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

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RE: Comments of Natural Resources Defense Council on "Strengthening Transparency in Regulatory Science (Supplemental notice of proposed rulemaking)" 85 Fed. Reg. 15396-15406 (March 18, 2020), 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 supplemental proposal to the original proposed rule, "Strengthening Transparency in Regulatory Science," 85 Fed. Reg. 15396 (March 18, 2020) (the "Supplemental 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 Supplemental Proposal, just like the Proposal, is an attack on science and violates the law. EPA should withdraw it immediately.

NRDC previously submitted comments on August 15, 2018 opposing the original proposed rule.[1] EPA's Supplemental Proposal fails to address the fundamental flaws with the

[1] Natural Resources Defense Council, "Comment Submitted by the Natural Resources Defense Council (NRDC) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science," Docket No. EPA-HQ-OA-2018-0259-8283, Aug. 15, 2018 *available at* https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-8283. We incorporate those comments on the Proposal here.

Proposal, and the expansive scope of the Supplemental Proposal in comparison to the original Proposal introduces numerous serious errors, inconsistencies, and implementation issues. Because of these serious shortcomings and the lack of any sound legal or technical rationale, EPA should withdraw both the Proposal and Supplemental Proposal immediately.

The Supplemental 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 or the Supplemental Proposal's standards. It does not explain why all "data and models" should meet an arbitrary standard.

The Supplemental Proposal, like the Proposal, is a "solution" in search of a problem. EPA, other federal agencies, EPA scientific advisory bodies, the National Academy of Science (NAS), and EPA's Science Advisory Board (SAB) have for decades 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 Supplemental Proposal.

The Supplemental 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 Supplemental Proposal, like the initial 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 original proposal or Supplemental Proposal. What statutes EPA does cite conflict with the Supplemental 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.

Most fatal to the Supplemental Proposal's legal viability is the Agency's reference to its "housekeeping authority" as authority for the rulemaking. As discussed extensively below, the Supplemental Proposal is far from an "internal rule of agency procedure," as it directly impacts how the Agency carries out its statutory mandates. EPA's reliance on supposed housekeeping authority as the justification for this far-reaching attack on science at the Agency underscores the baselessness of the rulemaking and proves it must be withdrawn.

The Supplemental Proposal also suffers from a host of other problems: its definitions are flawed and vague; it expands the scope of the original Proposal without justification; it is an unexplained reversal from prior agency policy and best practice; it handles confidential business

information and determinations about research quality 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; it allows for arbitrary exemptions on a case-by-case basis; it places significant new burdens on researchers and the U.S. Centers for Disease Control and Prevention.

Moreover, EPA did not seek adequate consultation on the Supplemental Proposal from the Science Advisory Board, and EPA has only attempted to partially clarify a small portion of key implementation questions in private briefings to Congress, entirely depriving the general public of an opportunity to meaningfully comment on EPA's apparent plans.

As explained throughout these comments, EPA's agenda, as reflected in the Proposal and reiterated in the Supplemental Proposal, is not greater public trust or understanding; rather, the Proposal and the Supplemental Proposal aim to censor 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 Supplemental Proposal, like the Proposal, is arbitrary, capricious, an abuse of the Agency's discretion, and should be withdrawn.

II. Background: The Tobacco Industry and Congressional Origins for the Censored Science Rulemaking

The instant rulemaking would force EPA to ignore health science and studies needed to protect Americans and our environment—when those studies use confidential patient or business information. This strategy is drawn directly from the tobacco industry playbook, and from failed Republican-sponsored congressional legislation meant to prevent federal agencies from adopting more protective safeguards for Americans' health, air & water quality, climate change and the environment. These attacks have specifically targeted the science EPA has used, historically, to adopt more protective safeguards for air, water, the climate, Americans' health and the environment more broadly.

In 1996, a tobacco industry lawyer named Chris Horner wrote his clients at RJ Reynolds Tobacco a memo later uncovered in tobacco lawsuits.[2] He outlined a strategy to "reform agency science" to prevent EPA from targeting Environmental Tobacco Smoke. Darkly, the strategy also was designed to target EPA regulation of mercury from power plants, hazardous waste, methylene chloride, dioxins and deadly fine particle pollution. *Id.* pg. 2.

The heart of Horner's strategy focused on agency "process," rather than "scientific substance" or pollutants or safeguards. This emphasis recognized that the tobacco industry stood "virtually no chance of affecting change" on the scientific substance and safeguards against [Environmental Tobacco Smoke], and so, designed an approach "of addressing process rather than scientific substance, …." *Id.* Like the tobacco industry strategy, the focus on "internal

[2] *See* Memo from Chris Horner (12/23/1996), attached.

agency process" 85 Fed. Reg. at 15,398, rather than "substance," *Id.,* is central to EPA's proposed Censored Science rulemaking.

In his letter, the tobacco lawyer advised that the process should demand that science and studies submitted to EPA should be 'transparent' and 'able to be reproduced'—or else EPA would not consider them. Ex.1, pg. 4. This ban would happen even if science and studies relied on confidential medical, business or proprietary information that could *not* be made public, by law or legal agreements with third parties. The result would be that EPA could not rely on critical science to protect Americans and the environment.

Mr. Horner worked for the tobacco industry, at the time, along with a former tobacco lobbyist, named Steve Milloy. Mr. Milloy has boasted that this EPA rulemaking is his "brainchild and pet project driving the communists crazy."[3] He tweeted about the proposed Censored Science rule that, "[I]f finalized, EPA will no longer be able to rely on secret data for pointless, job-killing regulations." *Id.* When Mr. Milloy learned that Administrator Wheeler planned to radically expand the scope of the Censored Science rule in the current Supplemental Proposal, he tweeted "YUGE WINNING!!!," and went on to say:

> Trump EPA to ban use of air quality studies based on secret data... i.e., the science fraud used to destroy the US coal industry. http://JunkScience.com and friends have worked toward this for 20+ years.[4]

Congressional Republicans followed Milloy and Horner's playbook in the leadup to the Censored Science rulemaking. In 2015, former Rep. Lamar Smith (R-TX) pushed a bill in Congress he called the "Secret Science Reform Act."[5] The Smith bill parroted the tobacco attorney's strategy, by banning EPA from considering science or studies that were not 'transparent' or 'reproducible.' *Id.* A key staffer for Smith on the bill was Richard Yamada.[6] Smith's bill passed the Republican-controlled House of Representatives with almost no Democratic support[7]; was referred to the Republican Senate, and the bill died.

Former Congressman Smith renewed his efforts in 2017, with a new bill, the HONEST Act, that met the same fate.[8] The bill passed the Republican-controlled House with even fewer Democratic votes, and was never referred to the Senate.[9]

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[3] @JunkScience (Steve Milloy), "My brainchild and pet project driving the communists crazy on their own front-page. If finalized, EPA will no longer be able to rely on secret data for pointless, job-killing regulations." *Twitter*, Nov. 12, 2019, 5:13 a.m., https://twitter.com/JunkScience/status/1194241809821687808.

[4] @JunkScience (Steve Milloy), "YUGE WINNING!!! Trump EPA to ban use of air quality studies based on secret data... i.e., the science fraud used to destroy the US coal industry. http://JunkScience.com and friends have worked toward this for 20+ years, Thank You @RealDonaldTrump," Nov. 11, 2019, 4:37 p.m.

[5] Secret Science Reform Act of 2015, H.R. 1030, 114th Cong.(2015)

[6] Scott Waldman, Meet the man helping Pruitt reshape science, E&E News, May 23, 2018. https://www.eenews.net/stories/1060082467

[7] "Secret Science Reform Act of 2015: Roll Vote No. 125." Congressional Record 161:46 (March 18, 2015) p. H1742 *available at* http://clerk.house.gov/evs/2015/roll125.xml.

[8] Honest and Open New EPA Science Treatment Act of 2017, H.R. 1430, 115th Cong. (2017).

[9] "Honest and Open New EPA Science Treatment Act of 2017: Roll Vote No. 206." Congressional Record 163:55 (March 29, 2017) p. H2536 *available at* http://clerk.house.gov/evs/2017/roll206.xml

After the Trump administration took office, the former Smith staffer, Richard Yamada, was named Trump's top political appointee in EPA's Office of Research & Development.[10] In January 2018, internal EPA emails disclosed through a Freedom of Information Act Request show that Lamar Smith met with former EPA Administrator Scott Pruitt to suggest that EPA 'implement his HONEST Act" through EPA rulemaking after Smith had failed to advance his legislation.[11]

An EPA official circulated to fellow EPA officials an email from a staff person for then-Chairman Smith:

> "All, see below follow up from Chairman Smith's meeting with the administrator," he wrote. "Want to check on who would be the most appropriate [for] them to speak to. In short, this is in regards to his pitch that EPA internally implement the HONEST Act (no regulation can go into effect unless the scientific data is publicly available for review)."[12]

These internal EPA emails make clear that agency officials and a member of Congress were discussing how to "implement" failed congressional legislation, "the HONEST Act," through an EPA rulemaking. The rulemaking would adopt the identical approach that the twice-unsuccessful legislation failed to make law: "no regulation can go into effect unless the scientific data is publicly available for review." *Id.* As the article noted, "[o]ne of the aides copied on Ringel's email was Richard Yamada, the deputy assistant administrator of EPA's Office of Research and Development. Yamada previously worked for years on the Republican staff of the House Science Committee led by Smith."[13]

Further internal EPA emails obtained through FOIA disclosed a briefing memo prepared for former Administrator Scott Pruitt prior to his meeting with then-Chairman Lamar Smith on January 9, 2018. The briefing memo described the "Decision Points/Objectives" for the meeting as follows:

> This meeting is occurring at the request of Chairman Lamar Smith. His main objective for the meeting is to have EPA find a way to implement the HONEST Act objectives outside of the legislative process since it is unlikely to pass the Senate.[14,15]

Talking points prepared for Administrator Pruitt read:

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[10] Kevin Bogardus, *Senior Research Official Leaving* Agency, E&E News, Sept. 14, 2018. https://www.eenews.net/stories/1060097095.
[11] Scott Waldman & Niina H. Farah, *Smith pitched Pruitt on 'secret science.' Now it's happening*, E&E News, Apr. 20, 2018. https://www.eenews.net/climatewire/stories/1060079655.
[12] Records received in response to EPA FOIA request, pg. 11, Email from Mandy Gunasekara (1/16/2018), Ex. 7
[13] *Supra,* n. 9.
[14] Administrator Pruitt's January 2018 briefing memo attached, Ex. 8.
[15] Environmental Defense Fund, Ben Levitan, "Public records confirm EPA's "censored science" proposal was an end-run around Congress," *available at* http://blogs.edf.org/climate411/2019/11/12/public-records-confirm-epas-censored-science-proposal-was-an-end-run-around-congress/, Ex. 9.

> HONEST Act: Happy to have our staff at EPA work with committee staff on identifying potential areas you think we might be able to implement the transparency initiatives outlined in the HONEST Act using our regulatory/guidance authority."

Id.

The EPA reaction to the Pruitt-Smith meeting was swift and enthusiastic; an email showed Pruitt's chief of staff "asked to have this rolled out by the end of" February.[16] Not long after the January 2018 meetings and emails, former Administrator Scott Pruitt signed the Censoring Science rulemaking proposal, on April 24, 2018.[17] 83 Fed. Reg. 18,768 *et seq.* (Apr. 30, 2018). Internal EPA emails show the HONEST Act/Censored Science rulemaking was "crafted by political staff with little input from scientists." *Id.*

As discussed later in these comments, the Proposal relied on eight substantive environmental statutes, and the Supplemental Proposal again offers these statutes as a purported source of authority. *See infra,* part III. NRDC and many, many other commenters pointed out (and point out here) that EPA's reliance on stray sections of these eight environmental laws to justify the rulemaking was arbitrary and illegal. *Id.* However, in the context of the rulemaking's evolution from tobacco strategy to failed congressional legislation to an EPA handshake deal to an end-run around Congress, it is unsurprising that the legal authority claimed for the rulemaking is absurd.

As discussed later in these comments, the Supplemental Proposal lurched abruptly to claim new authority for the rulemaking, "housekeeping" authority. *See infra,* Section III.I. In the Supplemental Proposal, EPA pivots away from its eight substantive, environmental laws to this procedural "federal housekeeping" law. This is because the Censored Science rule finds no authority in the eight environmental laws discussed in the Proposal, and runs afoul of those laws in multiple, fundamental ways.[18]

EPA *knows* there are conflicts between the instant rulemaking and its substantive environmental laws. The agency admits as much in the Supplemental Proposal when it declares that "in the event the procedures outlined in this proposed rulemaking conflict with the statute that EPA administers, or their implementing regulations, the statutes and regulations will control." 85 Fed. Reg. 15,398. This declaration, and the Proposal and Supplement themselves, are irrational and an abuse of the Agency's discretion.

Now, in order to pretend that this anti-science rule has nothing to do with EPA's substantive and statutory responsibilities, nor its mission, to protect public health and the environment, the Agency must rely on its "housekeeping" authority. Harkening back to the language in the tobacco lawyers' initial communications, EPA claims its authority in a "housekeeping" statute that by its terms does not apply to EPA and is limited to internal issues

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[16] *See supra,* n. 9, and Ex. 6.

[17] U.S. EPA, Press Release: EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations, April 24, 2018 *available at* https://archive.epa.gov/epa/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations.html.

[18] *See infra,* Section III, and NRDC Comments on Proposal, attached.

such as personnel management and recordkeeping. *See infra,* Section III.I. In pretending that the Censoring Science rule has *no* substantive impact, no basis in environmental statutes, nor science or health safeguards, the rulemaking returns full circle to the tobacco industry attorney's strategy to focus on process over substance, "[b]ecause there is virtually no chance of affecting change on this issue if the focus" is on substance.[19]

As we show in these comments, EPA is acting arbitrarily, capriciously and unlawfully in its renewed attempts to justify the instant rulemaking. This pretense, drawn from the tobacco industry playbook and having been rejected in Congress, is disingenuous and demonstrably wrong. *See infra.*

III. There is no legal authority for the Supplemental 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 either the 2018 Proposal or the Supplemental Proposal.

