Fed. Reg. at 18,769 (citing Memorandum for the Heads of Executive Departments and Agencies, Mar. 9, 2009). The Proposal points to the section of the 2009 Memo that states, "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." *Id.* n.2.

First, the cited sentence refers to information developed and used by the federal government, but EPA has long held that it may use published scientific studies without obtaining the underlying raw data. *See, e.g.*, Initial Brief of Respondent United States Environmental Protection Agency at 47–48, *Coalition of Battery Recyclers Ass'n v. EPA*, No. 09-1011 (D.C. Cir. January 19, 2010), ECF No. 1226234 (explaining that EPA does not have an obligation to obtain and docket raw data from scientific studies it uses). The Proposal has pointed to no instances where the EPA was not transparent in the preparation, identification, and use of scientific information, including published peer reviewed scientific studies. Second, the cited sentence takes a more nuanced approach than the Proposal and recognizes exceptions even for the information developed and used by the federal government.

Importantly, the 2009 Presidential Memo also states in the sentence immediately preceding the quotation singled out by EPA, "Political officials should not suppress or alter scientific or technological findings and conclusions." Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity, 74 Fed. Reg. 10,671 (Mar. 9, 2009). The

---

[197] June 28, 2018, Letter to Scott Pruitt re Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science, https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf.

[198] *Id.* at 2.

[199] *Id.* at 3.

ED_002389_00015391-00067

Proposal, far from preserving the integrity of science, attempts to suppress established scientific findings and conclusions in the name of transparency.

The Proposal's citation to the 2009 Presidential Memo misconstrues the Memo's aims by cherry-picking a single sentence and ignoring the remainder. While the Memo emphasizes the importance of transparency and validity of scientific information, it in no way supports the Proposal's use of transparency to justify the suppression of scientific findings. Unlike the Proposal, the 2009 Presidential Memo adopts a nuanced view of scientific integrity that balances transparency with other considerations, such as privacy and avoiding scientific censorship. To this end, several statements in the 2009 Presidential Memo on Scientific Integrity directly undercut the Proposal:

> (c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards . . .

Id. The Proposal seeks to preclude scientific information that has been subject to well-established scientific processes, including peer review. The Proposal also seeks to upend compliance and application of the relevant statutory standards. *See* section III.

> (d) 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 . . .

Id. The Memorandum requires agencies to make available the scientific findings or conclusions, and even that requirement has exceptions. The Proposal would arbitrarily exclude consideration of relevant scientific findings and conclusions if the underlying data is not publicly available.

The 2009 Presidential Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity does not support EPA's proposed actions. The Proposal does not enhance transparency and validity of scientific information relied upon by EPA. It requires the agency to ignore valid scientific studies in its decision making and thus will lead to arbitrary results and weaken the integrity of EPA's actions.

C. Footnote 3

The Proposal states that it 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." 83 Fed. Reg. at 18,769. In a footnote to this sentence the Proposal states:

> 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 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

ED_002389_00015391-00068

> 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.

83 Fed. Reg. at 18,769 n.3.

EPA recognizes the cited cases contradict the proposed rule but attempts to waive them away and asserting it has discretionary authority to do the opposite of what the D.C. Circuit decided. EPA's consideration of peer reviewed scientific studies that do not have public data is the norm, required by the Administrative Procedure Act and the programmatic statutes that EPA administers. *See* sections II, IV, & V. The proposed departure from this norm to preclude the use of such data, which the Proposal makes explicit in this footnote, is not within EPA's discretion and would violate the programmatic statutes. As explained above, nothing the Proposal provides EPA with authority to do so. The Proposal's citations to two cases that contradict its proposed actions does not support the unexplained assertion of authority.

The court in *American Trucking* stated:

> More generally, we agree with EPA that requiring agencies to obtain and publicize the data underlying all studies on which they rely "would be impractical and unnecessary." Particulate Matter NAAQS, 62 Fed. Reg. at 38,689. As EPA persuasively stated in denying Petitioners' original request for the information:
>
>> 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.... [S]uch 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].

Am. Trucking Associations, Inc., 283 F.3d at 372.

In *Coalition of Battery Recyclers*, the D.C. Circuit cited *American Trucking*, explaining that the court had "rejected the notion that EPA had improperly failed to obtain and make public data underlying studies on which it had relied during a NAAQS rulemaking, holding that '[t]he Clean Air Act imposes no such obligation' and that 'requiring agencies to obtain and publicize the data underlying all studies on which they rely would be impractical and unnecessary.'" 604 F.3d at 623 (citations omitted). The court noted "that raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants." *Id.*

The Proposal at least concedes that D.C. Circuit law does not support its actions. Yet EPA not explain how the Proposal is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers. To the extent EPA believes this to be true, it should withdraw the Proposal and explain its belief.

ED_002389_00015391-00069

D. Footnotes 4 & 5

The Proposal states that it is consistent with Executive Orders 13,777 and 13,783. 83 Fed. Reg. at 18,769.

The Proposal states that "[r]egulatory 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.'" 83 Fed. Reg. at 18,769 n.4 (quoting Exec. Order No. 13,777, 82 Fed. Reg. 12,285, 12,286 (Mar. 1, 2017)). President Trump's Executive Order No. 13,777 requires Regulatory Reform Task Forces to evaluate existing regulations and "make recommendations to the agency head regarding their repeal, replacement, or modification, consistent with applicable law." 82 Fed. Reg. at 12,286. The Executive Order requires the task force to identify regulations that, among other things, "impose costs that exceed benefits," and "create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies." *Id.* The Proposal does not identify any regulations that it believes should be repealed, replaced, or modified, consistent with applicable law. Instead, the Proposal creates a new burdensome regulation. Notwithstanding EPA's unsupported assertion that it "believes the benefits of this proposed rule justify the costs," 83 Fed. Reg. at 18,772, the proposed rule will impose costs that exceed benefits, *see* section II.D & E. The inconsistencies within the Proposal are overwhelming (for one of the many examples, the unexplained willingness to consider certain scientific studies in some contexts while excluding the consideration of those same studies in other contexts, *see* section XI). And the Proposal, as explained in sections IV. & V., is not consistent with applicable laws. Rather than being consistent with President Trump's Executive Order, the proposed rule contradicts it.

Regarding President Trump's Executive Order 13,783, the Proposal quotes, "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." 83 Fed. Reg. at 18,769 n.5 (quoting Exec. Order No. 13,783, 82 Fed. Reg. 16,093 (Mar. 31, 2017). EPA presumably believes the proposed rule is consistent with the language "transparent processes that employ the best available peer-reviewed science and economics." But that language, and the rest of the quotation, contradicts the Proposal. As explained throughout these comments, the Proposal would prevent EPA from promulgating regulations that comply with the law, would cost more than any benefit it could achieve, and would preclude the use of the best available peer-reviewed science.

E. Footnote 6 & 15

The Proposal cites to the 2002 OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies to justify the Proposal's focus on transparency, 83 Fed. Reg. at 18,769 n.6, and to support its contention that the guidelines "require" that "regulators to ensure that key findings are valid and credible," *id.* at 18,770 n.15. Despite these citations, the Guidelines do not support EPA's proposal to preclude the consideration of peer-reviewed scientific studies. *See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information*

Disseminated by Federal Agencies, 67 Fed. Reg. 8,452, 8,454 (Feb. 22, 2002). The Proposal points to no agency finding that it believes is invalid and not credible. Rather, the Proposal will cause EPA to reach findings that are invalid and not credible because the agency will make these findings without consideration of the best available science. The Proposal contradicts the Guidelines.

The 2002 OMB Guidelines contain many statements that undercut the Proposal on their face.

Text of 2002 OMB Guidelines
"As a general matter, in the scientific and research context, we regard technical information that has been subjected to formal, independent, external peer review as presumptively objective. . . . An example of a formal, independent, external peer review is the review process used by scientific journals." 67 Fed. Reg. at 8,454.[200]
Analysis
While the 2002 OMB Guidelines recognize technical information that has been subjected to formal, independent, external peer review as "presumptively objective," the Proposal upends this idea and forces the EPA to regard such technical information as invalid and not worthy of consideration.
Text of 2002 OMB Guidelines
"'Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicably be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints.' Further, as we state in our expanded definition of 'reproducibility' . . . 'If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (*e.g.,* standards for replication of laboratory data).' 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. For example, it may not be ethical to repeat a 'negative' (ineffective) clinical (therapeutic) experiment and it may not be feasible to replicate the radiation exposures studied after the Chernobyl accident. When agencies submit their draft agency guidelines for OMB review, agencies should include a description of the extent to which the reproducibility standard is applicable and reflect consultations with relevant scientific and technical communities that

[200] This statement is qualified by a section on the sufficiency of peer review: "Some comments argued that journal peer review should be adequate to demonstrate quality, even for influential information that can be expected to have major effects on public policy. OMB believes that this position overstates the effectiveness of journal peer review as a quality-control mechanism. Although journal peer review is clearly valuable, there are cases where flawed science has been published in respected journals." *Id.* at 8,455. Nonetheless, nothing in the guidelines suggest that peer-reviewed science can be wholesale ignored simply because the underlying data cannot be made public.

ED_002389_00015391-00071

were used in developing guidelines related to applicability of the reproducibility standard to original and supporting data." *Id.* at 8,456.
Analysis
The OMB Guidelines emphasize the ethical, feasibility, and confidentiality constraints associated with reproducing particular types of studies, and underscore the importance of consultation with relevant scientific and technical communities in the development of reproducibility requirements. The Proposal recklessly ignores these precautions, subjecting "regulatory science" to requirements that the underlying data be made publicly available in a manner sufficient for independent validation. The Proposal does so without consultation of relevant scientific communities and without concern as to whether such data can practicably be subjected to such requirements. As explained in section II, the data underlying many scientific studies affected by the Proposal cannot be made publicly available given the ethical, feasibility, and confidentiality concerns addressed by the OMB Guidelines.
Text of 2002 OMB Guidelines
"With regard to original and supporting data related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement. Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicable [sic] be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints. It is understood that reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (i.e., a new experiment, test, or sample) shall not be required prior to each dissemination." *Id.* at 8,460.
Analysis
The Guidelines state that reproducibility of data is one indication of transparency but does not suggest that reproducibility is the *only* indication of transparency, nor does it suggest that agencies should preclude non-reproducible, non-publicly available scientific studies from agency consideration, as the Proposal envisions. Contrary to the Proposal, the Guidelines state that agencies should not require data to be subjected to a reproducibility requirement.
Text of 2002 OMB Guidelines
"With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g– 1(b)(3)(A) & (B)). Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent situations

ED_002389_00015391-00072

(*e.g.,* imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines." *Id.*
Analysis
The Guidelines recognize the ethical, feasibility, and confidentiality constraints of reproducing certain types of data. The Proposal ignores these issues. Furthermore, the Guidelines recommends that risk assessments related to human health, safety, and the environment are subject to quality principle standards established by Congress through the SDWA, which differ from the Proposal.
Text of 2002 OMB Guidelines
"Even in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard. For example, a qualified party, operating under the same confidentiality protections as the original analysts, may be asked to use the same data, computer model or statistical methods to replicate the analytic results reported in the original study. *See, e.g.,* 'Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality,' A Special Report of the Health Effects Institute's Particle Epidemiology Reanalysis Project, Cambridge, MA, 2000." *Id.* at 8,456.
Analysis
Unlike the Proposal, the OMB Guidelines recognize that studies have been able to be reproduced even without publicly disclosing all their data. Although the OMB Guidelines positively discuss this option, the Proposal would preclude EPA from considering both the initial study and the reanalysis study from consideration in regulatory decision making.

The Proposal's concerns about transparency are addressed by the Guidelines and do not justify precluding consideration of the best available science. The 2002 OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies does not support the Proposal. *See also* section II.A.

F. Footnote 7

The Proposal claims that it is consistent with the OMB Memorandum 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 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.

ED_002389_00015391-00073

83 Fed. Reg. at 18,770 n.7. However, the Open Data Policy required that agencies balance the "value of openness against the cost of making those data public." 2013 OMB Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy at 6. Included in the costs of making those data public is an individual's right to privacy, which the agencies are required to consider when releasing data. *Id.* at 10. The EPA's Proposal does not balance these values, and instead pursues public availability of data in the realm of dose response data at all costs.

The Open Data Policy Memorandum contains a number of passages that conflict with, rather than support, the Proposal:

> Nothing in this Memorandum shall be construed to affect existing requirements for review and clearance of pre-decisional information by OMB relating to legislative, budgetary, administrative, and regulatory materials. Moreover, nothing in this Memorandum shall be construed to reduce the protection of information whose release would threaten national security, invade personal privacy, breach confidentiality or contractual terms, violate the Trade Secrets Act, violate other statutory confidentiality requirements, or damage other compelling interests.

Id. at 12. The Open Data Policy Memorandum specifically called out the problem of exposing personally identifiable information:

> As defined in OMB Memorandum M-1 0-23, 'personally identifiable information' (PII) refers to information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. In performing this assessment, it is important for an agency to recognize that non-PII can become PII whenever additional information is made publicly available (in any medium and from any source) that, when combined with other available information, could be used to identify an individual.

Id. at 4. The Memorandum expresses concern for individual privacy and notes the ease with which non-personally identifiable information can be used to identify an individual when combined with other publicly available information. The Proposal attempts to wave away these concerns with assertions that confidential information can be de-identified. 83 Fed. Reg. at 18,770–71. The problems with the Proposal's emphasis of such "de-identification" techniques are explored further in section II.D. Far from weighing considerations of privacy, the Proposal would simply bar the use of studies based on confidential information that could not be de-identified.

Again, while the Memorandum makes clear that agencies must consider privacy, it says nothing about barring agency consideration of documents based on that analysis. Rather, the thrust of the Memorandum is ensuring that private information is not inadvertently publicly disclosed, and balancing that obligation with the presumption of government openness:

ED_002389_00015391-00074

> Agencies must incorporate privacy analyses into each stage of the information's life cycle. In particular, agencies must review the information collected or created for valid restrictions to release to determine whether it can be made publicly available, consistent with the *Open Government Directive's* presumption in favor of openness, and to the extent permitted by law and subject to privacy, confidentiality pledge, security, trade secret, contractual, or other valid restrictions to release. If the agency determines that information should not be made publicly available on one of these grounds, the agency must document this determination in consultation with its Office of General Counsel or equivalent.

Id. at 9.

It is not clear to what extent EPA believes the Proposal is consistent with the Memorandum. But given the Memorandum's recognition of the various constraints on, and nuanced approach to, the release of data publicly, EPA's reliance on the Memorandum is misplaced. The Proposal's attempt to preclude consideration of peer reviewed science from regulatory review is not consistent with the Memorandum.

G. Footnotes 8 & 9

The Proposal states that it "builds upon prior EPA actions in response to government wide data access and sharing policies, as well as the experience of other federal agencies in this space." 83 Fed. Reg. at 18,770 (footnotes omitted). A footnote to this sentence generally lists the following, without any explanation of how the Proposal builds upon them:

> 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 Policy; Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.

83 Fed. Reg. at 18,769 n.8. Another footnote generally lists the following agencies, again without any explanation of how the Proposal builds upon their experience:

> For example, see related policies from the National Science Foundation, National Institute of Science and Technology, the National Institutes of Health; and the U.S. Census Bureau, which provides secure access to data from several agencies in an environment that protects against unauthorized disclosure (https://www.census.gov/fsrdc).

Id. n.9. First, EPA does not explain what it means by "builds upon." The EPA's own Science Advisory Board Work Group states that the preamble to the rule does not "describe precisely how the [P]roposal builds on previous efforts to promote transparency such as the Information Quality Act and EPA's Information Quality Guidelines." May 12, 2018 Memorandum to Members of the Chartered Science Advisory Board (SAB). The citations are to large documents and policies and it is not clear what, if any, parts EPA believes the Proposal "builds upon." Second, none of these documents or agency policies bar, or recommend barring, the use of

ED_002389_00015391-00075

studies in regulatory decision making, as the Proposal seeks to do. Third, many of these documents contradict, and support the withdrawal of, the Proposal.