EPA identified its eight environmental statutes as the legal authority for the 2018 Proposal. 83 Fed. Reg. 18,768, 18,769 (April 30, 2018). The Supplemental Proposal references the 2018 Proposal's reliance on these eight statutes for authority. See 85 Fed. Reg. 15,396, 15,397 (March 18, 2020). In an abrupt shift, however, the Supplemental Proposal now cites entirely different authorities as the sole authority for the rulemaking.[20] But none of the various statutes cited provides support for the rule's provisions, definitions, requirements, or exemptions, nor do they support the newly proposed elements in the Supplemental Proposal. Rather, EPA invents statutory authority where none exists, and creates proposed regulatory text out of thin air. In most cases in the Proposal, EPA simply cites its general authority for rulemaking under the eight environmental statutes; in the Supplemental Proposal, EPA relies on generic alleged "housekeeping" authority. But that general authority alone cannot provide a basis for the rule, especially when, as explained in subsections A-H, below, the rule would *conflict* with the requirements of each of the environmental 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.

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[19] *See Supra,* n. 1, Ex. 1.

[20] *Id.* ("EPA is authorized to promulgate this regulation under its housekeeping authority."); *Id.* at 15,404/3 ("The authority citation for part 30 is revised to read as follows: Authority: 5 U.S.C. 301; 5 U.S.C. App.; Pub. L. 98–80, 84 Stat. 2086.")

The Supplemental Proposal follows the same lawless approach as the 2018 Proposal, making clear the extent to which the Censoring Science rulemaking, in all of its iterations, lacks any legal basis. Over the course of two years and three attempts to find a shred of statutory authority for the rulemaking, fatally, EPA still cannot. Although the Supplemental Proposal now lurches to relying upon alleged "housekeeping authorities" as the exclusive authority for the rulemaking, we reiterate our objections to any attempted reliance on particular statutory sections cited in the 2018 Proposal, along with the new citations EPA provides in the Supplemental Proposal. See 85 Fed. Reg. at 15,397/2. Any attempt by EPA to rely on these eight environmental statutes as authority for any element proposed in the Supplemental Proposal would be arbitrary and capricious and unlawful. The agency has announced that it is relying exclusively on its alleged "housekeeping" authority for the entire rulemaking. See 85 Fed. Reg. at 15,397/2 ("EPA is authorized to promulgate this regulation under its housekeeping authority.") & 15,404/3 ("The authority citation for part 30 is revised to read as follows: Authority: 5 U.S.C. 301; 5 U.S.C. App.; Pub. L. 98–80, 84 Stat. 2086.") EPA has failed to analyze or explain how any of its eight environmental statutes authorizes or justifies any newly proposed portion of the Supplemental Proposal. Indeed, EPA now disclaims that it is even interpreting or implementing any of its substantive environmental statutes; the agency claims instead, preposterously, that the instant rulemaking merely concerns a rule of "internal agency procedure," pursuant to "housekeeping" authority. 85 Fed. Reg. at 15,398/2. This claim is entirely baseless, as we explain later in these comments. See *infra* subsection I.

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 and Supplemental Proposal are in direct conflict with other provisions of the Act. EPA cannot rely on 42 U.S.C. § 7601(a) to support any final 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 rulemaking.

Nothing in the Proposal (or Supplemental 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, "data and models underlying pivotal regulatory science and pivotal science," 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 or the Supplemental 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" to studies or analyses that "are publicly available in a manner sufficient for independent validation." *See* 83 Fed. Reg. at 18,773 (proposed § 30.5) (and modified at 85 Fed. Reg. at 15,402). 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.

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 (and Supplemental 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.

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

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

As the italicized language above reveals, 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 any other action under the Clean Water Act the Proposal targets should be any different.

Accordingly, the Clean Water Act does not authorize the Proposal or the Supplemental 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 and Supplemental 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) , 8001; 42 U.S.C. §§ 6912(a)(1), 6981

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 or the Supplemental Proposal.

In the Supplemental Proposal, EPA states that its citation to 42 U.S.C. § 6979 is a mistake and should be corrected to Section 8001, 42 U.S.C. § 6981. Just as the previous incorrect citation failed to support the Proposal, this new citation fails to support the Proposal or Supplemental Proposal. As explained above, a general grant of authority cannot support the

instant rulemaking, especially when the proposed text conflicts with the Act. Section 8001 outlines general authority under the statute to fund or conduct research, and to implement management programs. It does not remotely authorize the proposed rulemaking's various provisions, definitions, requirements, or exemptions The Resource Conservation and Recovery Act does not authorize 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. §§ 9615, 9660

EPA states in the Supplemental Proposal that it finds authority under the Comprehensive Environmental Response, Compensation, and Liability Act section 42 U.S.C. § 9615. The entirety of this section reads that "[t]he President is authorized to delegate and assign any duties or powers imposed upon or assigned to him and to promulgate any regulations necessary to carry out the provisions of this subchapter." As explained above, that general grant of authority cannot support the rule, especially when the rule conflicts with the Act. The Comprehensive Environmental Response, Compensation, and Liability Act does not authorize 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 and Supplemental Proposal as a matter of its own policy preferences, contrary to the Act. This EPA may not do. CERCLA does not authorize the rulemaking.

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 or Supplemental 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, "data and models underlying pivotal regulatory science and pivotal science," or any 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 and Supplemental Proposal as a matter of its own policy preferences, contrary to the Act. This EPA may not do.

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 or Supplemental 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 and Supplemental Proposal as a matter of its own policy preferences, contrary to the Act. This EPA may not do.

I. Federal Housekeeping Statute, 5 U.S.C. § 301

Finally, and equally problematic in the Agency's quest to find authority for the rulemaking, is the assertion that authority for the Proposal may be found under the Agency's so-called "housekeeping authority." EPA first floated this claim in its notice extending the comment period for the initial rulemaking, stating that "EPA is proposing this rule under authority of 5 U.S.C. § 301, in addition to the authorities listed in the April 30th document." See 83 Fed. Reg. 24,255, 24,256 (May 25, 2018). This statute, by its own terms, does not apply to EPA. 5 U.S.C. § 301. In citing this authority, EPA implicitly admits that the statutory authorities invoked in the original Proposal are lacking, and reveals that the rulemaking lacks a basis in any statute.

The Agency again cites the federal housekeeping authority as a supposed statutory basis for the rulemaking in the Supplemental Proposal. 85 Fed. Reg. 15,396, 15,397 (March 18, 2020). EPA states that Section 301 of Title 5 provides "[t]he head of an Executive department or military department" authority to "prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." *Id.* The Agency then quotes the Supreme Court's description of section 301 as designed to "grant early Executive Departments the authority 'to govern internal department affairs'" and "authorizes 'what the [Administrative Procedure Act] terms 'rules of agency organization, procedure or practice, as opposed to

substantive rules.'" 85 Fed. Reg. at 15,397 (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 308-12 (1979)).[21]

The fatal problem with the Agency's citation to this authority is that, under plain statutory language, EPA is "not one of the 15 'Executive Departments' listed at 5 U.S.C. § 101, to which section 301 applies. *Id.* 5 U.S.C. § 101. As such, the Agency has invoked a statute as a source of authority that by its own terms does not apply to EPA. Congress has had ample opportunity since 1970 to add EPA to the list of "Executive Departments" defined in 5 U.S.C. section 101. Congress has not done so. This is dispositive and fatal to the rulemaking's reliance on the Federal Housekeeping statute. *See, e.g., Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984)("First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, [] as well as the agency, must give effect to the unambiguously expressed intent of Congress."); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress.")

1. The Reorganization Plan No. 3 of 1970 Provides No Authority for the Rulemaking.

The Agency acknowledges that 5 U.S.C. § 301 does not apply to EPA in the Supplemental Proposal. 85 Fed. Reg. at 15,397. However, the Supplemental Proposal then claims that EPA "gained housekeeping authority through the Reorganization Plan No. 3 of 1970." *Id.* The agency suggests that *this* housekeeping authority is sufficient to authorize the instant rulemaking. *Id.* This suggestion is wrong.

The Supplemental Proposal starts its inapposite line of argument by noting that "[t]he Reorganization Plan created EPA, established the Administrator as 'head of the agency' and transferred functions and authorities of various agencies and Executive departments to EPA." *Id.* at 15,397/3. The Supplemental Proposal does not argue, nor could it, that creation of EPA or establishment of the Administrator as its head authorizes the instant rulemaking. *Id.* Instead, the Supplemental Proposal appears to argue that the transfer of "functions and authorities of various agencies and Executive departments to EPA" somehow authorizes the current rulemaking. *Id.* This is wrong.

EPA first argues that "[s]ection 2(a)(1)–(8) of the Reorganization Plan transferred to EPA functions previously vested in several agencies and executive departments including the Departments of Interior and Agriculture." *Id.* Notably, however, EPA does not and cannot identify any subsection(s) in section 2 that even pretend to authorize the instant rulemaking and its myriad of restrictions and exemptions and other provisions. *Id.* EPA ducks the issue and simply references section 2(a)(1)–(8). This is understandable. There is no congressional

[21] In fact, *Chrysler* lays out the legislative history of the statute, which was "enacted to help General Washington get his administration underway by spelling out the authority for executive officials to set up offices and file Government documents." 441 U.S. 281, 309. It "was adopted in 1789 to provide for the day-to-day office housekeeping in the Government departments." *Id.* at 310. Nowhere does EPA explain how this rulemaking relates to setting up offices and filing government documents, or other "day-to-day office housekeeping." *Id.*

delegation, no legislative history, no factual evidence and no suggestion of authorization for EPA to adopt the instant rulemaking via the transfer of the listed functions from the Secretary of the Interior, the Secretary of Health, Education and Welfare, the Council of Environmental Quality, the Atomic Energy Commission, the Federal Radiation Council or the Secretary of Agriculture to the EPA. See the section 2(a)(1)–(8), Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970) ("Reorganization Plan"). EPA's struggle to find authority for the instant rulemaking in 2(a)(1)–(8) of the Reorganization Plan fails badly.

Next, EPA argues that "Section 2(a)(9) also transferred so much of the functions of the transferor officers and agencies 'as is incidental to or necessary for the performance by or under the Administrator of the functions transferred.'" 85 Fed. Reg. at 15,297/3. Section 2(a)(9) transfers to EPA:

> So much of the functions of the transferor officers and agencies referred to in or affected by the foregoing provisions of this section as is incidental to or necessary for the performance by or under the Administrator *of the functions transferred by those provisions or relates primarily to those functions.* The transfers to the Administrator made by this section shall be deemed to include the transfer of (1) authority, provided by law, to prescribe regulations relating primarily to the transferred functions, ….

Reorganization Plan, section 2(a)(9) (emphasis added). EPA's inability to identify any specific transferred function that authorizes the instant rulemaking is fatal. 85 Fed. Reg. at 15,297/3. EPA's tautological argument about section 2(a)(9) fails for the same reason as the argument about section 2(a)(1)–(8): the transferred functions in no way provided authority for the instant rulemaking. EPA is unable to identify any authority for the rulemaking in the actual text of the Reorganization Plan or its legislative history, or in the actual text of any of the transferred functions, their referenced statutes or their legislative history. EPA's own silence speaks volumes about this inability.

EPA's argument, here, about section 2(a)(9) echoes the original Proposal's reliance on the general authority to prescribe regulations in section 301 of the Clean Air Act. But as NRDC noted in its comments on the Proposal:

> 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.

NRDC Comments on Proposal, at 36. Federal courts have held, repeatedly and resoundingly, that congressional grants of general authority to issue regulations to carry out functions of a statute provide *no additional authority* to "trump" portions of a law (*American Petroleum Institute*, 52 F.3d at 1119); to "define other functions well beyond the statute's specific grants of authority," (*Gonzales,* 546 U.S. at 264–65); or to "supplement" statutory provisions "when Congress has not left the agency a gap to fill." *NRDC*, 749 F.3d at 1064. Yet, this is precisely what EPA is doing, here, by purporting to "prescribe regulations relating primarily to the transferred functions" under the Reorganization Plan. See section 2(a)(9), Reorganization Plan. Reliance on section 2(a)(9) for this authority is unlawful for the same reasons that courts have found it unlawful for EPA and other agencies to rely on congressional grants of general authority to issue regulations to carry out functions of a statute.

a) The Interpretations Offered in the 2008 Office of Legal Counsel Memo Provide No Authority for the Rulemaking.

Finding no support in the Reorganization Plan itself, EPA must resort to citing a 2008 Department of Justice Office of Legal Counsel (OLC) memo "opin[ing]" that the "Reorganization Plan 'convey[s] to the [EPA] Administrator all of the housekeeping authority available to other department heads under section 301.'"[22]

First, the OLC memo itself reiterates that 5 U.S.C. 301 does not apply to EPA. OLC memo, p.81. Accordingly, EPA's reliance on 5 U.S.C. 301, or any interpretations made in the OLC memo, itself, as any authority for the instant rulemaking is completely inapposite, arbitrary and capricious. See *e.g.*, 85 Fed. Reg. at 15,404/3 (citing 5 U.S.C. 301 as statutory authority for proposed 40 C.F.R. part 30). This defect, by itself, is fatal to the lawfulness of the entire proposed rulemaking.

Second, the interpretations offered in the OLC memo supply no authority for the instant rulemaking, and obviously lack the force of law. See, *e.g.*, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress.") Congress has delegated no authority to EPA to adopt the instant rulemaking. Neither the OLC memo, nor EPA's reliance on it, will receive any deference from a reviewing court.

Third, the OLC was not reviewing or analyzing any facts or activities remotely similar to the subject of the instant rulemaking when the OLC issued the memo on which EPA now relies. Rather, the OLC was addressing the inherently internal issue of "destruction of government

[22] 85 Fed. Reg. at 15,397/3, n.3 (citing "Authority of EPA to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property, 32 U.S. Op. Off. Legal Counsel 79, 2008 WL 4422366 at *4 (May 28, 2008) (''OLC Memo'')").

personal property [and] the unauthorized personal use of agency-issued cell phones," which bore no relation to an agency's performance of its substantive, statutory and regulatory responsibilities. OLC Memo, 79.

Moreover, even in the narrow bureaucratic situation present there, while the OLC concluded that "[t]he Reorganization Plan establishing the EPA vests the Administrator with authority equivalent in many respects to that enjoyed by the head of an executive department" OLC memo at 82, neither the Reorganization Plan nor 5 U.S.C. 301 authorizes the instant rulemaking. Nowhere in the Supplemental Proposal can EPA identify any passage in the OLC memo that purports to authorize a rulemaking that impacts EPA's performance of its substantive, statutory responsibilities as sweepingly as the instant rulemaking would. Instead, the OLC memo fully supports the opposite conclusion, that neither 5 U.S.C. 301 nor the EPA "Reorganization Plan" supports "substantive rules" like the instant rulemaking. Footnote 4 of the OLC memo states unambiguously that:

> As a general matter, regulations that "directly affect the rights and obligations of private parties" or regulate the "citizenry at large" constitute "substantive rules" under the APA and usually must be promulgated in accordance with notice and comment procedures. Authority to Prescribe Regulations, 28 Op. O.L.C. at 107. In contrast, agency rules "govern[ing] only the conduct of government employees" are not substantive rules within the meaning of the APA and are specifically excluded from publication and notice and comment requirements. *Id.* The EPA policies at issue here pertain solely to the conduct of EPA employees and have no application to the "citizenry at large." Those policies are therefore not "substantive rules" that must be published under the APA.