The Proposal cites the 2016 EPA Plan to Increase Access to Results of EPA-Funded Scientific Research ("2016 EPA Plan"). 83 Fed. Reg. at 18,770 n.8. But the Proposal is a significant departure from the policy advanced in the 2016 EPA Plan. The Plan recognized that some data could not be made publicly available due to privacy and confidentiality concerns, acknowledged that peer-reviewed publications based on such data were no less scientifically valid, and specifically excluded this data from the purview of the plan to increase access. 2016 EPA Plan, at 4–6, 19. In contrast, the Proposal would prevent the EPA from considering a peer-reviewed publication related to dose response if its underlying data could not be made publicly available.

In fact, statements in the 2016 EPA Plan undercut the Proposal:

> While the Agency strives to increase access to its research results, it recognizes, consistent with the OSTP Memo, that Federal agencies have a responsibility to protect confidentiality and personal privacy, respect proprietary interests and property rights, and balance between the value of providing long-term access and its associated costs. It 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.*

Id. at 4–5 (emphasis added). The Proposal ignores the 2016 EPA Plan's express acknowledgment that the validity of peer-reviewed scientific research does not depend on the public availability of the underlying data. Though the 2016 EPA Plan clearly states that research can be valid even if its data are not publicly available, the Proposal requires EPA to disregard this valid research.

The 2016 EPA Plan also makes clear that it does not restrict EPA's ability to consider conclusions or data:

> Nothing in this Plan shall be construed to impair or otherwise affect the authority granted by law to EPA. 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.

Id. at 6. In contrast, the Proposal requires that EPA ignore certain conclusions or data that is not publicly available.

The 2016 EPA Plan also contains definitions that EPA claims to include in the Proposal, but, in reality, does not:

> *Scientific research data* are defined, consistent with the OSTP Memo and 2 C.F.R 200.315 as the digital recorded factual material commonly accepted in the scientific

community as necessary to validate research findings. *Research data* as used in this Plan are the digital scientific research data resulting from EPA-funded scientific research.

Id. at 19.

Consistent with the definition in 2 C.F.R. § 200.315(e)(3), research data does not include:

- Preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues;
- Physical objects (e.g., laboratory samples);
- Trade secrets and commercial information;
- Materials necessary to be held confidential by a researcher until publication of results in a peer-reviewed journal; and
- *Personnel, medical, and similar files 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.*

The following specific examples of scientific research are excluded from this Plan:

- Interim results or other preliminary scientific research data not used to generate the results in the final peer-reviewed publication;
- Preliminary scientific research documentation beyond the article, supplementary materials, and metadata regarding preliminary research plans, including preliminary study protocols and other preliminary *a priori* decisions (recognizing that preliminary plans may have changed during the research project);
- Information that may disclose intellectual property rights;
- National security and other classified information.

2016 EPA Plan, at 19 n.8 (emphasis added).

The Proposal purports to define Research Data in the same way as the 2016 EPA Plan, as that term is defined in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, or at 2 C.F.R. § 200.315(e)(3). 83 Fed. Reg. at 18,773 (to be codified at 40 C.F.R. § 30.2). As explained above, in the 2016 EPA Plan, Research Data does not include, among other things, personnel and medical information, and similar information which would constitute an unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study. *See* 2 C.F.R. § 200.315(e)(3); 2016 EPA Plan, at 19 n.8. But puzzlingly, the Proposal does not apply this definition in the Proposal's text, instead creating a new term "dose response data and models" and only excluding from that definition "physical objects (like laboratory samples), drafts, and preliminary analyses." 83

Fed. Reg. at 18,773 (to be codified at 40 C.F.R. § 30.2). Not only is the Proposal inconsistent with the 2016 EPA Plan, but its definitions and application of those definitions conflict with the regulations it purports to apply.

The Proposal also ignores an important distinction between future EPA-funded research, which the agency presumably has more control over, and research funded by other entities or generated in the past, which EPA cannot control:

> This Plan prospectively covers peer-reviewed scientific research publications in scholarly journals and digital research data that result from EPA-funded research. The Plan does not apply to research publications or research data generated from scientific research conducted prior to the implementation of the Plan.

2016 EPA Plan at 5. The Proposal, which overlooks this distinction and creates a conflicting definition of research data to preclude consideration of peer reviewed science in regulatory decision making, does not "build upon" the 2016 EPA Plan.

In short, there are key differences between the 2016 EPA Plan and the Proposal:

- The Plan in no way restricts the materials the EPA can consider in its decision-making, *id.* at 5, whereas the Proposal categorically prohibits the EPA from considering certain scientific publications.
- The Plan focuses on making EPA-funded research publications and data available to the public, *id.*, whereas the Proposal applies to research used by the EPA, no matter how it is funded.
- The Plan is forward-looking and does not apply to research conducted prior to implementation, *id.*, whereas the Proposal will, in practice, apply retroactively.
- The Plan applies broadly to EPA-funded publications and data that could be made publicly available, *id.*, with exceptions for sensitive data, while the Proposal specifically targets "dose response data and models" underlying "pivotal regulatory science."

The Proposal also cites the Open Data Implementation Plan, but again it is not clear how EPA believes the Proposal builds upon that plan. The Open Data Implementation Plan notes exceptions that the Proposal does not adequately address:

> The Open Data Policy requires agencies to develop and strengthen policies and processes to ensure that only appropriate data are released to the public and made available online. EPA must designate one of three 'access levels' for each data asset (public, restricted public and non-public). Exceptions to publicizing data may result from law, regulation or policy, which address privacy, confidentiality, security or other valid restrictions.

Open Data Implementation Plan, February 11, 2015, at 4. The Open Data Policy recognizes not all data can be made publicly available; it does not suggest that EPA disregard studies based on such data.

The Proposal then cites the Scientific Integrity Policy, which similarly does not support the Proposal. First, the Scientific Integrity Policy "describes the scope and role of a standing committee of Agency-wide scientific integrity officials," which would presumably include issues the Proposal seeks to address. U.S. Environmental Protection Agency Scientific Integrity Policy, at 1. The Proposal makes no mention of this committee and does not suggest the committee was consulted in developing the Proposal. The Policy states, "To operate an effective science and regulatory agency like the EPA, it is also essential that political or other officials not suppress or alter scientific findings," *id.*, and "policy makers shall not knowingly misrepresent, exaggerate, or downplay areas of scientific uncertainty associated with policy decisions," *id.* at 5. Yet this is precisely what political officials at EPA are doing—the Proposal seeks to suppress well-established and peer-reviewed science from consideration by the agency. As explained in section III.G.4, the Proposal's assertion, without any citations or support, that "there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects," 83 Fed. Reg. at 18,770, is precisely the type of activity the Policy warned against.

The Proposal also cites EPA's 2002 Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA (OMB Guidance) to support its claim that the Proposal "builds upon prior EPA actions." 83 Fed. Reg. at 18,770 n.8. Like many of the sources cited, the OMB Guidance does not support the Proposal and contradicts the Proposal's aims:

> When evaluating environmental problems or establishing standards, EPA must comply with statutory requirements and mandates set by Congress based on media (air, water, solid, and hazardous waste) or other environmental interests (pesticides and chemicals). Consistent with EPA's current practices, application of these principles involves a "weight-of-evidence" approach that *considers all relevant information and its quality, consistent with the level of effort and complexity of detail appropriate to a particular risk assessment.*

OMB Guidance, at 21 (emphasis added). The Proposal's categorical exclusion of non-publicly available "dose response data" is a departure from EPA's previous practice, as described in the OMB Guidance, of weighing all relevant information. EPA reiterated this in exacting detail in other places in the OMB Guidance:

> In the Agency's development of "influential" scientific risk assessments, *we intend to use all relevant information*, including peer reviewed studies, studies that have not been peer reviewed, and incident information; evaluate that information based on sound scientific practices as described in our risk assessment guidelines and policies; and *reach a position based on careful consideration of all such information* (*i.e.*, a process typically referred to as the 'weight-of-evidence' approach). In this approach, *a well-developed, peer-reviewed study would generally be accorded greater weight than information from a less well-developed study that had not been peer-reviewed, but both studies would be considered.* Thus the Agency uses a "weight-of-evidence" process when evaluating peer-reviewed studies along with all other information.

ED_002389_00015391-00079

Id. at 26 (emphases added). The OMB Guidance consistently make clear that the agency will consider all scientific information (even non-peer reviewed science). Contrary to the OMB Guidance, the Proposal seeks to disseminate information that excludes consideration of relevant peer-reviewed science. The Proposal does not "build upon," but rather directly conflicts with, the 2002 OMB Guidance.

H. Footnote 10

The Proposal states that it "takes into consideration the policies or recommendations of third party organizations who advocated for open science." 83 Fed. Reg. at 18,770. It states that "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." 83 Fed. Reg. at 18,770 n.10.

The Proposal does not explain what it means by "takes into consideration." To the extent EPA is relying on these policies or recommendations, it has not provided enough information to evaluate that reliance and it must withdraw the Proposal. And consistent with the Proposal's other citations, EPA points to nothing in the policies or recommendations from these third-party organizations that supports the Proposal's preclusion of peer-reviewed science from consideration in regulatory decision making.

The Bipartisan Policy Center (BPC) states that "*the proposed rule is not consistent with the BPC report in substance or intent.*"[201] The BPC further explained that the Science for Policy Project "report never suggested excluding studies from consideration in developing regulation if data from those studies were not publicly available."[202] The BPC concludes "EPA must use the best available science in the most effective way to truly fulfill its mission of protecting human health and the environment."[203]

The Proposal's "consideration" of these works can be summed up by the author of the Administrative Conference of the United States' Science in the Administrative Process Project Report, and member of the seven-author panel that produced the Bipartisan Policy Center's Science for Policy Project:

> "I really don't know what the problem is that they think they're fixing," she said, adding that many of her co-authors "would laugh and hoot" at some of the scientific ideas expressed in the rule.

---

[201] Grumet, J. 2018. Bipartisan Policy Center comments on "Strengthening Transparency in Regulatory Science," Docket ID No. EPA-HQ-OA-2018-0259, May 22, https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0670.
[202] *Id.*
[203] *Id.*

ED_002389_00015391-00080

> "They don't adopt any of our recommendations, and they go in a direction that's completely opposite, completely different," she told me after reading the rule. "They don't adopt any of the recommendations of any of the sources they cite. I'm not sure why they cited them."[204]

The Proposal *rejects* the policies or recommendations of these third-party organizations. The policies and recommendations of these third-party organizations do not support the EPA's proposal to preclude the consideration of peer-reviewed studies in regulatory decision making. *See also* section II.E.

I. Footnotes 11 & 12

The Proposal states, "These policies are informed by the policies recently adopted by some major scientific journals, spurred in some part by the 'replication crisis.'" 83 Fed. Reg. at 18,770 (footnotes omitted). The Proposal cites, as examples "related policies from the Proceedings of the National Academy of Sciences, PLOS ONE, Science, and Nature," *id.* n.11, as well as articles from three of those journals, plus the Economist, a magazine-format newspaper, *id.* n.12.

It's not clear to what extent, if any, the Proposal considered or relied on the cited policies. The scientific journal policies appear to have been considered secondarily, to the extent they informed the other organizations' policies. As explained throughout these comments, the third-party organizations' policies offer no support for the Proposal. Importantly, all the cited scientific journal policies are for prospective publication, do not suggest disregarding consideration of studies without public data, and have exceptions to protect confidential or private information. *See also* section II & II.E.

The Editors-in-Chief of the Science family of journals and Nature, the Executive Editor of Public Library of Science (PLOS) Journals, the Interim Editor-in-Chief of Proceedings of the National Academy of Sciences, and the Vice President of Editorial/Acting Editor-in-Chief of Cell Press/Cell issued a joint statement on the Proposal:

> We are writing in response to a proposed rule announced by the Environmental Protection Agency (EPA) in a 24 April 2018 press release (1). The release reads, "The rule will ensure that the regulatory science underlying Agency actions is fully transparent, and that underlying scientific information is publicly available in a manner sufficient for independent validation."
>
> Data sharing is a feature that contributes to the robustness of published scientific results. Many peer-reviewed scientific journals have recently adopted policies that support data sharing, consistent with the Transparency and Openness Promotion (TOP) standards. These standards, however, recognize the array of workflows across scientific fields and make the case for data sharing at different levels of stringency; in not every case can all

---

[204] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic, April 25, 2018, https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/.

ED_002389_00015391-00081

> data be fully shared. Exceptional circumstances, where data cannot be shared openly with all, include data sets featuring personal identifiers.
>
> We support maintaining the rigor of research published in our journals and increasing transparency regarding the evidence on which conclusions are based. As part of these goals, we require that all data used in the analysis must be available to any researcher for purposes of reproducing or extending the analysis. 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.
>
> *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.*[205]

And John P.A. Ioannidis, the author of one of the articles the Proposal cites regarding the alleged "replication crisis" that the Proposal mentions but does not explain, *see* section II., published an editorial in response to the Proposal.[206] The article is informatively titled: "All science should inform policy and regulation," and not surprisingly, it does not support the Proposal. Ioannidis states "[i]f the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim." *Id.* Ioannidis explains that "we should recognize that most of the raw data from past studies are not publicly available," and

> [s]ome deficiencies may be unavoidable. For example, researchers cannot ethically randomize people to harmful exposures in order to tackle confounding, nor violate informed consent agreements that prohibit open sharing of private data from past studies.

Id.[207] Ioannidis goes on to say that "simply ignoring science that has not yet attained such standards, is a nightmare," and "we would see governments discarding science at massive scale because of perceived imperfections and impurities." *Id.*

---

[205] Jeremey Berg, et al., Letter, "Joint statement on EPA proposed rule and public availability of data," *Science,* Vol. 360, Issue 6388, 4 May 2018, *available at* http://science.sciencemag.org/content/360/6388/eaau0116 (emphasis added).

[206] Ioannidis, J. P., "All science should inform policy and regulation," *PLoS Medicine* 15(5) (May 3, 2018), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576.

[207] As explained in section III., the Proposal would preclude the consideration of many past studies whose raw data are not and cannot be made available. This issue is also described in the May 12, 2018 SAB Memo discussed above: "For studies published many years ago, it may not be feasible to deliver public access to data and analytic methods." Whatever strategies the Proposal suggests EPA consider in the future to address confidential and personal information (and the flaws with a proposed rule suggesting a key issue will be solved sometime in the future

ED_002389_00015391-00082

Ioannidis also notes that "we have extremely strong evidence that the tobacco pandemic is devastating; that the MMR vaccine is generally safe; that climate change is happening; and that air pollution is a major health hazard," in contrast to "most dietary advice one might hope to give about specific nutrients." *Id.* The subjects that Ioannidis explains have strong evidence are the issues EPA is responsible for addressing that the Proposal seeks to discredit. Ioannidis further notes:

> For example, the pivotal research on the health effects of air pollution is particularly strong. The Six Cities and American Cancer Society studies are exemplary large-scale investigations, with careful application of methods, detailed scrutiny of measurements, replication of findings, and, importantly, detailed re-analysis of results and assessment of their robustness by entirely independent investigators. The re-analysis and sensitivity analyses were conducted by the Health Effects Institute that was funded by stakeholders some of whom may have desired to see opposite conclusions. It would be wonderful, if in the future the same rigorous re-analysis and replication standards could become the standard for all important areas of research that can inform policy.

Id. (footnotes omitted).

The Proposal does not explain how it takes into consideration the sources cited in footnotes 10–12. Nevertheless, these major scientific journal policies and articles offer no support for EPA's Proposal to preclude consideration of scientific studies from regulatory decision making.

J. Footnote 13

When seeking comment on how to ensure that more data is available over time for public validation, the Proposal states "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." 83 Fed. Reg. at 18,770 n.13. The Proposal provides no support for the idea that EPA has not consistently followed previous EPA policy that encouraged the use of non-proprietary data and models. To the extent EPA believes this is a problem, EPA should withdraw the Proposal and explain what policies it has not followed and how it has not followed those policies. EPA should present options to address those alleged shortcomings. At all events, this general reference to previous EPA policy, just like the references in Footnote 8 discussed above, does not support the Proposal. *See also* sections IV.J & VI.C.

K. Footnote 14

The Proposal states that "EPA's regulatory science should be consistent with the Office of Management and Budget's Final Information Quality Bulletin for Peer Review." 83 Fed. Reg. at 18,770. For this proposition, the Proposal links to a one-page Memorandum on the "Issuance of OMB's 'Final Information Quality Bulletin for Peer Review.'" *Id.* n.14 (citing

---

described below), EPA does not present any strategies for dealing with past studies. This is another reason why the Proposal should be withdrawn.

ED_002389_00015391-00083

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). This Memorandum does not contain enough information to determine whether or how the Proposal is consistent with it. The Memorandum merely states that the Bulletin "establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents," and that "[p]eer review is an important procedure used by the scientific community to ensure that the quality of published information. Peer review can increase the quality and credibility of the scientific information generated across the federal government." Memorandum on the "Issuance of OMB's 'Final Information Quality Bulletin for Peer Review.'" Nothing in the Memorandum or EPA's description of it supports the Proposal to exclude peer reviewed science from consideration in regulatory decision making.

Similarly, nothing in the Bulletin supports the Proposal either. The Proposal does not point to any peer-reviewed studies without publicly available data that reached incorrect conclusions. The Proposal also does not explain how the current peer review process EPA uses for disseminating information conflicts with the Bulletin. And the Bulletin says nothing about standardized test methods, consistent data evaluation procedures, or good laboratory practices, which the EPA proposes to use in the prior sentence. As explained in throughout these comments and in sections VII., VII, & XV, EPA does not provide enough information on what EPA's regulatory science would look like under the Proposal to determine if it would be consistent with the Bulletin. If EPA has a plan for how it intends to make its regulatory science consistent with the Bulletin, the agency has not included it in the Proposal. The Proposal should be withdrawn.

The Proposal's regulatory text states, "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 FR 2664) and the exemptions described therein." 83 Fed. Reg. at 18,774. As explained in section XV, this section is far too vague for the reader to understand what EPA intends and the Proposal provides no justification for why this vague requirement is necessary. The Proposal fails to provide fair notice or justification for its "independent peer review" requirement and before EPA could adopt any final rule with this requirement, EPA must propose a new rule with regulatory text and supporting legal, factual, scientific, and technical information providing fair notice to the public.

L. Footnotes 16-22

The Proposal recognizes that there are concerns about access to confidential or private information. The Proposal cites to various agencies and documents to support its general and unexplained, belief "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." 83 Fed. Reg. at 18,770. Tellingly, EPA concedes that concerns about access to confidential or private information cannot always be addressed, but says nothing about these instances or how it intends to evaluate them. For the times that EPA believes concerns about access to confidential or private information can be addressed, the Proposal does not explain how it plans to do so nor address the costs. The Proposal merely directs readers to general and vague statements from different contexts. The Proposal fails to provide fair notice or justification of what EPA would do to address issues with confidential or private information.

The Proposal merely says to "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," *id.* n.16, and points generally to 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," *id.* n.17. The Proposal does not say what actions from these examples EPA proposes to use.

The Proposal states that the National Academies have noted that in the past, restricted data products were created by relatively simple data masking, coding, and de-identification techniques, and notes that "Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach." 83 Fed. Reg. at 18,771 (citing *Expanding Access to Research Data Reconciling Risks and Opportunities*, The National Academies Press, 2005, https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities at 27, 36). First, this is not fully supported as experience shows increasing access to data can damage privacy and confidentiality rights. *See* section II.D. Again, the Proposal does not say which, if any of these techniques the EPA will use, or how the EPA will use them. And while the National Academies may believe that increasing access to data without damage to privacy and confidentiality is not beyond scientific reach, the Proposal does not explain how this belief translates to past, present, and future scientific studies EPA considers in regulatory decision making. This document does not explain how EPA will address concerns about confidential or private information and does not support EPA's Proposal to preclude consideration of those studies that do not make public underlying data for those, or other reasons.

The Proposal next cites to two National Academies documents and a document from the Bipartisan Commission on Evidence Based Policy. 83 Fed. Reg. at 18,771 & n.19. But the Proposal fails to explain how these documents support its proposed actions or explain how EPA intends to protect confidential information. The Proposal merely states that they "have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts." 83 Fed. Reg. at 18,771. The Proposal does not address those challenges or describe the opportunities it intends the EPA to use. Again, these documents do not support the vague Proposal.

The Proposal states that "the requirements for availability may differ," and "may range from deposition in public data repositories, consistent with requirements for many scientific journals, to, for certain types of information, controlled access in federal research data centers that facilitate secondary research use by the public." *Id.* (footnotes omitted). The Proposal again cites to journal policies or recommendations generally and the policies for access to data from National Institute of Health and Census Bureau. *Id.* nn.20 & 21. Section II.E. explains how the Proposal misrepresents these policies and that the Proposal is inconsistent with best practices and unworkable in reality.[208] Importantly, the Proposal does not say how the requirements would

---

[208] Contrary to the Proposal, the journals cited have exceptions to their data sharing policies and some do not require, but merely encourage, data sharing (https://authorservices.taylorandfrancis.com/data-sharing-faqs/, https://www.elsevier.com/about/our-business/policies/research-data/research-data-faqs, http://journals.plos.org/plosone/s/data-availability, https://www.springernature.com/gp/authors/research-data-

differ, what studies would be required to deposit what data into what repositories, and what studies would be required to allow controlled access to what data in what federal research data centers. Moreover, the Proposal does not address the costs that these actions would entail. Again, if EPA intends to use these different ways to provide data that meet concerns about confidential and private information, the agency must withdraw the rule and issue a new proposed rule that explains the methods it proposes to use.

The Proposal generally wraps up this section with:

> 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.

83 Fed. Reg. at 18,771 (footnote omitted). The Proposal's many flaws are clear in these sentences. EPA does not know what the Proposal entails. The Proposal suggests that EPA *should* identify strategies in the future and that these strategies *should be* cost-effective. The Proposal does not say what cost-effective means, nor what EPA should do if it does not identify any cost-effective strategies, yet it still seeks to alter legal obligations and regulatory decision making in reliance on this unexplained suggestion. The EPA also does not point to any authority for the proposition that the agency's consideration of peer reviewed scientific studies depends on the cost-effectiveness of some strategy the agency develops for publicizing and protecting the underlying data.

And listing options EPA can use does not help. The Proposal fails to explain why EPA has not already identified the strategies or options and in what circumstances it would use them. The Proposal suggests that it will exclude a large class of scientific studies from regulatory decision making but contains a vague assertion that it will look for "cost effective" ways in the future to exclude less them.

The corresponding footnote to these sentences offers no further explanation or support: "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." The document cited is a Working Paper from the Mercatus Center, which advertises itself as "world's premier university source for market-oriented ideas."[209] The Working Paper does not provide concrete strategies or regulatory text. Nor does it analyze any strategies' application by EPA and

---

policy/faqs/12327154). And the National Institute of Health and Census Bureau repositories referenced do not provide access to the repositories to the public but a more limited subset of researchers (e.g., "tenure-track professor, senior scientist, or equivalent," for NIH access, https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/). *See also* section II.V.

[209] https://www.mercatus.org/about.

ED_002389_00015391-00086

their cost-effectiveness. It similarly states, "the range of potential measures includes . . ." and lists thirteen options.[210] Contrary to the Proposal, the Working Paper recommends that:

> In the event that authors do not supply their underlying data and an agency still believes that relying on the results of a study is warranted, the agency ought to explain why it has sufficient confidence to use the study. For example, the agency might note that other researchers have already reproduced the study results or that the data are available to third parties who sign nondisclosure agreements but that the data cannot be posted publicly.[211]

When discussing concerns about access to confidential or private information, the Proposal ignores an important aspect of the problem that it creates: the data masking, coding, and de-identification techniques might not adequately protect confidentiality or privacy. Research has documented that de-identification techniques to render data anonymous is not "simple" as the Proposal characterizes and can lead to the publication of protected confidential or private data. One study explained "[b]y linking demographics to public records such as voter lists, and mining for names hidden in attached documents, we correctly identified 84 to 97 percent of the profiles for which we provided names."[212] Another explained that "87% (216 million of 248 million) of the population in the United States had reported characteristics that likely made them unique based only on {5-digit ZIP, gender, date of birth}."[213] Finally, another explains that "any data that is even minutely useful can never be perfectly anonymous."[214] The Proposal does not address these difficulties and should be withdrawn. *See also* section II.D.

EPA's belief that concerns about access to confidential or private information caused by the Proposal should be addressed in the future is problematic by itself. The cited materials—describing ways different organizations can address concerns in different contexts—do not support this belief. The Proposal does not propose or analyze any strategies it notes EPA should consider, even though it seeks to implement a binding legal change. The Proposal also does not consider important limitations of making underlying data publicly available. This is not surprising given that the Proposal sent for the Office of Information and Regulatory Affairs four-day Executive Order 12,866 review stated that "EPA believes that concerns about access to confidential or private information are without merit."[215] While at least EPA recognized the merit to concerns about confidential or private information, in the four days since sending the

---

[210] Randall Lutter and David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper, September 2016, at 31.
[211] *Id.* at 32–33.
[212] Sweeney, L., Abu, A., & Winn, J. Identifying Participants in the Personal Genome Project by Name, Harvard University, Data Privacy Lab White Paper at 1, Cambridge 2013, https://dataprivacylab.org/projects/pgp/1021-1.pdf.
[213] Sweeney, L., Simple Demographics Often Identify People Uniquely, Carnegie Mellon University, Data Privacy Working Paper 3 at 2. Pittsburgh 2000, https://dataprivacylab.org/projects/identifiability/paper1.pdf.
[214] Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. Rev. 1701, 1755 (2010).
[215] EO 12866 Proposal 2080-AA14 OIRA Review Start Document, Docket ID No. EPA-HQ-OA-2018-0259, at 6, April 17, 2018, https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0007; OIRA Conclusion of EO 12866 Regulatory Review, https://www.reginfo.gov/public/do/eoDetails?rrid=128014.

ED_002389_00015391-00087

version for review the agency clearly did not perform the analysis necessary to figure out how those concerns would be addressed.

The impact and costs of the Proposal are dependent on such strategies and cannot be measured or analyzed without proposed regulatory text. EPA cannot publish a final rule without first proposing what it will do about confidential and private information and analyzing the option it proposes. EPA should withdraw the Proposal.

M. Footnote 23

The Proposal states:

> The benefits of 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; *this is consistent with the conclusions of the National Academies.*

83 Fed. Reg. at 18,772 (emphasis added, footnote omitted). The last statement links to a 120-page document titled *Expanding Access to Research Data Reconciling Risks and Opportunities*, by the Panel on Data Access for Research Purposes, Committee on National Statistics, Division of Behavioral and Social Sciences and Education of the National Research Council of the National Academies Press. *Id.* (citing https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities).

The Proposal does not suggest that its plan to preclude the use of scientific studies from regulatory decision making is consistent or supported by the National Academies. Rather, the Proposal generally states that benefits of data availability the Proposal seeks is consistent with conclusions of the National Academies. The Proposal does not say what the conclusions of the National Academies are or how they support the Proposal. The charge to the Panel in the cited document was "to assess competing approaches to promoting exploitation of the research potential of microdata—particularly linked longitudinal microdata—while preserving respondent confidentiality."[216] The panel was asked to consider the tradeoffs between the benefits and risks of data access and to make recommendations about "how microdata should optimally (from a societal standpoint) be made available to researchers."[217] The panel offered various recommendations, focused on agencies that have data-collection responsibilities providing data to researchers. This is a different context than EPA's proposal to preclude the consideration scientific studies when undertaking its statutorily required decision making to protect human health and the environment. EPA's general citation to this 120-page document for consistent conclusions does not support the Proposal.

---

[216] *Expanding Access to Research Data Reconciling Risks and Opportunities*, The National Academies Press, 2005, at 1-2.
[217] *Id.*

ED_002389_00015391-00088

N. Footnote 24

The cost-benefits analysis for the Proposal is non-existent, violates Executive Orders 12,866 and 13,563, and on its own requires that the Proposal be withdrawn. *See also* section II.D. Without support, the Proposal states that "EPA believes the benefits of this proposed rule justify the costs." 83 Fed. Reg. at 18,772. The most discussion of costs occurs when the Proposal quotes the Mercatus Center free-market think-tank Working Paper discussed above:

> One recent analysis found 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. . . ." They concluded 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."

Id. (quoting Randall Lutter and David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper, September 2016).

This quote is not close to a sufficient cost-benefit analysis. First, the Working Paper's plausibility analysis is dubious. Among other problems, the analysis examines the time it takes for chemical manufactures, processors, and distributors to identify and provide *studies* in their possession related to a specific chemical and equates that to the time it would take EPA to obtain, review, process, redact, and publicly maintain *data* for any study it considers. Lutter and Zorn, at 21–22 (citing (40 C.F.R. pt. 716)). The chemical study Health and Safety Data Reporting Rule and the cost estimate the Working Paper's analysis is based on does not require submission of underlying data unless requested by EPA. 40 C.F.R. § 716.10(a)(4). The analysis also does not include time or costs to the researchers outside of the agency. Lutter and Zorn, at 21–22. Further, the Working Paper assumes that EPA would only receive the underlying data for 20% of the requested scientific studies EPA relies on. *Id.* at 25. Therefore, the Working Paper lowers the already questionable cost estimate by eliminating costs associated with collecting and preparing data for the other 80% of studies. *Id.* The Working Paper does not explain what the authors expect EPA to do about 80% of studies EPA currently relies on for which it does not receive the underlying data, but the Proposal would require the agency to unlawfully ignore those studies in regulatory decision making.

Importantly, even the partial quote the Proposal presents does not provide results of a cost-benefit analysis nor conclude the costs outweigh the benefits. Instead it says that *if* an increase in benefits occurred, the costs would be covered. The same article states this point explicitly:

> Of course, our estimates of the benefits of public access to data supporting federal regulatory decisions fall short of proving that the benefits outweigh the associated costs. They do show, however, the plausibility of such a claim.

Lutter and Zorn, at 29. The Proposal does nothing to address this or try to determine how plausible such a claim is. EPA has not provided a defined Proposal, nor done any cost analysis of its Proposal, that could be analyzed. The fact that this is the best support the EPA could provide

ED_002389_00015391-00089

for its baseless belief that the Proposal's benefits justify its costs further shows that EPA must withdraw the Proposal.

The additional materials cited by EPA do not provide any support for the Proposal, on scientific, technical, policy, logical, or legal grounds, and in fact, the materials actually undermine the Proposal. The cited materials demonstrate that the Proposal is unsupported, arbitrary, capricious, and otherwise inconsistent with law. The fact that EPA cites many of these materials because they contain, from different contexts, options EPA could enact as part of the proposed rule further demonstrates that the Proposal must be withdrawn as it fails to provide fair notice to the public of what is being proposed.

VII. The proposed rule's definitions are vague, arbitrary, and capricious, and fail to provide fair notice to the public of how EPA would implement any final rule

The Administrative Procedure Act requires notices of proposed rulemakings to include "the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). Proposals must "provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully." *Honeywell International, Inc. v. EPA*, 372 F.3d 441, 445 (D.C. Cir. 2004).

The instant Proposal lacks any statutory authority for regulatory terms and text, concepts, and other inventions that make up its foundation. Moreover, many of these regulatory terms and text are vague, unexplained, internally inconsistent, and otherwise arbitrary and capricious.

A. "pivotal regulatory science" (§§ 30.2, 30.3)

The term "pivotal regulatory science" is perhaps the most vague, unexplained and internally inconsistent term used in the Proposal. The term has no statutory basis in any statute cited by EPA, or otherwise. Beyond having no statutory underpinning, the meaning of the phrase is neither self-evident nor adequately defined in the Proposal.

EPA's choice to modify "regulatory science" with the adjective "pivotal" does nothing to clarify the scope of scientific studies and information encompassed by the Proposal. "Pivotal regulatory science" is defined within the regulation as "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions." 83 Fed. Reg. at 18,773/3 (proposed § 30.2). This definition is as unclear and unsupported as the term itself.

The use of the phrase "drive the requirements" within the C.F.R. definition is particularly incoherent. What does "drive the requirements" mean? The Proposal nowhere says. Does the definition apply only to scientific studies that were outcome determinative? Does it encompass any scientific study that was considered in making the requirements? What about studies that were useful but not determinative? Something else entirely? Can more than one study be "pivotal" to the regulatory decision, or does the term "drive the requirements" imply that only one study could be "pivotal" to a given decision? Furthermore, are most of the studies used by EPA considered to "drive the requirements" or is this term limited in some fashion, unrevealed to the public? Will EPA "know it when it sees it," making it up as the agency goes along?