OLC memo, pg 84, n. 4.

Faced with this fatal restriction, EPA attempts to claim that both the Proposal and the Supplemental Proposal "would not regulate the conduct or determine the rights of any entity outside the federal government" as it "exclusively pertains to the internal practices of the EPA." 85 Fed. Reg. at 15,398. Ironically, EPA offers up this preposterous assertion in the sentence immediately following a sentence "describ[ing] how EPA will handle studies when data and models underlying science that is *pivotal to EPA's significant regulatory decisions or influential scientific information* are or are not publicly available in a manner sufficient for independent validation and analysis." *Id.* Even the Agency's own description of the Proposal and Supplemental Proposal make clear that the rulemaking is intrinsically substantive in nature— "pivotal to EPA's significant regulatory decisions or influential scientific information." *Id.*

The EPA claim that this rulemaking addresses only internal practices at the Agency does not even pass the laugh test. As noted extensively in the now hundreds of pages of comments submitted by NRDC alone, the rulemaking would dramatically and "directly affect the rights and obligations of private parties" and regulate the "citizenry at large" by rewriting how science is considered, used and ignored in the Agency's substantive rulemakings. Further, the fact that EPA originally relied (without any basis), 83 Fed. Reg. at 18,769, and *still* relies, 85 Fed. Reg. at 15,397, on the agency's eight substantive environmental statutes, proves this point. As noted above, these statutes themselves dictate EPA's obligation to use the highest-quality scientific

information to inform the agency's work, in various different ways specific to each statute. Only once it was abundantly clear that the rulemaking lacks any authority in these substantive environmental statutes, did the Agency offer a wildly different, opposing theory that pretends this rulemaking governs "only the conduct of government employees."[23]

Courts have made abundantly clear what constitutes a substantive rule versus one of entirely internal effect under the housekeeping statute (were the housekeeping statute applicable here, which it is not). Courts have found, based on both "§ 301's text and its "long and relatively uncontroversial" history, []that § 301 "is indeed a 'housekeeping statute,' authorizing what the APA terms 'rules of agency organization procedure or practice' as opposed to 'substantive rules.' [] Subsequent courts have repeatedly rejected agency attempts [] to "twist this simple administrative statute into an authorization for the promulgation of substantive rules." [] *New York v. United States Dep't of Health & Human Servs.,* 414 F. Supp. 3d 475, 521 (S.D.N.Y. 2019)(internal citations omitted).

While there are numerous examples that make clear the substantive impact of both the Proposal and the Supplemental Proposal, we catalogue just a few here, for illustrative purposes. The Proposal explicitly restricts "pivotal regulatory science"—science specifically identified as that which is "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. 18,770. On its terms, for scientific research to be "pivotal" the rule must be "substantive"—it is critical to the makeup of a final agency regulation—and, thus, housekeeping authority cannot apply. The Supplemental Proposal expands the scope of the Proposal's reach even further, to "apply to influential scientific information as well as significant regulatory decisions." Both types of information involve substantive applications that "directly affect the rights and obligations of private parties," OLC Memo, 84 n.4, as well as the broader public; all are external to the agency. Making this substantive impact perfectly clear, EPA explicitly defines "influential scientific information" as "scientific information the agency reasonably can determine will have or does have a clear and *substantial impact on important public policies or private sector decisions*." 85 Fed. Reg. 15,398 n. 5 (emphases added). These impacts are precisely those that classify a rule as substantive under the OLC memo, and those that preclude the use of housekeeping authority in any form. OLC Memo, 84 n.4. Caselaw and common understandings of substantive impacts reinforce this conclusion.

Finally, EPA senior officials themselves have described the centrality of the instant rulemaking to the agency's substantive rulemaking processes; in so doing, they make clear that EPA's so-called 'housekeeping' authority cannot authorize this rulemaking. Former EPA Administrator Scott Pruitt described "the ability to test, authenticate, and reproduce scientific findings" as "vital for the integrity of rulemaking process," justifying the "substantive" goal of the rulemaking he announced in 2018. U.S. EPA., News Release: "EPA Administrator Pruitt

[23] Even the Agency's own past practice makes clear that the housekeeping authority is irrelevant here. The Agency has "used housekeeping statute authorities in 82 actions since 1994, but almost all of them deal with acquisitions and contracts. And all are focused on internal matters, not outward-facing public policy. EPA most recently cited it when revising Freedom of Information Act regulations last year." Jean Chemnick, "Agency leans on 1870s 'housekeeping' law to block science," E&E News, May 8, 2020. https://www.eenews.net/stories/1063076197

Proposes Rule To Strengthen Science Used In EPA Regulations" (April 24, 2018). Administrator Pruitt declared further that the rule would aid Americans in "assess [ing] the legitimacy of the science underpinning EPA decisions that may impact their lives." *Id.* In touting the centrality of the instant rulemaking to EPA's substantive rulemaking in general, Administrator Pruitt himself makes clear that the "citizenry at large" would be impacted by its issuance. In addition to former Administrator Pruitt's public statements acknowledging the substantive application of the proposed rule, EPA acknowledged the same to congressional staff. *See* Letter from Chairwoman Eddie Bernice Johnson to House Committee on Science, Space, and Technology, Summary of Staff-Level Briefings from the Environmental Protection Agency on the "Strengthening Transparency in Regulatory Science" Supplemental Proposed Rule.[24] Specifically, during two Congressional briefings, EPA reported to House Committee on Science, Space, and Technology staff that the rulemaking would apply to "statutorily mandated reviews of existing standards." *Id.* at 1. EPA's "housekeeping" authority does not authorize this rulemaking.

To deepen the arbitrary and capricious nature of the rulemaking, the Agency offers *both* the substantive environmental laws and its purported, non-substantive "housekeeping authority" as supposed authorities to justify the rulemaking, despite the fact that these authorities and arguments are mutually exclusive. If the rulemaking only addresses internal Agency issues, by its terms, substantive environmental laws would not provide authority for the rule. Similarly, if substantive environmental laws authorize the rulemaking, then any claimed internal housekeeping authorities are necessarily incompatible with the rulemaking's "substantive" aims and authorities, which "directly affect the rights and obligations of private parties" or regulate the "citizenry at large." OLC Memo, 84 n.4. Faced with these hopelessly arbitrary, internal contradictions, EPA nonetheless takes comment on "whether to use its housekeeping authority independently as authority or in conjunction with the environmental statutory provisions cited as authority." 85 Fed. Reg. at 15,398. Neither source provides authority for the Proposal, independently or combined. Neither the substantive statutes described above, nor the housekeeping authority, authorize the rulemaking.

Further, EPA attempts to paper over this arbitrary abuse of discretion by noting that the rulemaking is intended to "be consistent with the statutes that EPA Administers and … all applicable statutory and regulatory requirements." *Id.* The agency goes on to note that "in the event the procedures outlined in this proposed rulemaking conflict with the statute that EPA administers, or their implementing regulations, the statutes and regulations will control." *Id.* While it is certainly true that a rulemaking that conflicts with statutory authority would be struck down as arbitrary and capricious, EPA's statements here do nothing to "fix" the Proposal nor render it a valid exercise by the Agency. An administrative action that is arbitrary and capricious and an abuse of discretion does not change character through this type of Agency statement – the EPA does not get to pick and choose the statutory authorities it chooses to follow. Rather, Congress makes laws, and those laws contain certain proscriptions and prescriptions that the Agency to whom Congress has delegated rulemaking authority must follow. Implicit in EPA's

[24] Johnson, Eddie Bernice. 2020. "Letter from Chairwoman Eddie Bernice Johnson to House Committee on Science, Space, and Technology, Summary of Staff-Level Briefings from the Environmental Protection Agency on the 'Strengthening Transparency in Regulatory Science' Supplemental Proposed Rule," May 6, 2020. https://science.house.gov/chairwoman-johnson-letter-to-science-committee-democratic-caucus-on-epa-transparency-rule ("House Staff Memo").

recognition of the potential for "conflict" with statutes and implementing regulations is the understanding that this rule is arbitrary, capricious, and an abuse of the Agency's discretion. Neither the substantive statutes described above, nor the housekeeping authority, authorize the rulemaking.

J. No caselaw 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. The Supplemental Proposal modifies the Proposal where

> Proposed 40 CFR 30.5 would allow Agency consideration of studies where there is tiered access to data and models that have CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects. For all other studies, data and models should be publicly available if the studies are to be used as pivotal regulatory science or pivotal science.

85 Fed. Reg. at 15,402.

The Proposal and Supplemental Proposal fail 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. In the original Proposal, EPA cited two cases related to this question, and EPA admitted, as it must, that both cases "upheld EPA's use (sic) nonpublic data in support of its regulatory actions." 83 Fed. Reg. 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)). The Supplemental Proposal now quietly drops any mention of those two cases. Tellingly, the Supplemental Proposal still fails to identify *any* caselaw that even purports to support the specific restrictions on EPA's consideration of "data and models underlying pivotal regulatory science and pivotal science."

Similarly, the Supplemental Proposal does not identify any case law supporting EPA's claimed ability to "only use pivotal regulatory science and/or pivotal science if the data and models are available in a manner sufficient for independent validation." 85 Fed. Reg. at 15,399/1. Nor does the Supplemental Proposal identify any case law supporting EPA's claimed ability that, "when promulgating significant regulatory decisions or finalizing influential scientific information, other things being equal, the Agency will give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because they are publicly available or because they are available through tiered access when the data includes CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects." *Id.*

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 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 Supplemental 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 Supplemental 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 Supplemental 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 Supplemental 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 Supplemental 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 Supplemental Proposal runs counter to the D.C. Circuit's decision in *API* and would render EPA's regulatory actions based on the Supplemental Proposal arbitrary and capricious and an abuse of EPA's discretion. The Supplemental 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.

K. Should EPA Want to Move Forward with this Rulemaking, it Must Offer a Public Hearing for this Proposal

EPA summarily denied stakeholders' requests for a virtual public hearing, despite the immense public interest the Supplemental Proposal has garnered. To-date, thousands of public comments have already been submitted regarding the Supplemental Proposal in the short 60-day comment period the Agency has allowed. Indeed, NRDC members will submit over 114,000 comments expressing deep concern about the Proposal, and its harmful effects on science and the regulatory process. By the close of the comment period, the Agency will receive hundreds of thousands of comments from environmental advocates, scientists, and professors, alike, asking that the Agency reconsider the Proposal and Supplemental Proposal. Yet, instead of recognizing this substantial public interest, the Agency has refused to schedule a virtual public hearing regarding the Supplemental Proposal, completely ignoring the public's requests that it do so. *See, e.g.*, Email correspondence, C. Hawkins to A. Mesnikoff, Mar. 23, 2020.[25]

A virtual public hearing is necessary to allow those who would be affected by the Supplemental Proposal, were it to become final, to explain the basis of their objections to EPA's experts and policy makers. Likewise, a hearing will also allow opponents of the Supplemental Proposal to experience other witnesses offering testimony, consider their positions, and respond. A virtual hearing will ensure that all parties have an opportunity to learn about the Supplemental Proposal, consider its impacts, and provide meaning comments to assist the Agency in the rulemaking process. Such a full and frank exchange of ideas between stakeholders will, in the end, ensure the best, most reasoned result.

The need for a virtual public hearing is particularly critical now, when many who would ordinarily comment on the Supplemental Proposal are facing unprecedented limitations, due to the Coronavirus pandemic. The entire country—including scientists and researchers who would be directly affected by the Supplemental Proposal—has had their way of life uprooted, and is still adjusting. Many of those interested in or affected by the proposal may have limited access to the internet, are juggling family obligations, are balancing competing work obligations that have arisen because of the crisis, or are under newly imposed financial constraints; these new realities undoubtedly limit the public's ability to submit written comments. In light of these limitations, holding a hearing will increase access to the regulatory process, allowing stakeholders who may

[25] Hawkins, Cheryl A. 2020. "RE: Request for Extension of the Public Comment Period/Hearings Docket ID No. EPA-HQ-OA-2018-0259," March 23, 2020.

not be able to submit written comments because of the coronavirus to participate in the rulemaking. Without a virtual public hearing, the voices of scientists, professors, and regular people who are deeply concerned about the effects of this Supplemental Proposal, will not be adequately heard.

EPA's refusal to hold a virtual public hearing regarding the Proposal is puzzling, in light of its willingness to do so for other critical proposed rules. For example, the Agency has announced plans to hold two virtual public hearings for a proposed action titled "Review of National Ambient Air Quality Standards for Particulate Matter." The virtual hearings were announced on May 5, 2020, and are set to occur later this week, on May 20, 21 and 22, 2020,[26] proving that the Agency can act relatively quickly to plan to hold virtual hearings as part of the rulemaking process.

In fact, just today, EPA moved to add a fourth hearing date for that proposal, based on overwhelming demand for spots in the first three virtual hearing dates. EPA has not explained why the Particulate Matter proposed rulemaking requires four days of virtual public hearings, but the instant Proposal warrants none, particularly where both proposals raise matters of significant public importance. Clearly the Agency has the technological wherewithal, organizational experience, and staffing capacity to hold virtual public hearings on major proposed rules. It has not explained why it cannot do so here.

And the Agency is well-aware that public hearings are an important tool in making the public's voice heard regarding significant proposed rulemakings, like the Supplemental Proposal. For example, when the original proposed rule was issued in 2018, EPA not only held a public hearing, but extended the comment period to 90 days. The hearing on the 2018 Proposal was critical because it allowed the public to express their concerns about the limitations of the proposed rule. The Agency made sweeping changes to its proposal, in part, as a result of those concerns. Nonetheless, EPA refuses to explain why the original proposed rule—part of the very same rulemaking proceeding—required a public hearing, but the instant, much more expansive proposal merits none at all. Instead, EPA has summarily denied stakeholders' request for a hearing.

Unsatisfied by EPA's unwillingness to allow a full and reasoned discourse about the Supplemental Proposal, stakeholder Union of Concerned Scientists arranged for a virtual hearing regarding the Supplemental Proposal on April 14, 2020. That hearing lasted nearly five hours, attracted 41 virtual witnesses and at least 125 viewers, and provided a much-needed opportunity for those affected by the Supplemental Proposal to testify. Union of Concerned Scientists invited EPA to participate in the virtual hearing, noting that "[e]ngagement by EPA staff would allow the EPA to gain additional valuable information from commenters that can inform future decision-making." *See* Email correspondence, M. Halpern to C. Hawkins, April 7, 2020.[27] However, the day before the hearing was set to be held, EPA declined to participate, clarifying

[26] U.S. Environmental Protection Agency. 2020. "Public Hearing on Proposal to Retain the National Ambient Air Quality Standards for Particulate Matter." Announcements and Schedules. US EPA. April 22, 2020. https://www.epa.gov/pm-pollution/public-hearing-proposal-retain-national-ambient-air-quality-standards-particulate.

[27] Halpern, Michael. 2020. "EPA Science Rule Public Hearing Invitation," April 7, 2020.

only that "UCS is not hosting this meeting on EPA's behalf." *See* Email Correspondence, C. Hawkins to M. Halpern, April 13, 2020.[28] Because of the Agency's refusal to participate, EPA's experts did not hear critical testimony highlighting the dangers of the Supplemental Proposal.

EPA routinely holds public hearings about critical rulemakings. As discussed above, it has held public hearings relating to the 2018 proposed rule in the past, and announced plans to hold virtual public hearings relating to rulemakings of similar import later this week. The Agency has not explained why it cannot or will not do so here. And rather than join a hearing organized by stakeholders, EPA declined to participate without explanation, losing the opportunity to hear from those who will be most affected by the Proposal. The current comment period of 60 days is wholly inadequate for the public to meaningfully assess and weigh in on this Supplemental Proposal. This rule is controversial, complex, and would extend sweeping changes to the regulatory landscape. In this time of crisis, the Agency should be doing more, not less, to ensure that all parties have an opportunity to learn about the Proposal and the Supplemental Proposal, evaluate its impacts, and share meaningful comments to guide the Agency in its ultimate decision.

L. The Supplemental Proposal and Original Proposal Lack Any Statutory Authority or Other Legal Authority to Adopt Any of the Proposed Regulatory Text

The Supplemental Proposal and original Proposal lack any statutory authority or other legal authority to adopt any regulation based on the proposed regulatory definition, "*Capable of being substantially reproduced*." 85 Fed. Reg. at 15,405 (proposed 40 CFR § 30.2). "5 U.S.C. 301; 5 U.S.C. App.; Pub. L. 98–80, 84 Stat. 2086" in no way provides that authority. See *supra* at III.I. Nor do any of the organic environmental statutes that EPA cites in the Proposal or Supplemental Proposal.

The Supplemental Proposal and original Proposal lack any statutory authority or other legal authority to adopt any regulation based on the proposed regulatory definition, "*Data*." 85 Fed. Reg. at 15,405 (proposed 40 CFR § 30.2). "5 U.S.C. 301; 5 U.S.C. App.; Pub. L. 98–80, 84 Stat. 2086" in no way provides that authority. See *supra* at III.I. Nor do any of the organic environmental statutes that EPA cites in the Proposal or Supplemental Proposal.

The Supplemental Proposal and original Proposal lack any statutory authority or other legal authority to adopt any regulation based on the proposed regulatory definition, "*Independent validation*." 85 Fed. Reg. at 15,405 (proposed 40 CFR § 30.2). "5 U.S.C. 301; 5 U.S.C. App.; Pub. L. 98–80, 84 Stat. 2086" in no way provides that authority. See *supra* at III.I. Nor do any of the organic environmental statutes that EPA cites in the Proposal or Supplemental Proposal.

The Supplemental Proposal and original Proposal lack any statutory authority or other legal authority to adopt any regulation based on the proposed regulatory definition, "*Influential scientific information*." 85 Fed. Reg. at 15,405 (proposed 40 CFR § 30.2). "5 U.S.C. 301; 5 U.S.C. App.; Pub. L. 98–80, 84 Stat. 2086" in no way provides that authority. See *supra* at III.I.

[28] Hawkins, Cheryl A. 2020. "RE: Science Rule Public Comment Extension Request," April 13, 2020.

Nor do any of the organic environmental statutes that EPA cites in the Proposal or Supplemental Proposal.

IV. EPA's expansion of the Supplemental Proposal to apply to all "data and models" is unjustified and unworkable

In the Supplemental Proposal, EPA proposes to "expand the scope of this rulemaking to apply to influential scientific information as well as significant regulatory actions." 85 Fed. Reg. at 15,398. This significant expansion of scope from the original proposal is not explained or justified by EPA, and EPA does not adequately grapple with the major ramifications of such a fundamental process change.

Neither the Supplemental Proposal nor the original Proposal engage with the consequences for drastically altering decades of scientific practice, and key questions about the actual scope of the rule have not been resolved within the Supplemental Proposal. EPA staffers have apparently offered a limited degree of clarity to only some of these questions in recent briefings to Congress (see section XIII), but that information has not been endorsed by the agency nor described in any way in the Supplemental Proposal.

The expansion of scope would seriously undermine major science activities currently underway at the agency, and threaten existing public health protections in fundamental ways by censoring the underlying scientific information on which pollution limits and other regulatory actions designed to protect public health and the environment are based. In subsection A below, we identify a sample of problematic implications of the Supplemental Proposal in more detail.

Moreover, in expanding the scope of the proposal, EPA does not adequately clarify what types of influential scientific information and significant regulatory actions fall under the purview of this proposal.

For example, EPA already maintains an online Science Inventory[29] that is accessible to the public, which lists products that have been identified by the EPA as "Influential Scientific Information" (ISI) or "Highly Influential Science Assessments" (HISA) by the criteria of the Office of Management and Budget's (OMB) Final Information Quality Bulletin for Peer Review[30] whose peer review process is complete.

The Supplemental Proposal makes no mention of this EPA-managed inventory of ISI or any other resource, nor does it explain why such a sweeping change to the development of such information is warranted. Moreover, the proposal makes no distinction between ISI or HISA, and it is unclear whether the scope of the rulemaking as described in the Supplemental Proposal would include HISA. The lack of clarity from EPA about the scope of information ensnared by

[29] U.S. Environmental Protection Agency. n.d. "Influential Products with Completed Peer Reviews | Science Inventory | Science Inventory | US EPA." https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.
[30] Office of Management and Budget. 2004. "Final Information Quality Bulletin for Peer Review." The White House. December 16, 2004. https://obamawhitehouse.archives.gov/node/15417.

the Supplemental Proposal is troubling and deprives members of the public from understanding the consequences of the radical provisions enumerated in the text of the Supplemental Proposal.

The newly expansive scope described in the Supplemental Proposal does not engage with EPA's existing Peer Review Agenda,[31] despite the fact that it would significantly disrupt that effort by altering the process by which scientific assessments are developed and published.

The OMB bulletin defines scientific assessments as "an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information"; the Supplemental Proposal's expansion of scope even from the Proposal, to include all "data and models" for significant new restrictions covers only part of the definition in the OMB bulletin yet there is no clarification of this discrepancy within the Supplemental Proposal.

EPA's failure to explain how the Supplemental Proposal's expansion to cover "all data and models" would apply to preexisting processes or work in practice is further evidence that the Supplemental Proposal is arbitrary and capricious, an abuse of discretion, and otherwise unlawful.

A. Adverse impacts on key science activities at EPA

1. Clean Air Act

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.[32] In 2009, leading air pollution epidemiologists published 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).[33]

More recently, an updated Clean Air Act analysis commissioned by NRDC found that, in 2020, the annual benefits from the law include up to 370,000 avoided premature deaths, 189,000 fewer hospital admissions for cardiac and respiratory illnesses, and net economic benefits of up to $3.8 trillion for the U.S. economy. Moreover, the annual benefits of the Clean Air Act are up to 32 times greater than the cost of these regulations.[34]

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[31] U.S. Environmental Protection Agency. n.d. "Peer Review Agenda | Science Inventory | Science Inventory | US EPA." https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

[32] U.S. EPA, Benefits and Costs of the Clean Air Act 1990-2020, the Second Prospective Study, a*vailable at* https://www.epa.gov/clean-air-act-overview/benefits-and-costs-clean-air-act-1990-2020-second-prospective-study.

[33] 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.

[34] Natural Resources Defense Council. 2020. "Clearing the Air: The Benefits of the Clean Air Act." NRDC. May 5, 2020. https://www.nrdc.org/sites/default/files/iec-benefits-costs-us-air-pollution-regulations-report.pdf.

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.[35]

The 1993 Harvard Six Cities Study,[36] a groundbreaking research effort examining 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. 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.

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 (and whose editors have rejected EPA's initial Proposal[37]), EPA relied on the results of the Harvard Six Cities study and others in 1997 when it promulgated the NAAQS for fine particulate matter.[38]

Hundreds of additional studies into the health effects of air pollution have been conducted since then across the country[39] and internationally,[40] for both short-[41] and long-term[42] 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 its independent re-analysis[43] of the study, which confirmed the original findings.

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

[36] 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.

[37] 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.

[38] *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.

[39] 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.

[40] 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.

[41] 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.

[42] 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.

[43] 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 Pollution and

As explained in section IV.B.1, 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 Supplemental Proposal's requirement for the public sharing of underlying data of these studies contradicts HIPAA's legal protections for private medical data[44] and requirements researchers adhere to under Institutional Review Boards (IRBs),[45] 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,[46] heart disease,[47] lung cancer,[48] stroke,[49] and asthma exacerbations[50]— is at risk of being excluded from the regulatory process - seriously undermining the efficacy of regulations on which this research has historically been based - if the Supplemental 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.[51] The unprecedented requirements of the rulemaking threaten to undermine this progress by allowing EPA to rely on weaker science that could stall or reverse historical strengthening of the NAAQS.[52]

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")).

[44] U.S. Department of Health and Human Services, The HIPAA Privacy Rule, *available at* https://www.hhs.gov/hipaa/for-professionals/privacy/index.html.

[45] *See*, *e.g.*, National Institute of Environmental Health Sciences: Institutional Review Board, *available at* https://www.niehs.nih.gov/about/boards/irb/index.cfm.

[46] 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.

[47] 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.

[48] 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.

[49] 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.

[50] 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.

[51] 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.

[52] Tummala, Neelu. 2020. "Tummala: Our Health Is Dependent on Science, Don't Let EPA Limit It." The Roanoke Times. April 10, 2020. https://www.roanoke.com/opinion/commentary/tummala-our-health-is-dependent-on-science-don-t-let-epa-limit-it/article_411ac00b-99b7-5ac4-9214-bd39bdcb28bd.html.

Under the Supplemental 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.[53] 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 application of data release requirements and disregard for the quantitative complexities of epidemiologic research.

The Proposal and Supplemental 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[54] 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.[55, 56] This approach of using the NAAQS or LML as a safe threshold directly contradicts the best available science[57, 58] and EPA's own stance on the pollution threshold issue as recently as 2012.[59]The Supplemental Proposal is designed to support the indefensible notion that a safe threshold of air pollution like $PM_{2.5}$ could exist, despite evidence

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[53] Dockery, Douglas W., and C. Arden Pope. 2020. "The Threat to Air Pollution Health Studies Behind the Environmental Protection Agency's Cloak of Science Transparency." *American Journal of Public Health* 110 (3): 286–87. https://doi.org/10.2105/AJPH.2019.305531.

[54] 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.

[55] 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.

[56] 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.

[57] 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.

[58] 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.

[59] 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.

indicating that relatively low levels of exposure to air pollution may actually confer *more* risk[60] than even the current EPA dose-response approach for $PM_{2.5}$ exposure assumes.

Importantly, in briefings to the House Committee on Space, Science, and Technology on April 2, 2020, EPA staff have recently stated that the proposed rule "would open up existing regulations to being reworked" by confirming to staff that the rule's application to "prospective rulemaking" includes statutorily mandated reviews of existing standards.[61] In the April 2 briefing, EPA noted that such "prospective rulemaking" includes statutorily mandated reviews of existing standards, such as the NAAQS.

It is highly inappropriate for EPA to make this clarification in a private setting, rather than engaging with the issue within the Supplemental Proposal itself, a setting that would provide members of the public an opportunity to comment on the issue. Beyond making this clarification in the briefing, EPA has not explained how the ongoing NAAQS reviews for fine particulate matter and ozone air pollution would proceed in the drastically altered scientific review context envisioned by the Supplemental Proposal.

2. Clean Water Act

a) Adverse Impacts on the Total Maximum Daily Load (TMDL) Program

The Clean Water Act (CWA) requires each state to develop TMDLs for every waterbody the state identifies as having uses impaired because of pollution. The objective of the TMDL is to determine the pollutant loading capacity of the waterbody and to allocate that load among the pollutant sources so that the appropriate control actions can be taken to achieve the state's water quality standards. States are responsible for developing TMDLs and submitting them to EPA for approval. Even if a third party develops the TMDL with a proprietary model, the state is responsible for submitting that TMDL to EPA.

If EPA disapproves a state TMDL, EPA must develop a replacement TMDL. TMDLs are developed using a range of techniques from simple mass balance calculations to complex fate and transport mathematical models. To date, over 65,000 TMDLs have been developed and approved for use in regulating point sources of pollution and controlling pollutant discharges from nonpoint sources. If the final science transparency rule applies retroactively to influential scientific information, every one of these TMDLs will have to be re-examined.

If the model underlying a TMDL fails to meet the new tests of transparency and reproducibility, the enforceability of the state's point source permit limits and nonpoint source controls based on that TMDL will be undermined. If the science transparency rule applies only prospectively to new TMDLs, EPA will need to disapprove any new TMDL based on a

[60] 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.
[61] *See supra,* n. 23, House Staff Memo.

proprietary model since such a model would not meet the new transparency and reproducibility requirements. Whether the science transparency rule applies retroactively or prospectively, EPA will incur significant costs and time replacing TMDLs. Despite this major impact, the Supplemental Proposal provides no estimation of the costs and benefits.

b) Impact on Drinking Water Program

The Supplemental Proposal's expansion of the scope of the Science Transparency proposed rule to include "influential scientific information" will have a significant impact on two major elements of EPA's Safe Drinking Water Act (SDWA) program.

The first SDWA element impacted will be EPA's drinking water health advisories. To date, EPA has published 154 drinking water health advisories that identify the concentration of an unregulated drinking water contaminant not expected to cause noncarcinogenic effects from human exposures of 1 day, 10 days, or a lifetime.