It is arbitrarily, vague, and unexplained under the Proposal which science would be considered "pivotal," and under what conditions. Because the term was created out of thin air to serve EPA's purposes and has no statutory grounding or intuitive meaning, this ambiguity-ridden definition is woefully inadequate. It is also arbitrary and capricious and an abuse of EPA's discretion. EPA is well aware of the insufficiency of the definition, as is evident in the agency's solicitation of comments on the definitions of "pivotal regulatory science" and "dose response data and models" within the Proposal. *See* 83 Fed. Reg. at 18,771.

Notably, the proposed C.F.R. definition also differs substantially from a definition of "pivotal regulatory science" appearing earlier in the Proposal, which defines the term as "the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, or risks and other impacts on which a final regulation is based." 83 Fed. Reg. at 18,770.

Next, it bears repeating that EPA does not and cannot identify any statutory basis—in federal environmental statutes, the Administrative Procedures Act or otherwise—to apply the Proposal's approach "to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, or risks and other impacts on which a final regulation is based." 83 Fed. Reg. at 18,770. EPA simply makes this up.

EPA's separate explanation here suffers from additional defects, namely an internal inconsistency, incoherency and unbounded reach that do not accord with the proposed C.F.R. definition. EPA's preambular explanation says that "pivotal regulatory science" is "critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, or risks *and other impacts* on which a final regulation is based." 83 Fed. Reg. at 18,770 (emphasis added) The Proposal nowhere explains what these "other impacts" are. Nor does the Proposal limit or bound these "other impacts," nor link them to the sentence's incoherent notion of what is "critical" and what is not. Moreover, the preambular gloss is inconsistent with the proposed C.F.R. definition. The former says "pivotal regulatory science" is critical to hopelessly vague "other impacts" on which a final rule is based. *Id.* The proposed C.F.R. definition, by contrast, says "pivotal regulatory science" "drive[s] the requirements and/or quantitative analysis of EPA final significant regulatory decisions." 83 Fed. Reg. at 18,773/3 (proposed § 30.2). The Proposal does not square the contradictions between science that drives a final rule's requirements and science that is "critical" to "other impacts" in a final rule.

Furthermore, EPA not only fails to provide a passable definition for its invented term, "pivotal regulatory science," the agency fails to provide its rationale for limiting the scope of the rule to so-called "pivotal regulatory science." Within the unlawful, arbitrary, and capricious worldview reflected in the Proposal, why is the "public availability of science and data in a manner sufficient for independent validation" any less important or necessary or justified when the science is not "pivotal" or "critical" to a regulatory decision? Why should not all science, studies, data and information considered by EPA meet the standards for transparency, verifiability, independent validation, and trustworthiness that are the abiding concerns of the Proposal? Why is it not arbitrary and capricious for EPA to continue to consider science and data

ED_002389_00015391-00091

that are unavailable and insufficient for independent validation in areas outside the reach of the Proposal? EPA offers no explanation for this disparate treatment; the agency's reasoning, such as it is, is entirely conclusory.

By way of explanation for the limitation, EPA only suggests that the imposed standards "are of paramount importance when the government relies on science to inform its significant regulatory decisions." 83 Fed. Reg. at 18,769. This explanation is hopelessly circular and ultimately incoherent. For starters, EPA does not explain why it believes this explanation to be true. Next, the Proposal just substitutes the word, 'paramount,' for the word, 'critical,' that it substitutes for the word, 'pivotal.' (The Proposal's drafters evidently were just flipping through a thesaurus.) This failure to thoroughly explain both the term "pivotal regulatory science" in a way that meaningfully defines the scope of the regulation, and the rationale behind limiting the application only to pivotal (critical, paramount) science, makes it impossible for interested parties to comment fully and meaningfully on the Proposal. Should EPA intend to finalize this unlawful proposal, EPA first must withdraw the Proposal, then issue a supplemental proposal with the necessary definitions and explanations. Better yet, EPA should abandon this illegal and harmful proposal altogether.

B. "regulatory science" (§ 30.1)

Amazingly, the key regulatory purpose of the Proposal, addressed in proposed section 30.1, does not even use the term "pivotal regulatory science" (or critical or paramount regulatory science, for that matter). Instead, section 30.1 uses the altogether different term, "regulatory science." 83 Fed. Reg. at 18,773/2.

The Proposal makes no attempt to clarify how "pivotal regulatory science" is distinct from the separately defined, "regulatory science," a term integral to proposed section 30.1, which states the Proposal's very purpose. "Regulatory science" is defined to mean "scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions." *Id.* (proposed § 30.2). This definition is almost identical to that of pivotal regulatory science, with the exception that "regulatory science" encompasses information that "provide the basis for EPA final significant regulatory decisions," while "pivotal regulatory science" "drives the requirements."

The phrase "provides the basis" does nothing to illustrate the meaning of regulatory science, or to limit or particularize its scope, because it is equally vague and unexplained. *All* science, data, and information considered by EPA, and relied upon by EPA, "provides the basis" for final EPA regulatory decisions, insofar as EPA includes those materials in its administrative record, certifies that record for judicial review, and may cite and rely upon that information in explaining and defending its final regulatory decisions. Accordingly, the proposed "regulatory science" definition is capacious and unbounded, so long as EPA considered it, making the definition very far afield from the narrower, undefined, and no less incoherent, "pivotal regulatory science."

Alternatively, the phrase "provides the basis" in the proposed "regulatory science" (§ 30.2) definition could mean that science was one of many studies considered, that it was the

ED_002389_00015391-00092

bedrock study upon which regulation was grounded, that EPA relied on the study, or that the study was critical to EPA's determination. The Proposal nowhere addresses or explains whether or how these possible meanings are distinct from the possible meanings of the "drive the requirements" phrase of the "pivotal" definition. Therefore, it is entirely unclear from these definitions what makes science that "provides the basis" distinct from science that "drive the requirements." Neither of these terms meaningfully distinguishes "pivotal" regulatory science from ordinary regulatory science.

The Proposal goes on to exacerbate all of this internal confusion through the workings of its proposed regulatory text. There, EPA alternates between explaining the Proposal in terms of "regulatory science" and "pivotal regulatory science." For example, in proposed § 30.1, the Proposal "directs EPA to ensure that the *regulatory science* underlying its actions is publicly available . . . ." 83 Fed. Reg. at 18,773/2 (emphasis added). Later, in proposed § 30.3, the Proposal indicates that the provisions apply "to dose response data and models underlying *pivotal regulatory science* that are used to justify significant regulatory decisions." *Id.* at 18,773/3 (emphasis added). In the subsequent section, proposed § 30.4, the Proposal references "all studies (or regulatory science) relied upon . . . ." *Id.* The Proposal is arbitrarily vague and incoherent concerning whether "regulatory science" that is relied upon is the same as "pivotal regulatory science," or whether it is a new category of science entirely. Does this phrasing imply that the definition of "regulatory science" does not already include science that is "relied upon"? If so, does EPA mean that the phrase, "provides the basis," is not synonymous with "relied upon"? The Proposal provides no answers to these questions.

Taken together, this demonstrates that "regulatory science" and "pivotal regulatory science" are vague, even incoherent terms with definitions that lend no assistance to commenters in understanding the Proposal. The terms lack statutory authority, are vague, inconsistent, unexplained, and otherwise arbitrary and capricious.

C. "in a manner sufficient for independent validation" (§ 30.1)

Although the phrase, "in a manner sufficient for independent validation," is repeated frequently throughout the Proposal, and is integral to its very operation, the phrase is not defined in the proposed definitional section (§ 30.2). Later in proposed regulatory text, the Proposal does specify 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." 83 Fed. Reg. at 18,773–74 (proposed § 30.5). Proposed section 30.5 goes on to list categories of information that "may" be included in this concept. The explanation provided by proposed § 30.5 is a non-definition; it provides no additional clarification. How much information is sufficient for the public to understand, assess and replicate findings? Can this standard sometimes be met by releasing methodology but not raw data?

Critically, and fatally to the enterprise behind the Proposal, there is nothing in the proposed regulatory text or preambular language that requires information, science or data to be independently validated or replicated before EPA may consider it. EPA does not base the Proposal upon any requirement or expectation that the information, science or data be shown to

ED_002389_00015391-00093

be accurate, trustworthy, reliable or correct before EPA may consider it. This portion of the Proposal reveals EPA's unlawful agenda to be one concerned with prohibiting EPA from considering relevant, peer-reviewed, quality science, *not* one concerned with actual replication or validation. The Proposal's condition that science and information be "publicly available in a manner sufficient for independent validation and replication" is revealed to be mere smokescreen for an EPA enterprise to censor the best available science that would support adoption of more protective health and environmental safeguards.

The Proposal fails to explain how the term, "in a manner sufficient for independent validation," and the proposed § 30.5 definition will increase transparency in science or why it is necessary to ensure that EPA will consider the best available science. To the contrary, as explained elsewhere in these comments, *supra* sections II. & III., the Proposal's approach would *preclude* EPA from considering the best available science that is relevant to EPA's responsibilities. EPA also fails to explain why data underlying peer-reviewed studies must be publicly available "in a manner sufficient for independent validation" when independent researchers can verify science without making the underlying data, which is often confidential, publicly available.

D. "all terms not defined herein shall have the meaning given them in the Act or in Subpart A" (§ 30.2)

Proposed § 30.2 specifies that "all terms not defined herein shall have the meaning given them in the Act or in subpart A." The Proposal nowhere says to what "Act" it is referring. The Proposal purports to implement multiple Acts administered by EPA, with different terms and definitions and court interpretations that may contradict one another. Nowhere does the Proposal square this factual and legal reality with structure of its unlawful approach, and the language in proposed § 30.2. It seems clear that the Proposal's drafters just cut-and-paste boilerplate language from other EPA regulations that do, in fact, implement just one of the federal environmental statutes that EPA administers; in those other regulations, such an approach makes sense. In the Proposal at issue here, it is incoherent and internally inconsistent across the different statutes that EPA administers.

It also is not clear to what "subpart A" EPA is referring, because there is no citation to the Code of Federal Regulations. If this is intended to reference 40 C.F.R. Part 30, Subpart A, that Subpart was removed from the C.F.R. in 2014. *See* 79 Fed. Reg. 75,871; *see also* 80 Fed. Reg. 61,087.

E. "dose response data and models" (§ 30.2)

Dose response data and models is defined as "the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions typically underlie pivotal regulatory science that drives the size of benefit-cost calculations, the level of a standard and/or the points of departure from which reference values (reference doses or reference calculations) are calculated." (§ 30.2). Despite being an important phrase repeated through the Proposal and the proposed text, this compound definition is vague and arbitrary. It

also is circular—the very terms being defined are used in the definition. It's unclear what data EPA is referring to in this phrase and definition. Moreover, it's unclear what EPA means by "[s]uch functions typically under pivotal regulatory science . . ." And the problems with "pivotal regulatory science" have already been discussed. As explained in section XII, the definition does not adequately describe what the proposal covers. This definition, along with the rest of the Proposal, is arbitrary and capricious and must be withdrawn.

F. "case-by-case basis" (§ 30.6; § 30.9)

In proposed § 30.6, EPA proposes to "evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis." 83 Fed. Reg. at 18,774. In proposed § 30.9, the Proposal grants the Administrator the ability to "grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable" for a number of enumerated reasons. Both of these provisions inject additional arbitrariness into the rule, in that they ensure that the Proposal may be applied unevenly—for certain rulemakings the "rules" of the Proposal can be discarded or ignored where desired. This, in addition to and with other sections of the Proposal, underscores that it is arbitrary and capricious and must be withdrawn.

VIII. The Proposal is vague and misleading regarding which types of regulatory actions will be covered

EPA is proposing to apply the Proposal to regulatory actions defined by an unenforceable Executive Order that has few, if any, limiting principles. The Proposal states that it applies to "*dose response data and models* underlying *pivotal regulatory science* that are used to justify significant *regulatory decisions*." 83 Fed. Reg. at 18,773. Section § 30.2 then defines "regulatory decisions" as "final regulations determined to be 'significant regulatory actions' by the Office of Management and Budget pursuant to Executive Order 12866." 83 Fed. Reg. at 18,773. According to Executive Order 12866,

> (f) "Significant regulatory action" means any regulatory action that is likely to result in a rule that may:
> (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
> (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
> (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
> (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order

Regulatory Planning and Review, 58 Fed. Reg. 51,735, 51,735 (Sept. 30, 1993).

ED_002389_00015391-00095

EPA suggests in some places that the Proposal applies only to final rulemakings. *See* 83 Fed. Reg. at 18,771 ("EPA solicits comment on whether and to what extent these requirements, or other provisions and policies, should apply to other stages of the rulemaking process . . . ."). However, OMB guidance on Executive Order 12,866 states that the definition is intended to cover "any policy document of general applicability and future effect, which the agency intends to have the force and effect of law, such as guidance, funding notices, manuals, implementation strategies, or other public announcements, designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency." OMB, *Memorandum for Heads of Executive Departments and Agencies, and Independent Regulatory Agencies*, at 5 n.3 (Oct. 12, 1993). Therefore, there is an inconsistency between what EPA says it is doing, and what it is really proposing.

Indeed, under the OMB guidance and past agency practice, what qualifies as a "significant regulatory action" is a fluid and ad-hoc determination. It is impossible to truly know what effect—and how large an effect—the Proposal would have on rulemakings because it is impossible to know, at this point, what agency actions might be covered. Whether an action is deemed a "significant regulatory action" by OMB can only be determined after the regulation has been proposed and is subject to apparently unbridled discretion by OMB. and there is an infinite universe of rulemakings that EPA could propose in the future. Without knowing what types of agency actions would be covered, the public is left in the dark about the Proposal's true impact. By using the amorphous definition of "significant regulatory actions," EPA ensures that the Proposal would have sweeping effects.

IX. The proposed rule is a reversal of EPA's position without sufficient justification

When an agency reverses course, it must "provide reasoned explanation for its action." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Motor Vehicle Mfrs. Ass'n of U.S., v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). And when that reversal "rests upon factual findings that contradict those which underlay [the agency's] prior policy," a "more detailed justification" is needed. *Fox*, 556 U.S. at 515. Indeed, "an agency's decision to change course may be arbitrary and capricious if the agency ignores or countermands its earlier factual findings without reasoned explanation for doing so." *Id.* at 537 (Kennedy, J., concurring).

As the Supreme Court explained in its 2016 *Encino Motorcars* decision, an agency must supply "good reasons" for a policy revision, cannot leave "unexplained inconsistency," and must address "serious reliance interests." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016). In *Encino*, the Department of Labor reversed its decades-long practice of treating service advisors at automobile dealerships as exempt from the Fair Labor Standards Act's overtime provisions, offering minimal explanation for the policy change. *Id.* at 2123. The Court overturned the rule, holding that the Department had not met its obligation to offer a "reasoned explanation," especially given the decades of reliance on the policy. *Id.* at 2126. It was not enough that the Department included conclusory statements declaring its new policy to be a reasonable interpretation of the statute because the Department failed to provide any good reasons for the new policy. *Id.* at 2127. As explained by the Court, "[t]his lack of reasoned explication for a regulation that is inconsistent with the Department's longstanding earlier position results in a rule that cannot carry the force of law." *Id.*

ED_002389_00015391-00096

In *Organized Village of Kake v. United States Department of Agriculture*, the Department of Agriculture, relying on a detailed factual record, decided not to exempt the Tongass National Forest from a rule that would limit road construction and timber harvesting in national forests, explaining that the benefits would outweigh the potential economic loss. 795 F.3d 956, 959–61, 967–68 (9th Cir. 2015) (*en banc*). Just two years later, on "precisely the same record," the agency issued a new decision reversing course. *Id.* at 968. The court concluded that the "absence of a reasoned explanation for disregarding previous factual findings violate[d] the APA." *Id.* at 969. The court also recognized that "[e]lections have policy consequences," but even when reversing a policy after an election, "an agency may not simply discard prior factual findings without a reasoned explanation." *Id.* at 968.

EPA previously routinely used and considered science and studies for which the underlying data was not publicly available in regulatory actions. As explained above, EPA has not identified even *one* example in which EPA *has observed* the policies underlying the Proposal, and our research has likewise uncovered no such instance. The Proposal essentially admits as much, stating:

> Historically, EPA has not consistently observed the policies underlying this Proposal, and courts have at times upheld EPA's use 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).

83 Fed. Reg. at 18,769, n.3. The Proposal then goes on to say that "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.* The Proposal's categorical exclusion of non-publicly available "dose response data" is also departure from EPA's previous practice, as described in the 2002 EPA Guidelines, of weighing all relevant information.