The second SDWA element impacted will be EPA's human health benchmarks for pesticides in drinking water. To date, EPA has published 394 benchmarks that identify the concentration of a registered pesticide in drinking water not expected to cause adverse health effects. All of these advisories and benchmarks were subjected to external peer review. Neither the advisories nor the benchmarks are enforceable, but water utilities often use them when their source water is contaminated with a pollutant for which there is no federal drinking water standard.

If the final rule applies retroactively to influential scientific information, every one of these advisories and benchmarks will have to be re-examined. If the human toxicity studies underlying these advisories and benchmarks are excluded based on claims of "transparency" and "reproducibility," the treatment provided by utilities for these pollutants will be negatively impacted.

If the final rule applies only prospectively to new advisories and benchmarks, EPA will still need to replace the current methodologies for these recommended values in order to incorporate the new transparency and reproducibility requirements. EPA will incur significant costs and time replacing these methodologies and recommendations. Despite this major impact, the Supplemental Proposal provides no estimation of the costs and benefits.

3. Protection from Radiation

The epidemiologic science and associated studies that are the basis of adherence to the current EPA's radiation protection standards are likely to be expressly excluded from consideration by EPA by the terms of this Proposal. EPA relied on radiation dose-response models to develop its radiation protection reports and regulations.

For the past several decades, these models have been used when developing practical and prudent guidance on ways to protect the public from potentially harmful effects of radiation-

while, at the same time, balancing the beneficial, justified and optimized use of radiation. These models are derived from studies by authoritative scientific bodies, including the US National Academy of Sciences (NAS)[62], and the National Council on Radiation Protection and Measurements (NCRP).[63] EPA's proposal, if implemented, would limit EPA's staff from basing regulatory actions on precisely these types of studies by requiring that all the underlying data be publicly shared.

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 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 and unethical as this data comes from individuals exposed to significant acute and a 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 weakened.

Examples of regulations that could be adversely impacted by this rule include:

- Cancer Risk Coefficients for Environmental Exposure to Radionuclides[64]
- EPA Radiogenic Cancer Risk Models and Projections for the US Population (the "Blue Book")[65]
- The Uranium Fuel Cycle (40 CFR Part 190) – a standard that sets generally applicable environmental limits for the entire uranium fuel cycle[66]
- Soil cleanup levels for Superfund sites
- The concept of ALARA (As Low As Reasonably Achievable) in radiation protection

4. Toxics

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

[62] National Research Council. Health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2. Vol. 7. National Academies Press, 2006.
[63] NCRP Commentary 27. "Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection." NCRP, 2018.
[64] Eckerman, Keith F., et al. "Cancer risk coefficients for environmental exposure to radionuclides." *Federal Guidance Report* 13 (1999).
[65] *See* https://www.epa.gov/sites/production/files/2015-05/documents/bbfinalversion.pdf.
[66] *See* https://www.epa.gov/radiation/environmental-radiation-protection-standards-nuclear-power-operations-40-cfr-part-190.

strokes in adults, and neurological damage that can cause pain in the muscles and joints.[67] 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.[68]

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.[69] The LCR rule applies to water utilities, and 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.[70] 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. If these studies are excluded from consideration under the Supplemental Proposal, the integrity of regulations designed to limit exposure to lead would be seriously undermined.

Further, precisely because of 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.[71] Studies like these—longitudinal cohort studies, particularly those that capture exposures that may no longer occur—are not reproducible.

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[67] 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.
[68] Lead; Identification of Dangerous Levels of Lead, 66 Fed. Reg. 1206 (Jan. 5, 2001).
[69] 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.
[70] 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.
[71] 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.

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.[72] The VC monomer was first reported to cause cancer in 1969 based on animal laboratory studies.[73] 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.[74,75]

Vinyl chloride is regulated in workplaces, and in drinking water, food, and air:[76]

- 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.[77] Despite predictions of dire job losses, virtually all U.S. manufacturing facilities met the new standard within a few years while reducing costs, largely through better containment of the unpolymerized monomer and improved exposure monitoring.[78]

- 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).[79, 80]

- FDA regulations limit vinyl chloride in food contact materials and packaging.[81]

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

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[72] 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").
[73] 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.
[74] Creech JL Jr, Johnson MN. Angiosarcoma of liver in the manufacture of polyvinyl chloride. J Occup Med. 1974 Mar;16(3):150–51.
[75] 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").
[76] *Id.*
[77] United States Department of Labor, Occupational Safety and Health Administration, Regulations for Vinyl Chloride, *available at* https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10021; 29 C.F.R. 1910.1017 *et seq.*
[78] 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.
[79]U.S. EPA, "National Primary Drinking Water Regulations," *available at* https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations.
[80] *Supra* n.72, Vinyl Chloride.
[81] *Id.*

health-protective regulatory actions by EPA, OSHA and other federal agencies - regulatory actions that were based on these studies – 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. Because these studies cannot meet the "standards" set out in the Supplemental Proposal, they may no longer form the basis of regulatory action, seriously compromising the safeguards on which we rely to protect against exposure to VC.

c) Pyrethroids

Pyrethroids are a class of insecticides that includes deltamethrin and permethrin, used on food crops including vegetables, fruit, and corn.[82] Permethrin is also used as a spray in homes and public spaces like hotels, theaters, restaurants, and hospitals.[83] It is also used to impregnate clothing, shoes, bed nets, and camping gear advertised to repel mosquitoes and ticks.[84] Pyrethroid pesticides are classified by EPA as a "likely human carcinogen," and is linked in published studies to Parkinson's Disease and adverse behavioral problems in prenatally exposed children.[85, 86]

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).[87] CAPHRA

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[82] 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).

[83] 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")

[84] 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/.

[85] *See supra,* n.79, Pesticide Maps.

[86] 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.

[87] 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.

identifies its participating parties as chemical and agrochemical manufacturers.[88, 89] 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."[90]

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."[91]

At this point, the EPA Scientific Advisory Panel meeting is postponed indefinitely.[92] The stated reason is "due to the unavailability of experts," but the more likely reason is to bias the panel with the addition of industry experts, as EPA has done recently with its Scientific Advisory Boards.[93] 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 (FQPA), which was passed by Congress unanimously in 1996.

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[88] 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.

[89] 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.

[90] Id.

[91] 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.

[92] 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.

[93] 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.

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.[94] 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.[95] 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.[96]

To protect these children, in October 2015, 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 pregnant women and children; residue levels were far above their target risk level—in some cases, by up to 140 times.[97]

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. Without these epidemiological studies, our regulators will no longer be able to use the best available science to ensure that pregnant women, fetuses, and young children receive protection from exposure to chlorpyrifos. The exclusion of these studies and its corresponding impact reveals EPA's Proposal and Supplemental Proposal to be arbitrary, capricious, and an abuse of discretion. It must be withdrawn.

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[94] U.S. EPA, Ingredients Used in Pesticide Products: Chlorpyrifos, *available at* https://www.epa.gov/ingredients-used-pesticide-products/chlorpyrifos.
[95] *Id.*
[96] 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.
[97] 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.

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.[98] EPA has also summarized the health and environmental effects of mercury in previous TSCA rulemakings.[99] 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.[100] Commonly consumed fish may have methylmercury levels 100,000 times that of the ambient water.[101] Mercury contamination of fish stocks is widespread in the United States.[102, 103] 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.[104]

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 incorporated into food chains and ultimately into fish.[105] Local sources have been implicated in

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[98] U.S. EPA, Health Effects of Exposures to Mercury, *available at* https://www.epa.gov/mercury/health-effects-exposures-mercury.

[99] *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).

[100] U.S. EPA, How People are Exposed to Mercury, *available at* https://www.epa.gov/mercury/how-people-are-exposed-mercury.

[101] 79 Fed. Reg. 63,258 *et seq.,* Effluent Limitations Guidelines and Standards for the Dental Category, at 63,277, (Oct. 22, 2014).

[102] 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).

[103] 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.

[104] 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.

[105] 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.

elevated levels of mercury measured in ambient air,[106] precipitation,[107, 108] soils,[109] and methylmercury levels in biota, including fish.[110] Reductions in local mercury emissions levels have been tied to decreasing levels measured in the environment and biota.[111, 112, 113] Therefore, to achieve the National Academy of Sciences' public-health goal of reducing mercury concentrations in fish,[114] 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.[115, 116] 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.[117]

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

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[106] 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.

[107] 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.

[108] 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.

[109] 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.

[110] 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.

[111] 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.

[112] 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.

[113] *See supra* n. 101, Mercury in Streams.

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

[115] 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.

[116] 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.

[117] 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.

mercury emissions are reduced.[118, 119] Mercury releases associated with mercury uses in products and processes contribute "significantly" to this mercury pollution.[120]

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.[121] 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.[122]

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."[123] 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.[124] About two years later, EPA promulgated a SNUR covering mercury-added barometers, manometers, hygrometers, and psychrometers, essentially for the same reasons.[125]

EPA also regulates mercury dischargers to surface waters under the Clean Water Act. This Administration recently finalized effluent guidelines for dental offices.[126] 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).[127]

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.[128] Even the EPA

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[118] 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.
[119] 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.
[120] Great Lakes Regional Collaboration, *Mercury in Products Phase-Down Strategy* 1 (June 2008).
[121] U.S. EPA, Guidelines for Eating Fish that Contain Mercury, *available at* https://www.epa.gov/mercury/guidelines-eating-fish-contain-mercury.
[122] 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.
[123] 72 Fed. Reg. 56,903 *et seq.*, Mercury Switches in Motor Vehicles; Significant New Use Rule (Nov. 5, 2007).
[124] 75 Fed. Reg. 42,330 *et seq*., Elemental Mercury Used in Flow Meters, Natural Gas Manometers, and Pyrometers (July 21, 2010).
[125] 77 Fed. Reg. at 31,728 *et seq.,* Elemental Mercury Used in Barometers, Manometers, Hygrometers, and Psychrometers; Significant New Use Rule (May 30, 2012).
[126] 82 Fed. Reg. 27,154 *et seq.,* Effluent Limitations Guidelines and Standards for the Dental Category: Final Rule, (June 14, 2017).
[127] U.S. EPA, Environmental Laws that Apply to Mercury, *available at* https://www.epa.gov/mercury/environmental-laws-apply-mercury.
[128] 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.

RfD likely underestimates the extent of risks to newborns due to bio-concentration of methylmercury across the placenta.[129] 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.[130]

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.[131] 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. If EPA may no longer rely on these studies under the Supplemental Proposal, the Agency will not have access to the information it needs to ensure its regulations are sufficiently protective of public health. Putting blinders on the Agency in this way reveals the Proposal and Supplemental Proposal to be arbitrary, capricious, and an abuse of discretion.

5. Superfund

The Supplemental Proposal's expansion of the scope of the original Proposal to include influential scientific information will have a significant impact on the cleanup levels at the 1335 sites on the Superfund National Priorities List. Since 2003 EPA has used a three-tier hierarchy to select human health toxicity values for use in risk assessments at Superfund sites. Superfund risk assessments are performed to evaluate whether action is warranted under the statute; to establish protective cleanup levels for air, water, and soil; and to determine the residual risk posed by cleanup actions.

The hierarchy recognizes that EPA should take action to reduce public health risks using the best available science without waiting for further study to improve the certainty of the toxicity values.

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[129] 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.

[130] 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.

[131] 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.

The first priority, Tier 1, is to use Integrated Risk Information System (IRIS) values since these values have undergone rigorous peer review and reflect EPA's consensus toxicity values.

Tier 2 consists of Provisional Peer Reviewed Toxicity Values (PPRTVs) that are developed by the Superfund Technical Support Center in EPA's Office of Research and Development. PPRTVs are developed when a contaminant without an IRIS value poses a health risk at a Superfund site.

Tier 3 includes other EPA and non-EPA sources of toxicity information with priority given to those sources of information that are most current, are based on methods and processes that are publicly available, and are peer reviewed. Tier 3 sources are used when neither IRIS values nor PPRTVs are available, and cleanup action must proceed. Tier 3 sources include CalEPA toxicity values and ATSDR minimal risk levels. If the final science transparency rule applies retroactively to influential scientific information, every one of these toxicity values will have to be re-examined.

If the human toxicity studies underlying these values fail to meet the new tests of transparency and reproducibility, the cleanup levels for air, water and soil based on these toxicity values will be discredited. As a result, the cleanup actions underway at all 1335 Superfund sites will be undermined, as well as the cleanups completed at 424 sites that have been deleted from the Superfund National Priorities List.

If the final science transparency rule applies only prospectively to new toxicity values, EPA will still need to revise the hierarchy of human health toxicity values to incorporate the new transparency and reproducibility requirements. EPA will incur significant costs and time replacing the hierarchy, the toxicity values, and the cleanup levels at many sites. Despite this major impact, the Supplemental Proposal provides no estimation of the costs and benefits.

B. The Supplemental Proposal fails to consider impacts on influential science

As with the original proposed rule, the Supplemental Proposal does not identify any specific deficiencies in the agency's current science review policies that justify the need for such expansive and radical requirements to be imposed. For example EPA's own website[132] on the role of science at the agency notes that "the Agency's stringent scientific peer review processes are designed to ensure that all EPA decisions are founded on credible science and data." The proposal does not explain why drastic and burdensome new requirements on science and data are needed. This failure to define the problem is further evidence that the Supplemental Proposal is arbitrary and capricious, an abuse of discretion, and otherwise unlawful.

[132] U.S. Environmental Protection Agency. 2014. "Role of Science at EPA." Overviews and Factsheets. US EPA. July 2, 2014. https://www.epa.gov/research/role-science-epa.

1. Adverse impacts on analyses of environmental rules

The Supplemental Proposal is even more expansive than the Proposal and would seriously reduce the agency's ability to characterize health impacts of proposed regulations in influential science products, including key regulatory impact analyses regularly produced by the agency. For example, in the last three years alone, EPA has regularly relied on a set of peer-reviewed epidemiology studies that relate long-term air pollution exposures to premature mortality risks (see Table 1).

Importantly, each of the environmental epidemiology studies identified in Table 1 does not meet the strict data release requirements identified in the Supplemental Proposal; nevertheless, EPA has identified these studies as providing robust dose-response information upon which to base regulatory impact analyses across a range of sectors..

EPA has justifiably relied on these consensus studies to estimate the human health ramifications of these rules related to changes in ambient air pollution; this Supplemental Proposal represents a significant departure from that process by radically altering the scientific information upon which the agency can rely on to articulate human health co-benefits of pollution regulation.

Therefore, the approach proposed in the Supplemental Proposal is not consistent with EPA's established and fully vetted process. Implementing such a major change in the agency's process for considering scientific information threatens to significantly disrupt the rulemaking process by jeopardizing the data upon which prior analyses have been based. Disrupting the process in such a way is arbitrary, capricious, and an abuse of the Agency's discretion.

Table 1: Recent EPA Air Actions Relying on Underlying Scientific Data that Would Be Restricted from Consideration By the Proposed Rule

Date	EPA Action	Underlying Epidemiology studies cited by EPA
October 2017	Regulatory Impact Analysis for the Review of the Clean Power Plan: Proposal[133]	Krewski et al. 2009[134] Lepeule et al. 2012[135]

[133] U.S. Environmental Protection Agency. 2017. "Regulatory Impact Analysis for the Review of the Clean Power Plan: Proposal." Reports and Assessments. https://www.epa.gov/sites/production/files/2017-10/documents/ria_proposed-cpp-repeal_2017-10_0.pdf.

[134] Krewski, Daniel, Michael Jerrett, Richard T Burnett, Renjun Ma, Yuanli Shi, Michelle C Turner, C Arden Pope Iii, George Thurston, Eugenia E Calle, and Michael J Thun. 2009. "Extended Follow-Up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality." *140*, May, 50. https://www.healtheffects.org/publication/extended-follow-and-spatial-analysis-american-cancer-society-study-linking-particulate.

[135] Lepeule, Johanna, Francine Laden, Douglas Dockery, and Joel Schwartz. 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): 965–70. https://doi.org/10.1289/ehp.1104660.

May 2018	User's Manual for the Co-Benefits Risk Assessment Health Impacts Screening and Mapping Tool (COBRA)[136]	Krewski et al. 2009 Lepeule et al. 2012 Additional studies, see table C-3 (page C-7)
August 2018	Regulatory Impact Analysis for the Proposed Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units; Revisions to Emission Guideline Implementing Regulations; Revisions to New Source Review Program[137]	Krewski et al. 2009 Lepeule et al. 2012
July 2019	Public Health Benefits per kWh of Energy Efficiency and Renewable Energy in the United States: A Technical Report[138]	Deploys COBRA Health Impacts Screening and Mapping Tool
January 2020	Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter[139]	Jerret et al. 2016[140] Pope et al. 2015[141] Turner et al. 2016[142] Thurston et al. 2016[143]

[136] U.S. Environmental Protection Agency. 2017. "User's Manual for the Co-Benefits Risk Assessment (COBRA) Screening Model." Data and Tools. US EPA. June 26, 2017. https://www.epa.gov/statelocalenergy/users-manual-co-benefits-risk-assessment-cobra-screening-model.
[137] U.S. Environmental Protection Agency. 2018. "Regulatory Impact Analysis for the Proposed Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units; Revisions to Emission Guideline Implementing Regulations; Revisions to New Source Review Program," August, 289. https://www.epa.gov/sites/production/files/2018-08/documents/utilities_ria_proposed_ace_2018-08.pdf.
[138] U.S. Environmental Protection Agency. 2019. "Public Health Benefits per KWh of Energy Efficiency and Renewable Energy in the United States: A Technical Report." https://www.epa.gov/statelocalenergy/estimating-health-benefits-kilowatt-hour-energy-efficiency-and-renewable-energy.
[139] U.S. Environmental Protection Agency. 2020. "Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter." https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf.
[140] Jerrett, M, Turner, MC, Beckerman, BS, Pope, CA, van Donkelaar, A, Martin, RV, Serre, M, Crouse, D, Gapstur, SM, Krewski, D, Diver, WR, Coogan, PF, Thurston, GD and Burnett, RT (2016). Comparing the health effects of ambient particulate matter estimated using ground-based versus remote sensing exposure estimates. Environ Health Perspect 125(4): 552-559.
[141] Pope, CA, Turner, MC, Burnett, R, Jerrett, M, Gapstur, SM, Diver, WR, Krewski, D and Brook, RD (2015). Relationships between fine particulate air pollution, cardiometabolic disorders and cardiovascular mortality. Circul Res 116(1): 108-U258.
[142] Turner, MC, Jerrett, M, Pope, A, III, Krewski, D, Gapstur, SM, Diver, WR, Beckerman, BS, Marshall, JD, Su, J, Crouse, DL and Burnett, RT (2016). Long-term ozone exposure and mortality in a large prospective study. Am J Respir Crit Care Med 193(10): 1134-1142.
[143] Thurston, GD, Ahn, J, Cromar, KR, Shao, Y, Reynolds, HR, Jerrett, M, Lim, CC, Shanley, R, Park, Y and Hayes, RB (2016). Ambient particulate matter air pollution exposure and mortality in the NIH-AARP Diet and Health Cohort. Environ Health Perspect 124(4): 484-490.

		Di et al. 2017[144] Baxter et al. 2017[145] Ito et al. 2013[146] Zanobetti et al. 2014[147]
March 2020	Safer Affordable Fuel-Efficient 'SAFE' Vehicles Rule[148]	Cites several EPA Integrated Science Assessments for criteria pollutants For $PM_{2.5}$ air pollution: Krewski et al. 2009 Lepeule et al. 2012
April 2020	Final Subcategory of Certain Existing Electric Utility Steam Generating Units That Fire Coal Refuse - Analysis of Potential Costs and Benefits for the "National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units – Subcategory of Certain Existing Electric Utility Steam Generating Units Firing Eastern Bituminous Coal Refuse for Emissions of Acid Gas Hazardous Air Pollutants"[149]	Krewski et al. 2009 Lepeule et al. 2012 Peters et al. 2001[150]

[144] Di, Q, Wang, Y, Zanobetti, A, Wang, Y, Koutrakis, P, Choirat, C, Dominici, F and Schwartz, JD (2017b). Air pollution and mortality in the Medicare population. New Engl J Med 376(26): 2513-2522.
[145] Baxter, LK, Crooks, JL and Sacks, JD (2017). Influence of exposure differences on city-to-city heterogeneity in PM2.5-mortality associations in US cities. Environ Health 16(1): 1.
[146] Ito, K, Ross, Z, Zhou, J, Nádas, A, Lippmann, M and Thurston, GD (2013). National Particle Component Toxicity (NPACT) initiative: Study 3. Time-series analysis of mortality, hospitalizations, and ambient PM2.5 and its components. Boston, MA, Health Effects Institute**:** 95-125.
[147] Zanobetti, A, Dominici, F, Wang, Y and Schwartz, JD (2014). A national case-crossover analysis of the short-term effect of PM2.5 on hospitalizations and mortality in subjects with diabetes and neurological disorders. Environ Health 13(1): 38.
[148] Environmental Protection Agency and National Highway Traffic Safety Administration. 2020. "The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021-2026 Passenger Cars and Light Trucks." Federal Register. https://www.govinfo.gov/content/pkg/FR-2020-04-30/pdf/2020-06967.pdf.
[149] U.S. Environmental Protection Agency. 2020. "Final Subcategory of Certain Existing Electric Utility Steam Generating Units That Fire Coal Refuse - Analysis of Potential Costs and Benefits for the 'National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units – Subcategory of Certain Existing Electric Utility Steam Generating Units Firing Eastern Bituminous Coal Refuse for Emissions of Acid Gas Hazardous Air Pollutants.'" Policies and Guidance. https://www.epa.gov/sites/production/files/2020-04/documents/mats_coal_refuse_cost-benefit_memo.pdf.
[150] Peters, Annette, Douglas W Dockery, James E Muller, and Murray A Mittleman. 2001. "Increased Particulate Air Pollution and the Triggering of Myocardial Infarction." *Circulation* 103 (23): 2810–15.

April 2020	Review of the National Ambient Air Quality Standards for Particulate Matter[151]	See Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter

2. Adverse Impacts on EPA-led research

In addition to its striking inconsistency with prior regulatory impact assessments published by the agency, the proposed approach outlined in the Supplemental Proposal also significantly departs from the ways in which agency scientists in the Office of Research and Development (ORD) already handle data. A review of a sample of recently published peer-reviewed scientific studies with EPA staff scientists as lead authors and co-authors[152] indicates

[151] U.S. Environmental Protection Agency. 2020. "Review of the National Ambient Air Quality Standards for Particulate Matter." Federal Register. https://www.govinfo.gov/content/pkg/FR-2020-04-30/pdf/2020-08143.pdf.

[152] Achakulwisut, P., Anenberg, S. C., Neumann, J. E., Penn, S. L., Weiss, N., Crimmins, A., Fann, N., Martinich, J., Roman, H., & Mickley, L. J. (2019). Effects of Increasing Aridity on Ambient Dust and Public Health in the U.S. Southwest Under Climate Change. *GeoHealth*, *3*(5), 127–144. https://doi.org/10.1029/2019GH000187;
Anenberg, S. C., Weinberger, K. R., Roman, H., Neumann, J. E., Crimmins, A., Fann, N., Martinich, J., & Kinney, P. L. (2017). Impacts of oak pollen on allergic asthma in the United States and potential influence of future climate change: Climate Impacts on Oak Pollen and Health. *GeoHealth*, *1*(3), 80–92. https://doi.org/10.1002/2017GH000055
Baxter, L. K., Crooks, J. L., & Sacks, J. D. (2017). Influence of exposure differences on city-to-city heterogeneity in PM2.5-mortality associations in US cities. *Environmental Health*, *16*(1), 1. https://doi.org/10.1186/s12940-016-0208-y
Berman, J. D., Fann, N., Hollingsworth, J. W., Pinkerton, K. E., Rom, W. N., Szema, A. M., Breysse, P. N., White, R. H., & Curriero, F. C. (2012). Health Benefits from Large-Scale Ozone Reduction in the United States. *Environmental Health Perspectives*, *120*(10), 1404–1410. https://doi.org/10.1289/ehp.1104851
Carvour, M. L., Hughes, A. E., Fann, N., & Haley, R. W. (2018). Estimating the Health and Economic Impacts of Changes in Local Air Quality. *American Journal of Public Health*, *108*(S2), S151–S157. https://doi.org/10.2105/AJPH.2017.304252
Crimmins, A., Balbus, J., Gamble, J. L., Beard, C. B., Bell, J. E., Dodgen, D., Eisen, R. J., Fann, N., Hawkins, M. D., Herring, S. C., Jantarasami, L., Mills, D. M., Saha, S., Sarofim, M. C., Trtanj, J., & Ziska, L. (2016). *The Impacts of Climate Change on Human Health in the United States: A Scientific Assessment*. U.S. Global Change Research Program. https://doi.org/10.7930/J0R49NQX
Davidson, K. F., Fann, N., Zawacki, M., Fulcher, C., & Baker, K. (2020). The recent and future health burden of the U.S. mobile sector apportioned by source. *Environmental Research Letters*. https://doi.org/10.1088/1748-9326/ab83a8
Fann, N., Alman, B., Broome, R. A., Morgan, G. G., Johnston, F. H., Pouliot, G., & Rappold, A. G. (2018). The health impacts and economic value of wildland fire episodes in the U.S.: 2008–2012. *Science of The Total Environment*, *610–611*, 802–809. https://doi.org/10.1016/j.scitotenv.2017.08.024
Fann, N., Baker, K. R., Chan, E. A. W., Eyth, A., Macpherson, A., Miller, E., & Snyder, J. (2018). Assessing Human Health PM $_{2.5}$ and Ozone Impacts from U.S. Oil and Natural Gas Sector Emissions in 2025. *Environmental Science & Technology*, *52*(15), 8095–8103. https://doi.org/10.1021/acs.est.8b02050
Fann, N., Bell, M. L., Walker, K., & Hubbell, B. (2011). Improving the Linkages between Air Pollution Epidemiology and Quantitative Risk Assessment. *Environmental Health Perspectives*, *119*(12), 1671–1675. https://doi.org/10.1289/ehp.1103780
Fann, N., Fulcher, C. M., & Baker, K. (2013). The Recent and Future Health Burden of Air Pollution Apportioned Across U.S. Sectors. *Environmental Science & Technology*, *47*(8), 3580–3589. https://doi.org/10.1021/es304831q

that none of those studies would satisfy the data transparency requirements described in the Supplemental Proposal. The proposal does not explain if or how agency scientists would be required to comply with the data transparency requirements outlined in the Supplemental Proposal, or what complications or costs would be associated with any requirement that agency-authored scientific information also meet the burdensome data release requirements outlined in the Supplemental Proposal.

Because EPA-led scientific studies provide useful information to other academic researchers who cite these studies in their own peer-reviewed work[153], it is clear that any hampering of the scientific enterprise within ORD triggered by the Proposal would have detrimental downstream impacts far beyond the agency's regular activities. These severe implications are not described, analyzed, or mitigated within the Proposal. These failings are further evidence that the Supplemental Proposal is arbitrary and capricious, an abuse of discretion, and otherwise unlawful.

Furthermore, EPA has already developed and distributed a number of software modeling programs that facilitate health impact estimation for air pollution scenarios. These models include the Benefits Mapping and Analysis Program (BenMAP)[154], CO-Benefits Risk

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Fann, N., Lamson, A. D., Anenberg, S. C., Wesson, K., Risley, D., & Hubbell, B. J. (2012). Estimating the National Public Health Burden Associated with Exposure to Ambient PM2.5 and Ozone: U.S. Public Health Burden of PM2.5 and Ozone. *Risk Analysis*, *32*(1), 81–95. https://doi.org/10.1111/j.1539-6924.2011.01630.x

Fann, N., Nolte, C. G., Dolwick, P., Spero, T. L., Brown, A. C., Phillips, S., & Anenberg, S. (2015). The geographic distribution and economic value of climate change-related ozone health impacts in the United States in 2030. *Journal of the Air & Waste Management Association*, *65*(5), 570–580. https://doi.org/10.1080/10962247.2014.996270

Fann, N., & Risley, D. (2013). The public health context for PM2.5 and ozone air quality trends. *Air Quality, Atmosphere & Health*, *6*(1), 1–11. https://doi.org/10.1007/s11869-010-0125-0

Martinich, J., & Crimmins, A. (2019). Climate damages and adaptation potential across diverse sectors of the United States. *Nature Climate Change*, *9*(5), 397–404. https://doi.org/10.1038/s41558-019-0444-6

Nassikas, N., Spangler, K., Fann, N., Nolte, C. G., Dolwick, P., Spero, T. L., Sheffield, P., & Wellenius, G. A. (2020). Ozone-related asthma emergency department visits in the US in a warming climate. *Environmental Research*, *183*, 109206. https://doi.org/10.1016/j.envres.2020.109206

Neumann, J. E., Anenberg, S. C., Weinberger, K. R., Amend, M., Gulati, S., Crimmins, A., Roman, H., Fann, N., & Kinney, P. L. (2019). Estimates of Present and Future Asthma Emergency Department Visits Associated With Exposure to Oak, Birch, and Grass Pollen in the United States. *GeoHealth*, *3*(1), 11–27. https://doi.org/10.1029/2018GH000153

Sanderson, B. M., Wobus, C., Mills, D., Zarakas, C., Crimmins, A., Sarofim, M. C., & Weaver, C. (2019). Informing Future Risks of Record-Level Rainfall in the United States. *Geophysical Research Letters*, *46*(7), 3963–3972. https://doi.org/10.1029/2019GL082362

Voorhees, A. S., Fann, N., Fulcher, C., Dolwick, P., Hubbell, B., Bierwagen, B., & Morefield, P. (2011). Climate Change-Related Temperature Impacts on Warm Season Heat Mortality: A Proof-of-Concept Methodology Using BenMAP. *Environmental Science & Technology*, *45*(4), 1450–1457. https://doi.org/10.1021/es102820y

[153] Limaye, V. S., Vargo, J., Harkey, M., Holloway, T., & Patz, J. A. (2018). Climate Change and Heat-Related Excess Mortality in the Eastern USA. *EcoHealth*, *15*(3), 485–496. https://doi.org/10.1007/s10393-018-1363-0; Limaye, V. S., Max, W., Constible, J., & Knowlton, K. (2019). Estimating the Health-Related Costs of 10 Climate-Sensitive U.S. Events During 2012. GeoHealth, 3(9), 245–265. https://doi.org/10.1029/2019GH000202

[154] U.S. Environmental Protection Agency. (2014, March 14). *Environmental Benefits Mapping and Analysis Program—Community Edition (BenMAP-CE)* [Collections and Lists]. US EPA. https://www.epa.gov/benmap

Assessment (COBRA) Health Impacts Screening and Mapping Tool[155], and other Reduced-Form Tools for Calculating $PM_{2.5}$ Benefits[156].