In short, EPA provide no basis for changing course on this issue, especially when EPA has enshrined the previous policy in agency guidelines and litigation. EPA's failure to explain this change in course violates the law.

X. The proposed rule's handling of Confidential Business Information (CBI) is unlawfully vague and arbitrary and capricious

EPA's Proposal states that "where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, [and] confidential business information." 83 Fed. Reg. at 18,773. In crafting the Proposal, EPA has created a vague, double-edged sword that favors industry in some situations, and in others, creates barriers for industry groups submitting CBI. In both situations, the public could be harmed by the Proposal.

In an April 26, 2018 House hearing, then-Administrator Scott Pruitt suggested that CBI may be redacted and submitted to EPA under the Proposal, much like confidential health information:

ED_002389_00015391-00097

> **Rep. Cramer:** Maybe you could elaborate a little bit, how personal data can be protected and is protected. Nobody's asking for the names of every victim of every, you know, of every pollution source that's ever happened in the world, or that's been sourced in any study. They're not asking for personal data. We're asking simply for the science to be revealed. You can protect the data, right?
>
> **Administrator Pruitt:** Both the personal data, Congressman, as well as confidential business information, both CBI and personal information can be redacted and can be addressed and still serve the purposes of the proposed rule.

As others have noted, however, this is not always the case. "Industry-conducted studies could contain confidential business information required to be withheld by law. In addition, companies may have intellectual property rights that would be violated if access to underlying data allowed competitors to rely on a study without replicating it."[218] In certain cases, this will work to the detriment of regulated entities.

For example, industry stakeholders may submit studies, data or information for which CBI redactions would prevent EPA from considering those materials, because the information is not "publicly available in a manner sufficient for independent validation." 83 Fed. Reg. at 18,768. This could prevent EPA from adopting standards, exclusions, or other regulatory provisions informed by that information. Similarly, other industry stakeholders opposed to the appeals and demands sought by the first set of stakeholders, would be harmed if EPA nonetheless considers the latter industry's submissions, notwithstanding redacted CBI that is not "publicly available in a manner sufficient for independent validation"—while at the same time EPA refuses to consider confidential non-business information submitted by the opponent-stakeholders. *Id.*

In other cases, CBI exclusions will create a double standard, where the public, including adversarial industry stakeholders, will not have access to industry-funded studies or other information relevant to the rulemaking process, because EPA has designated that information CBI and refused to make it "publicly available in a manner sufficient for independent validation." *Id.* The Proposal nonetheless indicates that some or all of that CBI-redacted studies and information will be considered by EPA. This double standard, and unexplained, differential treatment of submissions relevant and even integral to EPA's rulemakings, is the essence of arbitrary and capricious action.

Industry groups themselves will be impacted by this double standard. During, or prior to, a rulemaking, industry groups sometimes appeal to EPA to loosen the rigor of agency regulations, accord industry operational flexibilities, extend compliance deadlines, or take other actions to reduce alleged regulatory burdens. Frequently industry accomplishes this by submitting information particular to a specific company or industry sector; a particular chemical or product formulation; or a particular process unit or manufacturing process. These submissions

---

[218] Bloomberg News, Energy & Environment Report, "Practitioner Insights: EPA's Flawed 'Secret Science' Plan Puts Good Science at Risk," May 21, 2018, *available at* https://www.bna.com/practitioner-insights-epas-n57982092715/.

ED_002389_00015391-00098

frequently are accompanied by claims that information is CBI, due to the company-specific or industry-specific nature of information that may be proprietary, confidential or the subject of trade secrets. Industry parties may also submit health studies or risk assessments they have conducted that may contain confidential clinical data or other information that they do not wish to make publicly available, or that they are barred from making publicly available due to confidentiality agreements, the death of study participants or other reasons.

The Agency itself is aware that its misguided Proposal works at odds with CBI. In a recent email exchange, an EPA staffer working on the rule, Richard Yamada, was informed of industry concerns by a colleague. Yamada

> included the concerns of the chemical industry when crafting the plan. Earlier this year, Nancy Beck, deputy assistant administrator of EPA's chemicals office, raised pointed concerns to Yamada and other EPA staffers about what a "secret science" policy would mean for regulating chemicals under the Toxic Substances Control Act (TSCA). Beck, a former senior director at the American Chemistry Council, wrote that requiring underlying data to be public would affect pesticide registrations and TSCA implementation, particularly if it did not account for confidential business information, or CBI.
>
> "Yes, thanks this is helpful – didn't know about the intricacies of CBI – ok, we will need to thread this one real tight! Thanks Nancy!" Yamada wrote in response to Beck's warning.[219]

Section 30.3, described below, may be the agency's attempt at such a "thread," but in attempting to carve out certain agency actions for special treatment, the Proposal again underscores just how arbitrary and capricious it is. The Proposal would create a dynamic in which EPA is unable to consider that CBI or otherwise confidential health or risk data in deciding whether to adopt regulations or issue guidance that grants industry the requested regulatory flexibilities.

When EPA exercises its regulatory authorities, the Proposal may constrain the agency's ability to be flexible or relieve regulatory obligations, precisely where and when it might be needed most: by being responsive to particular demonstrations made by specific companies based on persuasive information that also happens to be CBI. Former Administrator Pruitt appeared to sanction this outcome in his responses, above, to Rep. Cramer, where he suggested that any CBI could be redacted, much like health information.

The Proposal fails to address CBI in a coherent way, and in so doing furthers the problems inherent in its present use at the agency, while also creating a new set of obstacles for both industries and the public to deal with as it relates to business information and EPA's regulatory responsibilities.

---

[219] Scott Waldman, "Meet the man helping Pruitt reshape science," *Climatewire*, (May 23, 2018), https://www.eenews.net/stories/1060082467.

ED_002389_00015391-00099

XI. The Proposal arbitrarily and capriciously allows EPA to treat individual party adjudications, enforcement activities, and permit proceedings differently than "significant regulatory actions"

The Proposal at section 30.3 states that:

> Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

83 Fed. Reg. at 18,773. This provision most clearly highlights one of the arbitrary and capricious advantages that industry stakeholders enjoy under the Proposal: it exempts from its censoring coverage EPA activities where industry is the primary party likely to submit confidential information that EPA may consider and rely upon. This, notwithstanding that the submitted information is not "publicly available in a manner sufficient for independent validation," while still being highly relevant and even integral to EPA's legal responsibilities. *Id.* at 18,768.

Permitting activities are one key example. For permitting actions taken under the CAA, RCRA, CWA, etc., the Proposal arbitrarily and capriciously allows EPA to continue to rely on highly relevant regulatory science and other information supplied by industry that is not "publicly available in a manner sufficient for independent validation." *Id.* at 18,771–73. A company seeking a permit or permit revision may submit regulatory science, confidential business information or other non-confidential information that is not "publicly available in a manner sufficient for independent validation." *Id.* EPA could consider non-peer reviewed, non-transparent industry science or information to conclude that a non-transparent industry model demonstrates no adverse air quality impact on a neighboring national park or wilderness area. This, despite the inputs and assumptions behind the model being unavailable to the public. An applicant could assert that there are safe exposure levels for $PM_{2.5}$ or lead, and therefore EPA need not require any mitigation measures at concentrations below NAAQS levels in attainment areas. Industry applicants could rely upon hidden CBI to project no emissions increases for purposes of NSR permitting under the so-called "demand growth" exclusion, notwithstanding the unavailability of information critical to industry's claim and EPA's acceptance of that claim. Considering this and other non-transparent information, EPA could conclude that permits or permit revisions may be granted in situations where they should not lawfully be granted, notwithstanding that the non-transparent, unavailable information is scientifically erroneous and even absurd.

A second example is public information submitted during enforcement proceedings. The Proposal arbitrarily and capriciously allows EPA to continue to rely on highly relevant regulatory science and other information supplied to the agency by industry during enforcement proceedings, even when that information is not "publicly available in a manner sufficient for independent validation." *Id.* at 18,771–73. Consider, for example, a company that receives a notice of violation from EPA and meets with the agency to make the case that EPA and the Department of Justice should not file a complaint. The company may submit regulatory science, confidential business information, or other non-confidential information that is not "publicly available in a manner sufficient for independent validation." *Id.* at 18,768. EPA could consider

ED_002389_00015391-00100

non-peer reviewed, non-transparent, erroneous industry science to conclude that formaldehyde or asbestos are not carcinogens, or that $PM_{2.5}$ or lead have safe exposure levels, or that CO_2 does not endanger public health or welfare. Considering this and other non-transparent information, EPA could conclude that prosecution is not warranted, or that the information represents mitigating factors for penalties or injunctive relief, notwithstanding that the non-transparent, unavailable information is scientifically erroneous and even absurd.

The third case is public information submitted during individual party adjudications. *Id.* at 18,771–73. The Proposal arbitrarily and capriciously allows EPA to continue to rely on highly relevant regulatory science and other information supplied to the agency by industry during individual party adjudications, even when that information is not "publicly available in a manner sufficient for independent validation." *Id.* at 18,768. Consider, for example, a company facing an EPA order or applicability determination that qualifies as an adjudication under the APA or one of the federal statutes that the agency administers.

The company may submit regulatory science, confidential business information or other non-confidential information that is not "publicly available in a manner sufficient for independent validation." EPA could consider non-peer reviewed, non-transparent industry science to conclude that formaldehyde or asbestos are not carcinogens, or that $PM_{2.5}$ or lead have safe exposure levels, or that CO_2 does not endanger public health or welfare. Considering this and other non-transparent information during the individual party adjudication, EPA could conclude that adoption of the order is not warranted, or that agency regulations should be interpreted in a way that does not apply to that company's actions. Indeed, EPA could conclude, after considering the non-transparent, unavailable information, that the regulations should not apply in ways that would affect an entire industrial sector favorably, while harming the public meant to be protected by those regulations. Under proposed section 30.3, EPA could consider the non-transparent, unavailable information to reach these objectionable outcomes, notwithstanding that the information is scientifically erroneous and even absurd.

The Proposal nowhere explains why it is valid and consistent with EPA's statutory authorities and responsibilities to consider information that is not "publicly available in a manner sufficient for independent validation" under the situations allowed in proposed section 30.3 (individual party adjudications, enforcement activities, or permit proceedings), while prohibiting EPA consideration of that information in situations covered by the Proposal's prohibitions. Indeed, it is striking that the Proposal does not even *attempt* any such explanation or justification. *Id.* at 18,771–73. This is undoubtedly because there is no coherent, lawful justification or explanation that the agency could muster; it is unsurprising that the Proposal cannot overcome this.

Indeed, it is a hallmark of the Proposal's inherent arbitrariness and capriciousness that the Proposal prohibits EPA from considering the *identical regulatory science, studies, and information* in some regulatory situations, while allowing EPA to consider the *identical regulatory science, studies, and information* in other regulatory situations—based merely upon the *type of situation*, rather than any differences in availability, replicability, verifiability, or validation concerning the information. Proposed section 30.3 prohibits EPA from considering information that is not "publicly available in a manner sufficient for independent validation"

ED_002389_00015391-00101

during so-called "significant regulatory decisions," while prohibiting EPA from considering that *identical regulatory science, studies, or information* during "any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings." 83 Fed. Reg. at 18,768, 18,771. The Proposal does not and cannot explain or justify this differential treatment, so the Proposal does not even try.[220]

Finally, proposed section 30.3 is unlawfully vague, open-ended and arbitrary due to the capacious and unlimited way that EPA has drafted the exclusion from the Proposal's prohibitions. Section 30.3 indicates that "the provisions of this subpart do not apply to any other type of agency action." This grants EPA capacious and effectively unlimited discretion and authority to decide what "any other type of agency action" is and is not, without providing the public or regulated entities any criteria, understanding or advance notice as to how EPA will exercise that discretion and authority. That is the essence of arbitrary and capricious agency action. Indeed, the Proposal is structured in such a way that EPA will be exercising that discretion and authority—to decide what "any other type of agency action" does and does not cover—in secret, with no public input and no public awareness, concerning the situations in which EPA will and will not consider non-transparent, unavailable information. In addition to this being perversely ironic, considering the "transparency" title of the Proposal, this fact renders the Proposal even more arbitrary and capricious and unlawful.

XII. The Proposal treats studies, models and analyses that are integral to the functioning of EPA regulatory programs and the implementation of statutes in an arbitrary and capricious manner

In the Proposal, EPA professes concern with transparency, clarity, and independence; using the best available information; making sure that information is replicable and verifiable, and ensuring the public is able to participate meaningfully in the regulatory process. The Proposal says this will help EPA carry out its mission in a manner the public can trust and understand:

> The proposed regulation provides that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis.

83 Fed. Reg. at 18,769/1.

> The best available science must serve as the foundation of EPA's regulatory actions. Enhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions. By better informing the public, the Agency in enhancing the public's ability to understand and meaningfully participate in the regulatory process.

---

[220] Should EPA realize and conclude that it must explain and justify this differential treatment in any final rule, EPA first must issue a supplemental proposal with these explanations and justifications for public review and opportunity for comment prior to issuing any final rule.

ED_002389_00015391-00102

Id. at 18,769/2.

> When EPA develops significant regulations using public resources, including regulations for which the public is likely to bear the cost of compliance, EPA should ensure that the data and models underlying scientific studies that are pivotal to the regulatory action are available to the public. This proposed rule is designed to increase transparency in the preparation, identification, and use of science in policymaking.

Id. at 18,769/3.

> Regulatory determinations based on science should describe and document any assumptions and methods used, and should address variability and uncertainty.

Id. at 18,770/2.

> "Pivotal regulatory science" is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based.

Id.

> This [P]roposal will help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand.

Id. at 18,769/1.

In this section of our comments, we make the following points opposing the Proposal and supporting its withdrawal:

- First, the Proposal as written sweeps broadly to capture—and thereby to prohibit EPA from considering—studies, models, and analyses that are integral to the functioning of EPA regulatory programs, implementation of statutes like the Clean Air Act, and protection of public health and the environmental. It is both destructive and unlawful for EPA to refuse or fail to consider these additional studies, models, and analyses. We discuss numerous examples below.
- Second, to the extent that the Proposal does capture one or more of the studies, models, or analyses below, the Proposal would require EPA to conduct independent peer review of these materials before considering or using them, or before continuing to make them available for public use and awareness. *See* 83 Fed. Reg. at 18,774 (proposed § 30.7). This is objectionable and absurd. It is also unlawful for the same reasons that the Proposal is unlawful, as detailed in these comments and others.
- Third, to the extent that EPA disagrees that one or more of these studies, models, and analyses are captured by the Proposal, continuing to consider these materials while

> prohibiting EPA from considering other materials would be arbitrary and capricious. This is because these studies, models and analyses have the same hallmarks as "pivotal regulatory science" that the Proposal would exclude, as discussed in greater detail below. We emphasize that we do not believe EPA *should* or that EPA *may* fail to consider these other studies, models, or data, for the reasons set forth in these comments. Rather, our point is that continuing to consider these materials demonstrates additionally that the Proposal is arbitrary, capricious, and an abuse of discretion.

The Proposal states that "[t]he provisions of this subpart apply to dose response data and models underlying pivotal regulatory science that are used to justify significant regulatory decisions regardless of the source of funding or identity of the party conducting the regulatory science." 83 Fed. Reg. at 18,773/3 (proposed § 30.3). Next, the Proposal defines "dose response data and models" to mean:

> the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions typically underlie pivotal regulatory science that drives the size of benefit-cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated.

Id. at 18,773/2 (proposed § 30.2). Then, the Proposals defines "pivotal regulatory science" to mean "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions." *Id.* Finally, the Proposal defines "regulatory science" to mean "scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions." *Id.*

The Proposal either covers on its face, or appears to cover, the following examples of studies, models, and analyses that are integral to the functioning of EPA regulatory programs, implementation of statutes like the Clean Air Act, and protection of public health and the environment. It would be harmful, unlawful, arbitrary and capricious, and an abuse of EPA's discretion to include these materials within the sweep of the Proposal's prohibitions.

Alternatively, if EPA disagrees that the following examples are covered by the Proposal, then continuing to consider these materials that have the same hallmarks as the prohibited materials, and that raise the same issues and concerns that cause EPA to prohibit their consideration, demonstrates that the Proposal is arbitrary and capricious, biased, and internally inconsistent and contradictory.[221] Moreover, in this case, the Proposal would suffer from fatal failures to explain why EPA may consider these materials, while the Proposal would prohibit EPA from considering other materials.