A key component of those models is the application of exposure-response epidemiology to estimate the health implications of specific energy, climate, and air quality scenarios. This modeling component includes many of the same peer-reviewed studies that EPA itself relies on in regulatory impact assessments (see Table 1). These failures to explain are further evidence that the Supplemental Proposal is arbitrary and capricious, an abuse of discretion, and otherwise unlawful.

The proposed rule does not explain how significant and burdensome data transparency requirements imposed on data and models used by the agency would affect the existing models that EPA currently hosts and distributes to the international research community.

It is not clear that the dose-response studies incorporated into these models would remain and, if not, the detrimental impact that change would have on efforts to describe health implications of future proposed rules. Importantly, EPA itself uses the BenMAP[157] model to conduct health impact assessments as part of proposed rules[158]; the Supplemental Proposal does not include any discussion of the implications of data transparency requirements on the future implementation and use of EPA-endorsed software packages.

V. EPA definitions of terms in the Supplemental Proposal are flawed, inconsistent, and vague

In the Supplemental Proposal, EPA introduces definitions of terms that are incomplete, inconsistent, and vague. In addition to these shortcomings, EPA declines to define additional key terms introduced in the Supplemental Proposal, including "tiered access." Below, we describe the flawed nature of these definitions. These definitions reveal the extent to which the Agency's Supplemental Proposal, like the Proposal, is arbitrary, capricious, an abuse of the Agency's discretion, and must be withdrawn.

A. "Influential scientific information"

In the Supplemental Proposal, EPA defines "influential scientific information" as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." This definition is

[155] U.S. Environmental Protection Agency. (2017, June 26). *CO-Benefits Risk Assessment (COBRA) Health Impacts Screening and Mapping Tool* [Data and Tools]. US EPA. https://www.epa.gov/statelocalenergy/co-benefits-risk-assessment-cobra-health-impacts-screening-and-mapping-tool

[156] U.S. Environmental Protection Agency. (2014, October 21). *Reduced-Form Tools for Calculating PM2.5 Benefits* [Data and Tools]. US EPA. https://www.epa.gov/benmap/reduced-form-tools-calculating-pm25-benefits

[157] U.S. Environmental Protection Agency. 2017. "Environmental Benefits Mapping and Analysis Program - Community Edition (BenMAP-CE)." Collections and Lists. US EPA. 2017. https://www.epa.gov/benmap.

[158] See U.S. Environmental Protection Agency. 2020. "Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter." https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf.

overly vague, as it does not describe how, when, or why the agency makes such a determination about any such information. It does not define what a "clear and substantial" impact are, and does not specify if and how such a determination is made or documented.

The definition is not specific to EPA's research review context and is vague and overly expansive in not describing the types of "public policies" and "private sector decisions" are affected by the nature of influence of the science itself, rather than EPA's determinations about that scientific content within the larger context of all available research. Notably, EPA does not restrict "influential scientific information" to include only "publicly available" scientific information, because a large portion of important science may or may not be publicly available.

The inconsistency between what EPA currently considers to be influential science on its own web site[159] and how it is defined in the Supplemental Proposal signals EPA's lack of adequate advance consideration to define this term.

B. "Independent validation"

In the Supplemental Proposal, EPA defines "independent validation" as "reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced."

This definition is inconsistent with the remainder of the proposal because it restricts the concept of "independent validation" to "subject matter experts who have not contributed to the development of the study." In the original 2018 Proposal, EPA contended that was intending to "strengthen the transparency of regulatory science" by introducing radical changes in EPA science activities to "ensure that the data underlying [scientific studies] are publicly available in a manner sufficient for independent validation."

Here, EPA restricts "independent validation" to an activity only conducted by "subject matter experts," a distinction in conflict with EPA's definition of "publicly available," which is more expansive. Thus, it is unclear whether validation of study data by any member of the public is consistent with EPA's definition. In this definition, EPA fails to define "subject matter experts" nor explain how expertise is to be evaluated.

EPA does not define how a "contribution" to a particular study is interpreted, and whether that contribution may be in the form of financial resources or not. EPA does not define a threshold that would qualify as "substantial" reproduction of study findings, and does not detail how "capable of being substantially reproduced" is interpreted. It is not clear from EPA's definition of "independent validation" to what degree study findings in all of their forms (e.g., general results, point estimates, confidence intervals, sensitivity analyses, statistical significance) must be "reproduced."

[159] U.S. Environmental Protection Agency. n.d. "Influential Products with Completed Peer Reviews | Science Inventory | Science Inventory | US EPA." https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

C. “Pivotal science”

In the Supplemental Proposal, EPA defines “pivotal science” as “specific scientific studies or analyses that underly influential scientific information.” EPA has included this vague definition which does not engage with the agency’s existing inventory of influential scientific information.[160] It does not make any distinction between different types of scientific studies, including scientific reviews and meta-analyses. It does not make clear how “underly” is to be interpreted, even though scientific studies and analyses are typically informative of key scientific information to differing degrees, depending on study quality, regulatory context, and EPA interpretation of scientific studies.

D. “Model”

In the Supplemental Proposal, EPA defines “model” as “a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic, or social system. A formal representation of the behavior of system processes, often in mathematical or statistical terms. The basis can also be physical or conceptual.” This definition of model is overly general and vague does not grapple with the concrete was in which EPA engages with models and modeling output in conducting its scientific activities.

The definition does not distinguish between physical models, conceptual models, and software modeling packages,, nor does it explicitly account for models applicable within the human health context, even though that type of tool is commonly deployed by EPA in its scientific work (see section IV.B.1). In failing to define models and distinguish between modeling inputs and outputs, EPA’s definition is flawed and insufficient.

E. “Reanalyze”

In the Supplemental Proposal, EPA defines “reanalyze” as “to analyze exactly the same data to see if the same result emerges from the analysis by using the same or different statistical software, models, and statistical methodologies that were originally used to analyze the data, as well as to assess potential analytical errors and variability in the underlying assumptions of the original analysis.”

In this definition, EPA does not restrict reanalysis to “subject matter experts” as it did for “independent validation.” EPA does not describe any assumptions underlying analyses that may lead a person to fail to arrive at the “same result” despite analyzing “exactly the same data.” EPA does not clarify what the “same result” is to be interpreted as.

Problematically, this definition focuses on using the “same” data but allows for “the same of different statistical software, models, and statistical methodologies,” yet expects “the same result” to emerge.

[160] Ibid.

This definition clashes with the reality that, even using the same underlying data, changes in software, modeling approach, and statistical techniques would reasonably be expected to deliver results that are not exactly "the same" as results produced in an original analyses. EPA's definition is unreasonable, illogical, and flawed.

F. "Data"

In the Supplemental Proposal, EPA defines "data" as the "set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party."

EPA makes mention of analysis by "an independent party" in its definition without any clear rationale, and this concept is not within the scope of "data" as it is typically conceived. EPA includes an overly broad definition here and focuses on "factual material" that is necessary to "validate research findings." In fact, scientific data are used to arrive at the research findings through the scientific method.

EPA's definition of "data" is fundamentally flawed and does not reflect the use of this term within the scientific community. It also makes a judgment that "obvious errors" are not "data," even though some errors may be part of raw data sets that are not ultimately included in the analytical data sets used as the basis for scientific investigation and validation. EPA does not define the "original researcher" in question here nor make any accommodation for the more typical situation in which teams of researchers and others collaborate to collect data, analyze it, and interpret it.

G. "Publicly available"

In the supplemental proposal, EPA proposes to define "publicly available" data at 40 CFR 30.2 similarly as in 16 FR 313.3, as "information that is made available to the general public." EPA further explains in the supplemental proposal that its definition "would encompass information legally available from government sources, the media and the Internet."

This definition is vague in not making it clear whether the information itself would be actively made available to members of the public by data holders in government sources, media sources, or other online sources, or whether data subject to public distribution from government sources through legal approaches, including data requests submitted to EPA via the Freedom Of Information Act (FOIA)[161], regardless of actual distribution, would also be subject to this definition.

[161] U.S. Environmental Protection Agency. 2013. "Learn about FOIA." Reports and Assessments. US EPA. October 21, 2013. https://www.epa.gov/foia/learn-about-foia.

The FOIA system at EPA and other federal agencies is widely known to be dysfunctional and slow, with thousands of pending requests in the backlog each year[162], and a number of major flaws arise from EPA's proposed definition of "publicly available" in the context of FOIA.

First, it is not clear that EPA would itself be the custodian of "data and models" subject to this rule, nor how EPA would ensure sufficient data security, integrity, and sharing mechanisms.

Second, it is not clear how members of the public could access "information legally available from government sources" given the volume and complexity of the underlying "data and models" that fall under the scope of this proposal. Would members of the public be expected to identify specific studies for release under FOIA? How would EPA evaluate such requests?

It is likely that, upon receipt of such a request, EPA would need to contact and potentially negotiate a public data release with study researchers and actual study participants, in the case of research analyzing human exposures and health responses. It is far from clear that such a FOIA request could be fulfilled by EPA, given existing legal restrictions on data sharing that are characteristic of many studies involving human subjects. Additionally, EPA's own interpretation states that FOIA "does not require agencies responding to requests to conduct research or analyze data."[163]

Moreover, EPA has not explained how its supplemental proposal would affect the existing FOIA activities at the agency, despite the potential for major disruption of the process if members of the public are expected to use FOIA requests in order to obtain "information legally available from government sources" as it pertains to this proposal. EPA has not described any modification of the online FOIA request and response system to accommodate a significant volume of requests for all "data and models" underlying specific scientific studies.

The proposal notes that EPA "does not intend to make all data and models underlying pivotal regulatory science and pivotal science publicly available," but it is not clear how EPA could justify making only a sample of "all data and models" available to the public. There is a significant potential that EPA could selectively release only specific types of studies to members of the public, including biased handling of data and models involving confidential business information (CBI). CBI is already protected from release under FOIA.

In the proposal, EPA notes that "Proposed 40 CFR 30.5 would allow Agency consideration of studies where there is tiered access to data and models that have CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects. For all other studies, data and models should be publicly available if the studies are to be used as pivotal regulatory science or pivotal science."

[162] U.S. Environmental Protection Agency, OGC. 2020. "EPA FOIA Annual Report for 2019." Reports and Assessments. US EPA. District of Columbia. February 27, 2020. https://www.epa.gov/foia/epa-foia-annual-report-2019.
[163] U.S. Environmental Protection Agency. 2013. "Learn about FOIA." Reports and Assessments. US EPA. October 21, 2013. https://www.epa.gov/foia/learn-about-foia.

This description of a tiered access system is vague in not defining a "sufficient" level of de-identification. EPA has not submitted any specific plan for such a determination to be made, nor has any independent group evaluated such an approach. The proposal does not sufficiently explain how such a process would avoid biased handling of data and models at EPA.

In 2019, EPA finalized an update to its Freedom of Information Act Regulations.[164] Under this rule, the administrator and other officials are allowed to review all materials that fit a FOIA request criteria and can decide "whether to release or withhold a record or a portion of a record on the basis of responsiveness or under one or more exemptions under the FOIA, and to issue 'no records'' responses."

Given the vague language in this proposal and existing FOIA regulations at EPA, there is a significant potential for political interference and arbitrary determinations within EPA for public release of data and models.[165]

For example, the Office of Pesticide Programs routinely relies heavily, and often exclusively on industry-sponsored toxicity studies submitted by the pesticide registrants to support product approvals.

The EPA risk assessments and supporting documents provide short summaries of the study data. Through a FOIA request, the public including NRDC can obtain longer study summaries - usually in the 8 to 30 page range - though this can often take a few weeks or more and is almost always beyond the deadline for submitting comments. Obtaining the full studies - which frequently number several hundred pages or more - requires a request through FOIA, and an additional document to affirm non-multinational status (not a competing company[166]).

Because the full studies are so lengthy, FOIA can also require substantial per-page fees levied on the public, unless an additional request for a fee waiver is submitted by the public and approved by EPA. Such a fee waiver must meet strict criteria, including that, "disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii); *see also* 40 C.F.R. §2.107(l)(1).