---

[221] *See, e.g.*, *Air Transport Ass'n of Am. v. DOT*, 119 F.3d 38, 43 (D.C. Cir. 1997) (vacating regulation: "the most serious logical problem with [the] regulation—which we simply cannot accept," is that the agency's explanation "is internally inconsistent").

ED_002389_00015391-00104

A. Integrated Planning Model

EPA uses the Integrated Planning Model (IPM) to analyze the projected impact of environmental policies on the electric power sector in the lower 48 contiguous states and the District of Columbia. The IPM is a proprietary multi-regional, dynamic, deterministic linear programming model of the U.S. electricity sector developed by ICF International, and is used to support public and private sector clients

The IPM provides forecasts of least-cost capacity expansion, electricity dispatch, and emission control strategies for meeting energy demand and environmental, transmission, dispatch, and reliability constraints. The IPM can and has been used by the EPA to evaluate the costs and emissions impacts of policies to limit emissions of SO_2, NO_x, CO_2, HCl, and Hg from the electric power sector, including the following:

- the Clean Air Mercury Rule;
- Clean Air Interstate Rule;
- Clear Skies legislation;
- Mercury and Air Toxics Standards;
- Cross State Air Pollution Rule;
- Notice of Availability of the Environmental Protection Agency's Preliminary Interstate Ozone Transport Modeling Data for the 2015 Ozone National Ambient Air Quality Standard, 82 Fed. Reg. 1733 (Jan. 6, 2017);
- EPA's Power Sector Modeling in Support of the Notice of Data Availability – Preliminary Interstate Ozone Transport Modeling Data for the 2015 Ozone NAAQS;[222]
- New Source Performance Standards for the electric power sector;
- Clean Power Plan, Clean Power Plan repeal, and proposed Clean Power Plan replacement.

As a proprietary model, the IPM is not "publicly available in a manner sufficient for validation and analysis." 83 Fed. Reg. at 18,769/1. The model's inputs, assumptions, methodologies, and operation are not "transparent" in the manner described in the Proposal, notwithstanding the model being pivotal to EPA regulatory actions. *Id.* at 18,770/3. EPA has used the IPM regularly to "drive the magnitude of the benefit-cost calculation and the level of standards" in Clean Air Act regulations. *Id.* at 18,770/2. "The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions." *Id.* at 18,770/3. The public lacks access to the IPM's "[c]omputer codes and models involved in the creation and analysis of such information." 83 Fed. Reg. at 18,774/1 (proposed § 30.5(c)).

---

[222] https://www.epa.gov/airmarkets/epas-power-sector-modeling-support-notice-data-availability-preliminary-interstate-ozone.

ED_002389_00015391-00105

B. National Electric Energy Data System

The National Electric Energy Data System (NEEDS) database contains the generation unit records used to construct the model plants that represent existing and planned/committed units in EPA modeling applications of the IPM. The NEEDS includes geographic, operating, air emissions, pollution control, planned retirement dates, and other information on generating units. The NEEDS is customarily updated simultaneously with IPM updates. Data contained in NEEDS are taken from EIA forms, EIA AEO, NERC ES&D database, Ventyx new entrants' database (subscription required), EPA's emission tracking system (EPA Emissions Collection and Monitoring Plan System, ECMPS), and utility and regional EPA comments.

Similar to the IPM, with which NEEDS is integrated by EPA, NEEDS contains information that is not "publicly available in a manner sufficient for validation and analysis." 83 Fed. Reg. at 18,769/1. The inputs, assumptions, methodologies, and operation are not "transparent" in the manner described in the Proposal, notwithstanding the database being pivotal to EPA regulatory actions. *Id.* at 18,770/3. The Ventyx database requires a paid subscription that prevents NEEDS data from being transparent and publicly available in a manner sufficient for validation and analysis. EPA has used the NEEDS regularly (with the IPM) to "drive the magnitude of the benefit-cost calculation and the level of standards" in Clean Air Act regulations. *Id.* at 18,770/2.

C. The National Energy Modeling System

The National Energy Modeling System (NEMS), developed by Energy Information Administration (EIA), generates the Annual Energy Outlook (AEO) forecasts. EPA relies on NEMS forecasts for power sector modeling inputs and assumptions in IPM, including electricity demand and fuel prices.

Similar to the IPM, with which NEMS is also integrated by EPA, NEMS contains information and assumptions that are not "publicly available in a manner sufficient for validation and analysis." 83 Fed. Reg. at 18,769/1. The inputs, assumptions, methodologies, and operation are not "transparent" in the manner described in the Proposal, notwithstanding the database being pivotal to EPA regulatory actions. *Id.* at 18,770/3. EPA has used the NEMS regularly (with the IPM) to "drive the magnitude of the benefit-cost calculation and the level of standards" in Clean Air Act regulations. *Id.* at 18,770/2.

D. Co-Benefits Risk Assessment

COBRA is a tool available for download from EPA that helps state and local governments: (1) evaluate how changes in air pollution from clean energy policies and programs affect human health at the county, state, regional, or national levels; (2) estimate the economic value of health benefits associated with clean energy policies and programs to compare against program costs; (3) map and visually represent the air quality, human health, and health-related economic benefits from reductions in emissions of $PM_{2.5}$, SO_2, NO_x, NH_3, VOCs resulting from clean energy policies and programs.

ED_002389_00015391-00106

COBRA is intended to be a preliminary screening tool that state and local policymakers can use to identify health benefits associated with clean energy policy approaches. It provides preliminary estimates of the impact of air pollution emission changes on ambient particulate matter (PM) air pollution concentrations, translates this into health effect impacts, and then monetizes these impacts. It was developed by Abt Associates and it is copyrighted. EPA's website lists multiple analyses that have used COBRA.[223]

COBRA contains information and assumptions that are not "publicly available in a manner sufficient for validation and analysis." 83 Fed. Reg. at 18,769/1. The inputs, assumptions, methodologies and operation are not "transparent" in the manner described in the Proposal, notwithstanding the database being pivotal to EPA regulatory actions. *Id.* at 18,770/3. COBRA was developed by Abt based upon taking models from the very same epidemiological studies that the Proposal would prohibit EPA from considering and converting them into health impact functions.[224] Accordingly, COBRA would be "tainted" and unusable by EPA or other parties based on the same (unlawful, arbitrary) prohibitions reflected in the Proposal. EPA and other parties have used the COBRA to "drive the magnitude of the benefit-cost calculation and the level of standards" in Clean Air Act regulations. 83 Fed. Reg. at 18,770/2.

E. Avoided Emissions and Generation Tool

The Avoided Emissions and Generation Tool, developed by Synapse, estimates the emissions benefits of energy efficiency and renewable energy policies and programs. The AVERT quantifies the particulate matter ($PM_{2.5}$), nitrogen oxides (NO_X), sulfur dioxide (SO_2), and carbon dioxide (CO_2) emissions benefits of state and multi-state EE/RE policies and programs. The target audience for this tool is state air quality planners evaluating county, state, and regional emissions displaced at electric power plants by energy efficiency and renewable energy programs. It enables state and local authorities to include AVERT-calculated emission impacts of EE/RE policies and programs in air quality modeling and Clean Air Act plans used to meet the National Ambient Air Quality Standards, with the concurrence of the appropriate EPA regional office.

---

[223] *See, e.g.*, Analysis of the Public Health Impacts of the Regional Greenhouse Gas Initiative (Abt Associates, 2017); Change is in the Air: How States Can Harness Energy Efficiency to Strengthen the Economy and Reduce Pollution (ACEEE, 2014); Comments on B21-0650 –Renewable Portfolio Standard Expansion Amendment Act of 2016 (Chesapeake Climate Action Network testimony to the DC Transportation and Environment Committee, 2016); Health Impact and Economic Costs of Volkswagen's Lack of Compliance with the United States' Emission Standards (International Journal of Environmental Resources and Public Health. 13(9): 891. 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5036724/; Minneapolis Climate Action Plan: Public Health and Environmental Justice; Plug-In Vehicles in California (UC- Berkeley Transportation Sustainability Research Center, 2012); A Retrospective Analysis of the Benefits and Impacts of U.S. Renewable Portfolio Standards (National Renewable Energy Laboratory and Lawrence Berkeley National Laboratory, January 2016); Staff White Paper on Benefit-Cost Analysis in the Reforming Energy Vision Proceeding (New York Department of Public Service. July 2015); Standardized Regulatory Impact Assessment: Computers, Computer Monitors, and Signage Displays (Prepared for California Energy Commission, June 2016).

[224] *See* U.S. EPA, User's Manual for the Co-Benefits Risk Assessment Health Impacts Screening and Mapping Tool (COBRA), Version 3.2 (May 2018), https://www.epa.gov/sites/production/files/2018-05/documents/cobra_user_manual_may2018_508.pdf.

ED_002389_00015391-00107

The AVERT contains information and assumptions that are not "publicly available in a manner sufficient for validation and analysis." 83 Fed. Reg. at 18,769/1. The inputs, assumptions, methodologies and operation are not "transparent" in the manner described in the Proposal, notwithstanding the database being pivotal to EPA regulatory actions. *Id.* at 18,770/3. AVERT was developed by Synapse based upon taking models from the very same epidemiological studies that the Proposal would prohibit EPA from considering.[225] Accordingly, AVERT would be "tainted" and unusable by EPA or other parties based on the same (unlawful, arbitrary) prohibitions reflected in the Proposal. EPA and other parties have used AVERT to "drive the magnitude of the benefit-cost calculation and the level of standards" in Clean Air Act regulations, including State Implementation Plans for energy efficiency and renewable energy measures. 83 Fed. Reg. at 18,770/2.

F. Community Multi-scale Air Quality Modeling System

The Community Multi-scale Air Quality Modeling System simultaneously models multiple air pollutants, including ozone, PM, and air toxics, to help regulators determine the best air quality management scenarios for their communities, states and countries. Using data about land use, meteorology, and emissions, CMAQ provides detailed information about the concentrations of air pollutants in a given area for any specified emissions or climate scenario. It combines three types of models—meteorological models, emissions models, and air-chemistry transport models.

EPA and states have used CMAQ for more than a decade. The National Weather Service also uses CMAQ to produce daily U.S. forecasts for ozone air quality. States use CMAQ to develop and assess implementation actions needed to attain National Ambient Air Quality Standards. EPA has used CMAQ to support the development of NAAQS; provide guidance on NAAQS implementation to State environmental agencies and EPA Regional Offices; assess impacts of changing air pollution levels on human health by EPA and the Centers for Disease Control and Prevention; and assess impacts of polluted rainfall to sensitive ecosystems such as the Chesapeake Bay.[226] EPA has said, bluntly, that "[t]he loss or stagnation of [CMAQ] would jeopardize protection of public health and adequate assessment of Clean Air Act compliance." *Id.*

The CMAQ contains information and assumptions that are not "publicly available in a manner sufficient for validation and analysis." 83 Fed. Reg. at 18,769/1. The inputs, assumptions, methodologies, and operation are not "transparent" in the manner described in the Proposal, notwithstanding the database being pivotal to EPA regulatory actions. *Id.* at 18,770/3. The CMAQ relies, in part, on the very same epidemiological studies that the Proposal would

---

[225] *See* U.S. EPA, User's Manual for the Co-Benefits Risk Assessment Health Impacts Screening and Mapping Tool (COBRA), Version 3.2 (May 2018), https://www.epa.gov/sites/production/files/2018-05/documents/cobra_user_manual_may2018_508.pdf.

[226] U.S. EPA, Community Multiscale Air Quality (CMAQ) Model Impact Statement, https://www.epa.gov/sites/production/files/2017-08/documents/cmaq_impact_statement_29aug2017.pdf.

ED_002389_00015391-00108

prohibit EPA from considering.[227] Accordingly, CMAQ would be "tainted" and unusable by EPA or other parties based on the same (unlawful, arbitrary) prohibitions reflected in the Proposal. EPA and other parties have used CMAQ to "drive the magnitude of the benefit-cost calculation and the level of standards" in Clean Air Act regulations. *Id.* at 18,770/2.

G. EPA U.S. Nine-region MARKAL Database.

The EPA MARKet ALlocation (MARKAL) model is a data-driven, bottom-up energy systems economic optimization model. A census region representation of U.S. energy system, it was developed by EPA researchers for use with MARKAL model, an energy system optimization model used by local and federal governments and academic researchers. It is used in more than 35 countries. "The EPAUS9r is a distinct representation of the U.S. energy system designed to be used within the MARKAL model structure. The database characterizes the flow of energy associated with the extraction or import of resources, the conversion of these resources into useful energy, and the use of the energy in meeting end-use demands within and between the nine census regions of the United States."[228]

The MARKAL contains information and assumptions, and is based on commercial software, that are not "publicly available in a manner sufficient for validation and analysis." 83 Fed. Reg. at 18,769/1. The software is not open source.[229] The inputs, assumptions, methodologies, and operation are not "transparent" in the manner described in the Proposal, notwithstanding the database being pivotal to EPA regulatory actions. *Id.* at 18,770/3. EPA and other parties have used MARKAL to "drive the magnitude of the benefit-cost calculation and the level of standards" in Clean Air Act regulations. *Id.* at 18,770/2.

H. Emissions & Generation Resource Integrated Database.

eGRID is a comprehensive source of data on the environmental characteristics, including emissions and resource mix data, for almost every power plant and company that generates electricity in the U.S. eGRID data can be used for: GHG registries and inventories, carbon footprints, consumer information disclosure, emission inventories and standards, power market changes, and avoided emission estimates. It was developed with Abt Associates.

eGRID data are used in the following applications and programs: "Power Profiler web application, Climate Leaders protocols, ENERGYSTAR's Portfolio Manager and Target Finder, Waste Wise Office Carbon Footprint Tool, the Personal Greenhouse Gas Emissions Calculator, the Greenhouse Gas Equivalencies Calculator, and the Green Power Equivalency Calculator."[230]

---

[227] *See* U.S. EPA, User's Manual for the Co-Benefits Risk Assessment Health Impacts Screening and Mapping Tool (COBRA), Version 3.2 (May 2018), https://www.epa.gov/sites/production/files/2018-05/documents/cobra_user_manual_may2018_508.pdf.
[228] U.S. EPA, EPA U.S. Nine-region MARKAL DATABASE, Database Documentation, https://nepis.epa.gov/Adobe/PDF/P100I4RX.pdf.
[229] Database Documentation, *supra* n.228.
[230] U.S. EPA, The Emissions and Generation Resource Integrated Database: Technical Support Document for eGrid With Year 2016 Data, https://www.epa.gov/sites/production/files/2018-02/documents/egrid2016_technicalsupportdocument_0.pdf.

ED_002389_00015391-00109

"eGRID is also used by other Federal Government agencies such as Oak Ridge National Laboratory (ORNL) for their Combined Heat and Power Calculator, the National Energy Technology Laboratory (NETL) for their sponsored distributed National Carbon Sequestration Database and Geographic Information System (NATCARB), and the National Renewable Energy Laboratory (NREL) for their micropower distributed generation optimization model named HOMER."[231]

eGRID contains information and assumptions that are not "publicly available in a manner sufficient for validation and analysis." 83 Fed. Reg. at 18,769/1. The inputs, assumptions, methodologies, and operation are not "transparent" in the manner described in the Proposal, notwithstanding the database being pivotal to EPA regulatory actions. *Id.* at 18,770/3. eGRID relies, in part, on the very same epidemiological studies that the Proposal would prohibit EPA from considering.[232] Accordingly, eGRID would be "tainted" and unusable by EPA or other parties based on the same (unlawful, arbitrary) prohibitions reflected in the Proposal. EPA and other parties have used eGRID to "drive the magnitude of the benefit-cost calculation and the level of standards" in Clean Air Act regulations. *Id.* at 18,770/2.

I. National Emissions Inventory (NEI)

The National Emissions Inventory is a comprehensive and detailed estimates of air emissions of criteria pollutants, criteria precursors, and hazardous air pollutants from air emissions sources, released every three years and based on data provided by state, local, and tribal air agencies for sources in their jurisdictions and supplemented by data developed by EPA. There is data for point sources, nonpoint sources, onroad sources, nonroad sources, and "event" sources.

The NEI contains information and assumptions that are not "publicly available in a manner sufficient for validation and analysis." 83 Fed. Reg. at 18,769/1. The inputs, assumptions, methodologies and operation are not "transparent" in the manner described in the Proposal, notwithstanding the database being pivotal to EPA regulatory actions. *Id.* at 18,770/3. "Raw input datasets" underlying the NEI, for example, are available to "all EPA staff, EIS data submitters (*i.e.*, the S/L/T air agency staff), Regional Planning Organization staff that support state, local and tribal agencies, and contractors working for the EPA on emissions related work"—but not available to the public.[233] Facility-level identification is also hidden from the public, while only some supporting material is publicly available.[234] EPA and other parties have used the NEI to "drive the magnitude of the benefit-cost calculation and the level of standards" in Clean Air Act regulations. *Id.* at 18,770/2.

---

[231] Technical Support Document for eGrid, *supra* n.230.
[232] *See* U.S. EPA, User's Manual for the Co-Benefits Risk Assessment Health Impacts Screening and Mapping Tool (COBRA), Version 3.2 (May 2018), https://www.epa.gov/sites/production/files/2018-05/documents/cobra_user_manual_may2018_508.pdf.
[233] U.S. EPA, 2014 National Emissions Inventory, version 2 Technical Support Document (July 2018), https://www.epa.gov/sites/production/files/2018-07/documents/nei2014v2_tsd_05jul2018.pdf.
[234] 2014 National Emissions Inventory, version 2 Technical Support Document, *supra* n.233, at 1–2.

ED_002389_00015391-00110

XIII. The Proposal's retroactivity provisions are arbitrary and capricious

In the Proposal, EPA states that the proposed regulation "is intended to apply prospectively." 83 Fed. Reg. at 18,771. However, a few pages later, the agency "solicits comments on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available." Also, the Proposal states that "for regulatory programs . . . in which future significant regulatory actions may be based on the administrative record from previous reviews . . . , EPA seeks comment on the manner in which this proposed rule should apply to that previous record." *Id.* at 18,772.

In short, despite its assertion that the rulemaking is "intended" to apply prospectively, the Proposal contemplates prohibiting EPA—or will prohibit EPA— from relying on studies generated *prior* to rulemakings that fail to meet the Proposal's ill-defined criteria for "publicly available data." This approach is arbitrary and capricious, runs counter to the specific language of many statutes the agency is tasked with administering, and would destroy the agency's ability to promulgate health-based standards to protect the American public using the best available science.

The Proposal ignores an entire body of case law that has considered and roundly rejected both retroactivity in rulemakings and limiting data that underlies rulemakings to "publicly available data." In so doing, the Proposal is arbitrary and capricious, and should be rejected.

The Supreme Court strongly disfavors retroactive application of rules. The Court has stated that:

> Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result. [] By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms. [] Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant.

Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208–09 (1988) (internal citations omitted). Notably, the Proposal does not identify a single provision in a single statute that EPA administers, or any other federal law, that requires or even authorizes any final rule based on the Proposal to have retroactive effect. *See generally* 83 Fed. Reg. at 18,768–74. There has been no power conveyed by Congress in express terms to promulgate retroactive rules related to any element of the Proposal; it is unsurprising that the Proposal does not and cannot identify *any* express or even implied grant of authority. *See Bowen*, 488 U.S. at 208–09.

The Proposal claims prospective application, while nonetheless noting that in some circumstances EPA may desire to apply the rule retroactively. 83 Fed. Reg. at 18,771. This, too, is unlawful and fails to meet the high burden in the Supreme Court's *Bowen* decision and its progeny concerning retroactive application of agency rules. The suggestion in the Proposal, for

ED_002389_00015391-00111

example, that EPA may invoke the Proposal's approach to review all prior health and scientific studies underlying the NAAQS is illegitimate, arbitrary and capricious, and contrary to caselaw.[235] *Bowen* and its progeny do not permit agency rules to have retroactive effect to disallow health studies and regulatory science generated prior to, or relied upon by EPA prior to, adoption of any final rule based on the Proposal. This caselaw does not entertain any such exception and accepting any such exception for these circumstances would circumvent the holdings and reasoning of this case law.

XIV. The Proposal fails to address environmental justice concerns and harms to children, as required by Executive Order 12,898 and Executive Order 13,045

EPA claims that it need not address Executive Order 12,898 (Environmental Justice in Minority Populations) nor Executive Order 13,045 (protecting children) because "this action does not concern an environmental health risk or safety risk" 83 Fed. Reg. at 18,773. This is an unsupported and inaccurate claim. The implementation of this rule would impact the rules and guidelines that are set to protect children, people of color, the elderly, low-income, and other underserved populations.

A. Executive Order 12,898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12,898 applies to agency "programs, policies and activities" and directs agencies such as the EPA, "[t]o the greatest extent practicable and permitted by law" to "identify[] and address[], as appropriate, disproportionately high and adverse human health or environmental effects" of agency programs, policies and actions on minority populations and low-income populations." Executive Order 12,898, Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 Fed. Reg. 7629 (Feb. 16, 1995). Because minority and low-income populations have historically been underrepresented in agency decision making, Executive Order 12,898 also aims to improve public participation of these populations in the decision-making process. *Id.* at 7630–32. Moreover, Executive Order 12898 aims to "improve research and data collection relating to the health of and environment of minority populations and low-income populations." *Id.* at 7630.

In keeping with these and other principles, EPA created a Guidance document for determining when environmental justice should be considered when developing regulations titled "Guidance on Considering Environmental Justice During the Development of Regulatory Actions." To achieve Executive Order 12,898's goals, the Guidance directs rule-writers and decision-makers to respond to three core Environmental Justice questions throughout the process:

---

[235] *See* 83 Fed. Reg. at 18,772/1 ("For regulatory programs, like the National Ambient Air Quality Standards program, in which future significant regulatory actions may be based on the administrative record from previous reviews—particularly where the governing statute requires repeated review on a fixed, date-certain cycle—EPA seeks comment on the manner in which this proposed rule should apply to that previous record.")

ED_002389_00015391-00112

1. How did the public participation process provide transparency and meaningful participation for minority populations, low-income populations, tribes, and indigenous peoples?

2. How did the rule-writers identify and address existing and/or new disproportionate environmental and public health impacts on minority populations, low-income populations, and/or indigenous peoples?

3. How did actions taken under #1 and #2 impact the outcome or final decision?

Guidance on Considering Environmental Justice During the Development of Regulatory Actions, May 2015, at ii, https://www.epa.gov/sites/production/files/2015-06/documents/considering-ej-in-rulemaking-guide-final.pdf (footnote omitted). It is important to note that a regulatory action may involve a potential environmental justice concern if it could:

• Create new disproportionate impacts on minority populations, low-income populations, and/or indigenous peoples;

• Exacerbate existing disproportionate impacts on minority populations, low-income populations, and/or indigenous peoples; or

• Present opportunities to address existing disproportionate impacts on minority populations, low-income populations, and/or indigenous peoples through the action under development.

Id. at 10. And "[i]n determining whether potential EJ concerns may be at issue in regulatory actions, some level of analysis is needed, be it qualitative, quantitative, or some combination of both." *Id.* at 15.

The Proposal improperly ignores Executive Order 12,898 and the agency's obligations to address Environmental Justice in minority and low-income populations. EPA does not appear to have considered the Proposals effect on minority and low-income populations at all or performed any analysis, let alone attempt to address the Environmental Justice concerns. Instead, the Proposal states "The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard." 83 Fed. Reg. at 18,773. But Executive Order 12,898 is not limited to actions that "establish an environmental health or safety standard," and EPA does not explain the basis for its conclusion that the Proposal is exempt. This is arbitrary and capricious.

The Proposal makes no mention of the Guidance on Considering Environmental Justice During the Development of Regulatory Actions, and the Proposal directly conflicts with many of the Executive Order's, and the Guidance document's provisions. With the single English language hearing EPA held in Washington DC, EPA has not provided for meaningful participation of minority populations, low-income populations, tribes, and indigenous peoples. Given that EPA has decided without explanation that the Proposal is categorically exempt from Environmental Justice considerations, the agency has not identified or addressed any existing or

new disproportionate environmental and public health impacts on minority populations, low-income populations, and/or indigenous peoples. And the Proposal's preclusion of agency consideration of peer reviewed studies in regulatory decision making unless the underlying data are made publicly available, will weaken research and data collection relating to the health of and environment of minority populations and low-income populations.

If EPA had fulfilled its obligations under Executive Order 12,898, the agency would have concluded that the Proposal does disproportionately harm minority and low-income populations that are most in need of protection. It is well established that minority and low-income populations are most likely to experience disproportionate exposure to harmful pollutants and chemicals. The Proposal seeks to preclude the use of scientific research critical to establishing safeguards against this disproportionate exposure.

Lastly, the Proposal will reduce research and data collection needed to protect the health of minority and low-income populations as individuals are deterred based on the fear their personal information will be released and researchers avoid seeking such information. EPA has not addressed this issue.

The Proposal does not comply with Executive Order 12,898 related to Environmental Justice or any EPA guidance implementing the Executive Order. It is arbitrary and capricious and should be withdrawn.

B. Executive Order 13,045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13,045 requires that every agency:

> (a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and
>
> (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.

Executive Order 13,045, Protection of Children From Environmental Health Risks and Safety Risks, 62 Fed. Reg. 19,885 (Apr. 21, 1997). The Executive Order requires that

> For each covered regulatory action submitted to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866, the issuing agency shall provide to OIRA the following information developed as part of the agency's decisionmaking process, unless prohibited by law:
>
> (a) an evaluation of the environmental health or safety effects of the planned regulation on children; and

(b) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.

Id. at 19,887. The Executive Order covers regulatory actions that are likely to result in a rule that may be economically significant under Executive Order 12,866 (which the EPA concluded applies to the Proposal, *see* 83 Fed. Reg. at 18,772) and "concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children." 62 Fed. Reg. at 19,885.

EPA created a Guide to help Agency staff involved in developing actions determine whether Executive Order 13,045 applies to an Agency action and, if so, how to implement the Executive Order. Guide to Considering Children's Health When Developing EPA Actions, at 1 Oct. 2006, https://www.epa.gov/sites/production/files/2014-05/documents/epa_adp_guide_childrenhealth.pdf. The Guide includes "a set of questions EPA staff involved in action development can ask risk assessors to ensure that the various types of information relevant to the assessment of risks to children are considered and may be useful in addressing the issue of disproportionate risks." *Id.* at 8. And, the Guide explains: "If a rulemaking is not covered by EO 13045, but it discusses environmental health or safety, it is advisable to characterize children's risk to the extent the data are available." *Id.* at 7.

EPA asserts that the Proposal is not subject to Executive Order 13,045 because it does not concern an environmental health risk or safety risk. 83 Fed. Reg. at 18,773. EPA does not explain how it reached this conclusion. EPA also does not characterize children's risk to the extent data are available. The Proposal applies to "Pivotal regulatory science," which it defines as "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions." *Id.* And the Proposal defines Regulatory science as "scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions." *Id.* The Proposal explains that "'Pivotal regulatory science' is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based." *Id.* at 18770. By its terms, the Proposal will impact (and therefore concern) all environmental health and safety risks, including many that EPA knows disproportionately affect children.

EPA failed its obligation to evaluate the environmental health or safety effects of the Proposal on children and explain why the Proposal is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. The Proposal is arbitrary and capricious and should be withdrawn.

C. Examples of how the Proposal could disproportionately affect minority populations, low-income populations, and children

As explained in section III.F. and elsewhere, the Proposal would preclude the use of many of the studies that EPA has relied on to set and revise the NAAQS for fine particulate

matter ($PM_{2.5}$). The regulatory impact assessment from the initial decision to set the $PM_{2.5}$ NAAQS explained that "benefits from these standards will likely be concentrated in urban areas with high concentrations of minority and low-income populations." Regulatory Impact Analyses for the Particulate Matter and National Ambient Air Quality Standards and Proposed Regional Haze Rule, at 11–31 (July 17, 1997). When EPA revised the $PM_{2.5}$ NAAQS in 2013, the agency confirmed:

> The EPA has identified potential disproportionately high and adverse effects on minority and/or low-income populations related to $PM_{2.5}$ exposures. In addition, the EPA has identified persons from lower socioeconomic strata as an at-risk population for PM-related health effects.

National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3085, 3267 (Jan. 15, 2013). EPA also stated that "[t]he protection offered by these standards is especially important for children because childhood represents a lifestage associated with increased susceptibility to PM-related health effects." *Id.* at 3266. EPA has not explained how its Proposal to preclude from consideration the foundational scientific studies for fine particulate matter protections that disproportionately benefit children, minority, and low-income populations will not affect those same children, minority, and low-income populations.

Similarly, as explained in section III.A., the Proposal would preclude the consideration of epidemiology studies published in the 1990's that correlate childhood blood lead levels with impaired brain function and adverse behavioral effects, which important EPA lead-reduction regulations are based on. A 2001 lead regulation under the Toxic Substances Control Act has been essential in helping to reduce lead poisoning among children, *see* section III.A. Lead; Identification of Dangerous Levels of Lead, 66 Fed. Reg. 1206 (Jan. 5, 2001). That rule explains "Young children are especially vulnerable to the toxic effects of lead because their nervous systems are still developing and they absorb more of the lead to which they are exposed." *Id.* at 1207. "Moreover, the standards selected by EPA are designed first and foremost to protect children from lead in residential paint, dust, and soil." *Id.* at 1237. Additionally, EPA explained:

> The Agency's standards will protect children in minority and low-income communities from disproportionate burdens. This is based on the findings of the Agency's economic analysis which shows that non-white populations receive more of the public health benefit associated with the standards.

Id. EPA has not explained how its Proposal to preclude from consideration the foundational scientific studies for lead protections that disproportionately benefit children, minority, and low-income populations will not affect those same children, minority, and low-income populations.

XV. The Proposal's peer review provision lacks any statutory basis, is vague and contrary to existing requirements for peer review

In addition to addressing how and whether the agency will consider science, the Proposal also contains a seemingly unrelated provision regarding agency peer review. The Proposal, in § 30.7, reads:

ED_002389_00015391-00116

What role does independent peer review in this section?

> 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 FR 2664) and the exemptions described therein.
>
> Because transparency in regulatory science includes addressing issues associated with assumptions used in models, EPA shall ask peer reviewers to articulate the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results.

83 Fed. Reg. at 18,774.

There is no statutory authority for EPA to "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 FR 2664) and the exemptions described therein." The federal statutes that EPA lists as putative authority for the Proposal provide no authority for proposed § 30.7. *See* 83 Fed. Reg. at 18,769/2 (citing Clean Air Act sections 103, 301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C. 1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C. 300j–1, 300j–9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660; Emergency Planning and Community Right-To-Know Act section 328, 42 U.S.C. 11048; Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w; and Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609, and the Administrative Procedures Act). The claimed authorities that EPA lists do not mention peer review or even allude to the concept. *Id.* Neither the Proposal nor accompanying docket materials identify *any* provision of any federal statute that authorizes EPA to promulgate proposed § 30.7. Our own research revealed no provision of any federal statute that authorizes EPA to promulgate proposed § 30.7.

When Congress writes federal statutes, Congress knows how to create legal authority for peer review, who shall conduct that peer review, what role, if any, that EPA or other parties will play, and how that peer review may be conducted. None of the provision in the law authorize EPA's Proposal in § 30.7. Instead, the statutes *require* that EPA use peer-reviewed science, regardless of whether it would meet EPA's definition of the term in § 30.7. And in cases where the law requires *EPA* to conduct the review, the statutes often spell out specifically how that should happen.

ED_002389_00015391-00117

Statute	Provisions on Peer Review
CAA	§ 7511b. Federal ozone measures (g) Ozone design value study The Administrator shall conduct a study of whether the methodology in use by the Environmental Protection Agency as of November 15, 1990, for establishing a design value for ozone provides a reasonable indicator of the ozone air quality of ozone nonattainment areas. The Administrator shall obtain input from States, local subdivisions thereof, and others. The study shall be completed and a report submitted to Congress not later than 3 years after November 15, 1990. The results of the study shall be subject to ***peer and public review*** before submitting it to Congress. 42 U.S.C. § 7511b (emphasis added). § 7412. Hazardous air pollutants (p) Mickey Leland National Urban Air Toxics Research Center (3) Scientific Advisory Panel The Board of Directors shall be advised by a Scientific Advisory Panel, the 13 members of which shall be appointed by the Board, and to include eminent members of the scientific and medical communities. The Panel membership may include scientists with relevant experience from the National Institute of Environmental Health Sciences, the Center for Disease Control, the Environmental Protection Agency, the National Cancer Institute, and others, and the Panel shall conduct ***peer review*** and evaluate research results. The Panel shall assist the Board in developing the research agenda, reviewing proposals and applications, and advise on the awarding of research grants. 42 U.S.C. § 7412 (emphasis added).
CWA	§ 1321. Oil and hazardous substance liability (a) Definitions (27) the term "best available science" means science that-- (A) maximizes the quality, objectivity, and integrity of information, including statistical information; (B) uses ***peer-reviewed*** and publicly available data; and (C) clearly documents and communicates risks and uncertainties in the scientific basis for such projects; 33 U.S.C. § 1321 (emphasis added).
SDWA	§ 300g-1. National drinking water regulations (b) Standards

ED_002389_00015391-00118

	(3) Risk assessment, management, and communication (A) Use of science in decisionmaking In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use-- (i) the best available, ***peer-reviewed science*** and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) 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). (B) Public information In carrying out this section, the Administrator shall ensure that the presentation of information on public health effects is comprehensive, informative, and understandable. The Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable-- (i) each population addressed by any estimate of public health effects; (ii) the expected risk or central estimate of risk for the specific populations; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and (v) ***peer-reviewed studies*** known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data. … (12) Certain contaminants (B) Sulfate (i) Additional study Prior to promulgating a national primary drinking water regulation for sulfate, the Administrator and the Director of the Centers for Disease Control and Prevention shall jointly conduct an additional study to establish a reliable dose-response relationship for the adverse human health effects that may result from exposure to sulfate in drinking water, including the health effects that may be experienced by groups within the general population (including infants and travelers) that are potentially at greater risk of adverse health effects as the result of such exposure. The study shall be conducted in consultation with interested States, shall be based on the best available, ***peer-reviewed science*** and supporting studies conducted in accordance with sound and objective scientific practices, and shall be completed not later than 30 months after August 6, 1996. 42 U.S.C. § 300g-1 (emphasis added).

ED_002389_00015391-00119

	§ 300j-2. Grants for State programs (d) New York City watershed protection program (1) In general The Administrator is authorized to provide financial assistance to the State of New York for demonstration projects implemented as part of the watershed program for the protection and enhancement of the quality of source waters of the New York City water supply system, including projects that demonstrate, assess, or provide for comprehensive monitoring and surveillance and projects necessary to comply with the criteria for avoiding filtration contained in 40 C.F.R. 141.71. Demonstration projects which shall be eligible for financial assistance shall be certified to the Administrator by the State of New York as satisfying the purposes of this subsection. In certifying projects to the Administrator, the State of New York shall give priority to monitoring projects that have undergone ***peer review***. 42 U.S.C. § 300j-2 (emphasis added).
RCRA	§ 6939a. Exposure information and health assessments (b) Health assessments (2) Whenever in the judgment of the Administrator, or the State (in the case of a State with an authorized program), a landfill or a surface impoundment poses a substantial potential risk to human health, due to the existence of releases of hazardous constituents, the magnitude of contamination with hazardous constituents which may be the result of a release, or the magnitude of the population exposed to such release or contamination, the Administrator or the State (with the concurrence of the Administrator) may request the Administrator of the Agency for Toxic Substances and Disease Registry to conduct a health assessment in connection with such facility and take other appropriate action with respect to such risks as authorized by section 9604(b) and (i) of this title. If funds are provided in connection with such request the Administrator of such Agency shall conduct such health assessment. … (e) Periodic reports The Administrator of such Agency shall issue periodic reports which include the results of all the assessments carried out under this section. Such assessments or other activities shall be reported after appropriate ***peer review***. 42 U.S.C. § 6939a (emphasis added).
CERCLA	§ 9604. Response authorities (i) Agency for Toxic Substances and Disease Registry; establishment, functions, etc.

ED_002389_00015391-00120

	. . . Any toxicological profile or revision thereof shall reflect the Administrator of ATSDR's assessment of all relevant toxicological testing which has been ***peer reviewed***. The profiles required to be prepared under this paragraph for those hazardous substances listed under subparagraph (A) of paragraph (2) shall be completed, at a rate of no fewer than 25 per year, within 4 years after October 17, 1986. A profile required on a substance listed pursuant to subparagraph (B) of paragraph (2) shall be completed within 3 years after addition to the list. The profiles prepared under this paragraph shall be of those substances highest on the list of priorities under paragraph (2) for which profiles have not previously been prepared. Profiles required under this paragraph shall be revised and republished as necessary, but no less often than once every 3 years. Such profiles shall be provided to the States and made available to other interested parties. . . . (7)(A) Whenever in the judgment of the Administrator of ATSDR it is appropriate on the basis of the results of a health assessment, the Administrator of ATSDR shall conduct a pilot study of health effects for selected groups of exposed individuals in order to determine the desirability of conducting full scale epidemiological or other health studies of the entire exposed population. (B) Whenever in the judgment of the Administrator of ATSDR it is appropriate on the basis of the results of such pilot study or other study or health assessment, the Administrator of ATSDR shall conduct such full scale epidemiological or other health studies as may be necessary to determine the health effects on the population exposed to hazardous substances from a release or threatened release. If a significant excess of disease in a population is identified, the letter of transmittal of such study shall include an assessment of other risk factors, other than a release, that may, in the judgment of the ***peer review*** group, be associated with such disease, if such risk factors were not taken into account in the design or conduct of the study. . . . (13) All studies and results of research conducted under this subsection (other than health assessments) shall be reported or adopted only after appropriate ***peer review***. Such ***peer review*** shall be completed, to the maximum extent practicable, within a period of 60 days. In the case of research conducted under the National Toxicology Program, such ***peer review*** may be conducted by the Board of Scientific Counselors. In the case of other research, such ***peer review*** shall be conducted by panels consisting of no less than three nor more than seven members, who shall be disinterested scientific experts selected for such purpose by the Administrator of ATSDR or the Administrator of EPA, as appropriate, on the basis of their reputation for scientific objectivity and the lack of institutional ties

ED_002389_00015391-00121

	with any person involved in the conduct of the study or research under review. Support services for such panels shall be provided by the Agency for Toxic Substances and Disease Registry, or by the Environmental Protection Agency, as appropriate. 42 U.S.C. § 9604 (emphasis added).
EPCRA	No mentions of peer review
FIFRA	<u>§ 136w. Authority of Administrator</u> (e) Peer review The Administrator shall, by written procedures, provide for ***peer review*** with respect to the design, protocols, and conduct of major scientific studies conducted under this subchapter by the Environmental Protection Agency or by any other Federal agency, any State or political subdivision thereof, or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for ***peer review***, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide. Whenever the Administrator determines that circumstances do not permit the ***peer review*** of the results of any such scientific study prior to the Administrator's exercising authority under section 136d(c) of this title to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of ***peer review*** as provided in this sentence. The evaluations and relevant documentation constituting the ***peer review*** that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term "***peer review***" shall mean an independent evaluation by scientific experts, either within or outside the Environmental Protection Agency, in the appropriate disciplines. 7 U.S.C. § 136w (emphasis added). <u>§ 136w-8. Pesticide registration service fees</u> (a) Definition of costs In this section, the term "costs", when used with respect to review and decisionmaking pertaining to an application for which registration service fees are paid under this section, means-- (1) costs to the extent that--

	(A) officers and employees provide direct support for the review and decisionmaking for covered pesticide applications, associated tolerances, and corresponding risk and benefits information and analyses; (B) persons and organizations under contract with the Administrator engage in the review of the applications, and corresponding risk and benefits information and assessments; and (C) advisory committees and other accredited persons or organizations, on the request of the Administrator, engage in the ***peer review*** of risk or benefits information associated with covered pesticide applications; (2) costs of management of information, and the acquisition, maintenance, and repair of computer and telecommunication resources (including software), used to support review of pesticide applications, associated tolerances, and corresponding risk and benefits information and analyses; and (3) costs of collecting registration service fees under subsections (b) and (c) and reporting, auditing, and accounting under this section. 7 U.S.C. § 136w-8 (emphasis added).
TSCA	<u>§ 2625. Administration</u> (h) Scientific standards In carrying out sections 2603, 2604, and 2605 of this title, 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. 15 U.S.C. § 2625 (emphasis added).

	§ 2617. Preemption (b) New statutes, criminal penalties, or administrative actions creating prohibitions or other restrictions (1) In general Except as provided in subsections (c), (d), (e), (f), and (g), beginning on the date on which the Administrator defines the scope of a risk evaluation for a chemical substance under section 2605(b)(4)(D) of this title and ending on the date on which the deadline established pursuant to section 2605(b)(4)(G) of this title for completion of the risk evaluation expires, or on the date on which the Administrator publishes the risk evaluation under section 2605(b)(4)(C) of this title, whichever is earlier, no State or political subdivision of a State may establish a statute, criminal penalty, or administrative action prohibiting or otherwise restricting the manufacture, processing, distribution in commerce, or use of such chemical substance that is a high-priority substance designated under section 2605(b)(1)(B)(i) of this title. … (f) Waivers (2) Required exemptions Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that-- (A)(i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance; (ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and (iii) the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in ***peer-reviewed science***; or (B) no later than the date that is 18 months after the date on which the Administrator has initiated the prioritization process for a chemical substance under the rule promulgated pursuant to section 2605(b)(1)(A) of this title, or the date on which the Administrator publishes the scope of the risk evaluation for a chemical substance under section 2605(b)(4)(D) of this title, whichever is sooner, the State or political subdivision of the State has enacted a statute or proposed or finalized an administrative action intended to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of the chemical substance. 15 U.S.C. § 2617 (emphasis added).

ED_002389_00015391-00124

	§ 2605. Prioritization, risk evaluation, and regulation of chemical substances and mixtures (b) Risk evaluations (E) Metals and metal compounds In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is ***peer reviewed*** by the Science Advisory Board. 15 U.S.C. § 2605 (emphasis added).

Under longstanding federal case law, when Congress authorizes an approach in one section of a statute using specific language but does not do the same in other sections of a statute, courts presume that Congress acted purposefully and did not mean to address or authorize that approach in those other statutory sections. *See, e.g.*, *Dean v. United States*, 556 U.S. 568 (2009) ("It is generally presumed that Congress acts intentionally when including particular language in one section of a statute but not in another." (citing *Russello v. United States*, 464 U.S. 16, 23 (1983)). Not only are there no implied grants of authority to an agency in the other statutory sections, but the congressional decisions to authorize the approach elsewhere in the statute give even *greater* force to the conclusion that the agency has *not* been given authority where Congress did not use the same or similar authorizing language.

The EPA approach proposed in § 30.7 is even more unlawful than would be the case, independently, under this case law. Proposed § 30.7 says "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 FR 2664) and the exemptions described therein." 83 Fed. Reg. at 18,774/2 (emphasis added). EPA proposes to bind itself ("shall") to conduct a particular form of peer review on "*all* pivotal regulatory science" based on an *unenforceable, non-binding* OMB bulletin that has never been the subject of notice and comment rulemaking and that itself is not authorized by any federal law. To the contrary, treating the content of the unenforceable bulletin as a binding regulation would itself violate the federal statutes that EPA implements, because those statutes do not codify the bulletin, and EPA would be unlawfully codifying a mere policy preference. This EPA may not do.

This Proposal is unlawful, arbitrary and capricious, and an abuse of EPA discretion. To reiterate, the Proposal identifies *no* statutory authority for EPA to conduct independent peer review for any, much less all, "pivotal regulatory science" consistent with the dense content (and exceptions) of the OMB bulletin. The Proposal identifies *no* statutory authority for EPA to bind itself, and future administrations, to conduct peer review only in this fashion, unless and until future notice-and-comment rulemaking is undertaken. The Proposal identifies no suggestion in statutory language or legislative history that Congress intended EPA to conduct binding peer review consistent with this OMB bulletin, notwithstanding that Congress has known about this

ED_002389_00015391-00125

bulletin since 2005. EPA has simply made up proposed § 30.7—with its the link to the OMB bulletin, and the putative authority for the Proposal—out of whole cloth. This EPA may not do.

The Proposal suffers additionally from unlawful vagueness. Proposed § 30.7 say that "EPA shall conduct independent peer review" without providing any coherent explanation or accompanying regulatory text about what that *means*: how will that peer review be conducted? By whom? Who will select the peer reviewers? How many will there be? Who will assure their independence and expertise? Will peer reviewers be subject to federal conflict of interest rules and policies? Will peer reviewers be anonymous? Where will the funds come from to conduct EPA peer reviews for "all pivotal regulatory science"? Has EPA estimated how many instances of "pivotal regulatory science" it anticipates conducting peer review for in one year? In prior years? Will the peer review be conducted openly and publicly? Will it be conducted in accordance with the Federal Advisory Committee Act? What will the duration of any peer review be? What purpose will that peer review serve? How will it affect future regulatory decisions? Or will it? Will there be an administrative docket? Will any product of the peer review be included in the administrative dockets for rulemaking? Will peer reviewer comments be part of the certified record for judicial review? Will the agency seek deference from future reviewing courts for the views expressed by peer reviewers? Does EPA not believe that peer review conducted by professional journals and societies is valid? Or sufficient? On what basis does EPA think professional peer review is invalid or insufficient, considering there is not one iota of evidence or support for that belief in the Proposal or the accompanying docket? What is the basic *justification* for proposed § 30.7? The Proposal provides no answers to these questions.

One obvious and serious objection to the proposed peer review mechanism is that it will be time-consuming, and it will necessarily slow EPA's responsibilities to meet statutory deadlines and/or protect Americans by issuing timely health and environmental safeguards. The Proposal ignores this serious concern. Indeed, the Proposal contains no indication that EPA has given any thought to this serious concern, and how it will impact EPA's statutory responsibilities and legal duty to meet congressional deadlines. EPA already misses an unacceptably high number of congressional deadlines in the statutes it administers, and the Proposal to apply peer review to "*all* pivotal regulatory science" will only exacerbate that endemic problem and the unlawfulness that it represents.

Finally, the final paragraph of § 30.7 appears to suggest that EPA should conduct peer review of the proposed agency action itself, rather than of the science underlying that action. 83 Fed. Reg. at 18,774 (stating that "EPA shall ask peer reviewers to articulate the strengths and weaknesses of *EPA's* justification for the assumptions applied and the implications of those assumptions for the results." (emphasis added)). It is entirely unclear how "peer review" could be applied to EPA's reasoning itself, rather than the cited science, and the Proposal contains no further clarification.

EPA should abandon the unlawful Proposal altogether but, if EPA does finalize any rule based on the Proposal, EPA still should abandon the unlawful approach reflected in proposed § 30.7.

ED_002389_00015391-00126

XVI. Conclusion

It is clear from the above that the Proposal violates the law and must be withdrawn. There is no support for the Proposal in any the statutes EPA cites, and in fact, those statutes conflict with the Proposal, as do other statutes that EPA failed to mention at all. Further, none of the other sources cited provide legal or logical support for the Proposal. The Proposal also suffers from a host of other problems: its definitions are vague; it is an unexplained reversal from prior agency policy; it handles confidential business information in a capricious manner; it treats other types of agency actions inconsistently; and it fails to analyze disproportionate impacts on communities of color, low-income communities, and children.

In the alternative, if EPA decides to move ahead with this reckless, unjustified, and unlawful effort to censor the science that EPA may consider, and must consider, to protect Americans' health and environment, the agency must first issue a supplemental proposal and actual administrative record to cover the multitude of issues, evidence, and specific regulatory text for which EPA fails to provide fair notice. The Proposal fails to provide fair notice or justifications addressing numerous issues that our comments detail—from an absence of any statutory authority, to failures to address statutory authorities that the Proposal squarely contravenes, to failures to provide reasoned explanations, including basic justifications for EPA's numerous departures from past practices. The Proposal fails to propose specific regulatory text addressing numerous implementation elements, as well as issues that are touched upon only in passing in the preamble (*e.g.*, non-linearity and LNT). Apart from all of the significant substantive and procedural defects from which the Proposal suffers, it still manages to be a shockingly shoddy effort missing actual regulatory text and supporting legal, factual, scientific, and technical information that would provide fair notice to the public.

ED_002389_00015391-00127