In fact, a 2014 report of the Office of the Inspector General identified this criteria as the single reason for roughly half of all fee waiver denials, noting that, "the DOJ's Guide to the Freedom of Information Act (2009) states that "[r]equesters who make no showing of how the information would be disseminated, other than through passively making it available to anyone

[164] U.S. Environmental Protection Agency. 2019. "Freedom of Information Act Regulations Update." https://www.govinfo.gov/content/pkg/FR-2019-06-26/pdf/2019-13290.pdf.
[165] Green, Miranda. 2019. "New EPA Rule Could Expand Number of Trump Officials Weighing in on FOIA Requests." Text. TheHill. June 25, 2019. https://thehill.com/policy/energy-environment/450169-new-epa-rule-would-allow-more-administration-officials-to-weigh-in-on-foia-requests.
[166] U.S. Environmental Protection Agency. 2014. "Limitations on Disclosure of Information under Pesticide Law." Reports and Assessments. US EPA. June 26, 2014. https://www.epa.gov/foia/limitations-disclosure-information-under-pesticide-law.

who might seek access to it, do not meet the burden of demonstrating with particularity that the information will be communicated to the public."[167]

The same report[168] shows that the overwhelming majority of the denials in this category are for "others', that are not members of the news media, education outlets, scientific organizations or commercial entities. Individual members of the public - including many people that may be harmed by pesticides but have no means of disseminating information other than through 'passively making it available', will presumably be denied a fee-waiver. In short, FOIA, is not a means for public transparency in many cases and is never timely.[169]

EPA's recent decision documents for the bee-killing neurotoxic neonicotinoid pesticides is a typical example of the failure of FOIA to provide a reliable and timely avenue to transparency. As detailed in NRDC comments to the EPA (May 2020)[170] EPA's January 2020 neonicotinoid pesticide Proposed Interim Decision (PID)[171] dockets are incomplete because they are missing full documentary support for models and scientific studies relied upon in the neonic risk assessments. In short, it is impossible for the public to fully evaluate and critique EPA's PIDs because of the absence of important information from the public dockets, including data, study results, and models.

Although most of the models that EPA relies upon are briefly described in docketed documents, they are not fully documented with detailed information on their structure or inputs in a way that would allow the public to critically examine them. For example, EPA apparently changed modeling parameters for its aquatic risk assessment in response to public comments. See Imidacloprid PID at 13 (EPA-HQ-OPP-2008-0844); Clothianidin and Thiamethoxam PID at 15-16 (EPA-HQ-OPP-2011-0865).[172]

However, the resulting Comparative Aquatic Risk Assessments not only fails to adequately explain EPA's risk conclusions for aquatic life, but the revised model is not available for public review. See generally Comparative Aquatic RA. Similarly, the Agency discusses and

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[167] EPA OIG. 2014. No Indications of Bias Found in a Sample of Freedom of Information Act Fee Waiver Decisions But the EPA Could Improve Its Process. Office of the Inspector General. Report No. 14-P-0319 July 16, 2014. p. 11-12. Available at: https://nsarchive2.gwu.edu//news/20150205/docs/2014-Jul-16-Inspector-General-Report-No-Indications-of-Bias-Found-in-a-Sample-of-Freedom-of-Information-Act-Fee-Waiver-Decisions-But-the-EPA-Could-Improve-Its-Process.pdf

[168] Ibid, p. 13, Table 6.

[169] Mervis, Jeffrey. 2020. "Critics Say EPA's 'Transparency' Rules Would Favor Industry." Science 368 (6490): 458–458. https://doi.org/10.1126/science.368.6490.458.

[170] See NRDC Comments on the Proposed Interim Registration Review Decisions for the Neonicotinoid Insecticide Class. May 4, 2020. These comments were submitted to the following dockets: And, in the following dockets: Imidacloprid (EPA-HQ-OPP-2008-0844); Thiamethoxam (EPA-HQ-OPP-2011-0581); Clothianidin (EPA-HQ-OPP-2011-0865); Acetamiprid (EPA-HQ-OPP-2012-0329); Dinotefuran (EPA-HQ-OPP-2011-0920)

[171] U.S. Environmental Protection Agency. 2013. "EPA Actions to Protect Pollinators." Overviews and Factsheets. US EPA. September 3, 2013. https://www.epa.gov/pollinator-protection/epa-actions-protect-pollinators.

[172] All of the January 2020 Proposed Interim Registration Review Decisions for Neonicotinoids are on EPA's webpage here https://www.epa.gov/pollinator-protection/proposed-interim-registration-review-decision-neonicotinoids
And, in the following dockets: Imidacloprid (EPA-HQ-OPP-2008-0844); Thiamethoxam (EPA-HQ-OPP-2011-0581); Clothianidin (EPA-HQ-OPP-2011-0865); Acetamiprid (EPA-HQ-OPP-2012-0329); Dinotefuran (EPA-HQ-OPP-2011-0920)

relies upon dozens of scientific studies, many submitted by the registrant, which are merely summarized in the documents contained in the dockets. The reports of the studies along with full supporting documentation are not included in the dockets.

In another example, the neonicotinoids ornamental benefits assessment prepared by AgInformatics on behalf of registrants is not in the online docket. While this docket is allegedly in the public reading room, social distancing measures in response to the COVID-19 pandemic largely prevent the public from accessing these and other documents available only for in-person inspection. Indeed, the reading room was closed on March 31, 2020.

To the extent that studies and models relied upon by registrants to support continued registration and tolerances for neonics have not been supported by full documentation in the neonicotinoid PID dockets. As a result, it is difficult or impossible to view the data underlying EPA's risk determinations except through FOIA, per-page fees or obtaining a fee waiver if eligible, and substantial delays taking it outside of the comment period. This has deprived NRDC and the public of a full and fair opportunity to comment on these issues.

In a policy article in Science magazine on the problems with this Rule related to FOIA, the article quotes the Federation of American Scientists, Director of Project on Government Secrecy, Steve Aftergood, who warns, "To say that something is FOIA-able is actually admitting that it is not publicly available … if it were, a FOIA request would be redundant," adding that he files FOIA requests "on an almost daily basis".[173] FOIA is not working as an effective means for public transparency, for the Federation of American Scientists.

The above examples represent just a fraction of the reasons why FOIA is not a reasonable tool for making data publicly available. Use of such a data release mechanism cannot ensure equitable access, could involve significant costs and would complicate the existing fee waiver system due to an anticipated surge in FOIA requests for underlying data and models used in pivotal regulatory science. There are significant and insurmountable hurdles involving long processing times and comparatively short public comment periods for EPA regulatory proposals, the significant burden of existing FOIA backlog on agency staff, and the ways in which the FOIA approach is ill-suited to provide the type of information EPA seeks to release through the mechanism in the proposed rule.

VI. EPA does not provide rationale or criteria for giving more consideration to specific studies

In the Supplemental Proposal, EPA proposes that "under proposed 40 CFR 30.5, when promulgating significant regulatory decisions or finalizing influential scientific information, other things being equal, the Agency will give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because they are publicly available or because they are available through tiered access when the

[173] Mervis, Jeffrey, 2020, and 2:55 Pm. 2020. "If You Have to Ask EPA for Data, Are They Really Public? Agency Critics Say No." Science | AAAS. April 3, 2020. https://www.sciencemag.org/news/2020/04/if-you-have-ask-epa-data-it-really-public-agency-critics-say-no.

data includes CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects."

A. Tiered access plan not adequately explained within EPA context

Within the Supplemental Proposal, EPA describes a "model" of a tiered access data approach as the Research Data Center (RDC), National Center for Health Statistics (NCHS), Centers for Disease Control (CDC). The Supplemental Proposal notes that "The NCHS operates the RDC to allow researchers access to restricted-use data. The RDC provides access to the restricted-use data while protecting the confidentiality of survey respondents, study subjects, or institutions. For access to the restricted-use data, researchers must submit a research proposal outlining the need for restricted-use data. The submitted research proposal is intended to provide a framework for NCHS to identify potential disclosure risks and how the data will be used (Ref. 15). EPA is currently conducting a pilot study using the RDC's secure data enclave to host EPA datasets in a restricted use environment."

EPA does not grapple with the fact that the RDC restricted-use data is not "publicly available" in that there are multiple barriers to data access. EPA highlights the RDC program as a model but does not explain how such an approach could be workable in the EPA context, nor does it explain the criteria that must be spelled out in a research proposal as a prerequisite for obtaining access to the data. EPA apparently is planning to rely on CDC to fulfill major data management responsibilities made necessary in the Supplemental Proposal (see section XIII.B), but has not made that clear within the text of the Supplemental Proposal.

Moreover, EPA does not explain why the RDC approach would work in the EPA context and the wide scope of scientific data and models that would be subject to new public data release requirements under the Proposed Rule.

EPA notes in the Supplemental Proposal that development of standard data repositories is "ongoing" but does not explain why EPA should, at this point in time, introduce burdensome new public data release requirements at a time when such repositories have not demonstrated the ability to handle such a massive influx of data and models in a way that actually improves public access to data in a meaningful way.

Moreover, EPA expects that "[i]nformation received during this public comment period will, among other things, help inform improved guidance and best practices related to preserving and providing access to data." It is inappropriate for EPA to use the public comment period to illuminate issues that the Agency itself should have clarified within the original Proposal and Supplemental Proposal. It is clear that EPA has not adequately planned for the major complications to science activities imposed by the Supplemental Proposal, because EPA is seeking the public to resolve fundamental implementation issues through the public comment period. Given these clear deficiencies, the Supplemental Proposal should be withdrawn.

B. Unclear how "greater consideration" will be given

EPA does not adequately describe the process by which "greater consideration" will be given to specific studies, and whether the characteristics of specific studies (e.g., sample size, confidence intervals of results, or overall methods validity) may compensate for any lack of full data transparency.

For example, the agency typically considers thousands of studies in compiling integrated science assessments as part of the Clean Air Act National Ambient Air Quality Standards.[174] Each of these studies may satisfy the new data requirements proposed in the rule to differing degrees, and it is not clear whether or not any agency-perceived shortcomings in meeting these data requirements may be compensated by other criteria that help EPA to determine the overall degree of study quality. This failure to address an important part of the process is further evidence that the Supplemental Proposal is arbitrary and capricious, an abuse of discretion, and otherwise unlawful.

C. Potential for bias in making determinations about study quality

The potential for dangerous bias with adverse impacts on achieving quality scientific input at EPA is large. For example, it may be relatively less burdensome for small epidemiologic studies with limited numbers of study participants to meet data release requirements-- but the results of such studies are generally less reliable and include the potential for more random error and larger confidence intervals than cohort studies that span larger population groups. The proposal threatens to bias agency decision making towards smaller studies and anecdotal case reports rather than robust scientific information provided in larger epidemiologic cohort studies.

The supplemental proposal "would apply to reviews of data, models, and studies at the time a rule is developed or influential scientific information is finalized, regardless of when the data and models were generated." This requirement raises numerous serious implementation issues.

Many scientific interpretation activities at EPA, including legally-mandated reviews of the National Ambient Air Quality Standards, are projects that build upon a growing scientific evidence base. For example, the recently-completed Integrated Science Assessment[175] and Policy Assessment[176] for Fine Particulate Matter rely on scientific data and models and other information previously synthesized by the agency for prior reviews. In this case, the agency is consulting thousands of peer-reviewed studies that already meet significant requirements established by EPA.

[174] U.S. Environmental Protection Agency. (2015, January 29). Integrated Science Assessments (ISAs) [Collections and Lists]. US EPA. https://www.epa.gov/isa

[175] U.S. Environmental Protection Agency. 2015. "Integrated Science Assessments (ISAs)." Collections and Lists. US EPA. January 29, 2015. https://www.epa.gov/isa.

[176] U.S. Environmental Protection Agency. 2019. "Particulate Matter (PM) Standards - Policy Assessments from Current Review." Policies and Guidance. US EPA. September 5, 2019. https://www.epa.gov/naaqs/particulate-matter-pm-standards-policy-assessments-current-review-0.

Any additional requirement that the underlying data and models used in these studies must satisfy, imposed at the time they are reviewed, would introduce a cascade of hugely disruptive, costly, and time consuming implementation problems.

D. No plan for assessing existing body of research

For example, agency staff would need to conduct large information gathering assessments to determine the degree to which any study previously considered by the agency in science reviews met the new requirements-- itself a huge task, given that each study would have to be assessed individually. It would be unreasonable at this stage in the process for the agency not to contact the study authors and inform them of the new data requirements in place at EPA.

Such communications will need to be comprehensively documented and coordinated for agency use and public reference. In many cases, it will be difficult to contact the primary study author, since in some cases years (or decades) have elapsed since study publication. Would additional authors be contacted in this case? What if, upon communication of the new requirements, there arises disagreement amongst the study authors, study funders, or academic institutions about how and whether to make all underlying data available for public inspection? This question is not answered in the supplemental proposal.

Moreover, in the case of epidemiologic cohort studies, will study participants be notified of the new requirements? Researchers may not have retained contact information for study participants, in which case it is not clear how consent will be given for release of sensitive information (even if partially masked or aggregated). 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) and the requirements researchers adhere to under the purview of Institutional Review Boards (IRBs) which typically require investigators to ensure study 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.

E. Lack of consideration for implications of Supplemental Proposal on future research involving human subjects

Importantly, the Supplemental 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 Supplemental 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.

F. EPA's proposal to use the availability of a study's data to give "greater consideration" to certain studies has no empirical basis

EPA's "Option 2" for revisions to § 30.5 proposes to consider studies differently based on the availability of the study's data. This proposal has no scientific basis as availability of data has not been empirically shown to affect the quality or validity of a study. EPA should use validated, demonstrated, peer-reviewed metrics and tools to evaluate studies and use all relevant data to inform science-based decisions.

Specifically, the Agency proposes to give "greater consideration" to studies:

> "where the underlying data and models are publicly available in a manner sufficient for independent validation" and
>
> "based on data and models that include confidential business information, proprietary information or personally identifiable information if these data and models were available through restricted access, such as through a secure data enclave, in a manner sufficient for independent validation."[177]

As public availability of data or access to data have not been identified in the scientific literature as factors that have any bearing on the quality or validity of science, these criteria should not be used by EPA to give greater consideration to particular studies.

Key considerations for evaluating individual studies come from decades of research systematic review methods in the clinical and environmental health sciences. Systematic review methods are used to evaluate the effectiveness of clinical interventions in medicine and related disciplines that inform decision-making in healthcare, saving lives and money.[178] These empirically-proven methods for research synthesis have been adapted to environmental health.[179]

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[177] 85 FR 15396 (pg 15405)

[178] Rennie D, Chalmers I. Assessing authority. JAMA. 2009;301(17):1819-21. Epub 2009/05/07. doi: 301/17/1819 [pii]10.1001/jama.2009.559. PubMed PMID: 19417202.
Fox DM. The Convergence of Science and Governance: Research, Health Policy, and American States. Berkeley, CA: University of California Press; 2010.
Antman EM, Lau J, Kupelnick B, Mosteller F, Chalmers TC. A comparison of results of meta-analyses of randomized control trials and recommendations of clinical experts. Treatments for myocardial infarction. JAMA. 1992;268(2):240-8. Epub 1992/07/08. PubMed PMID: 1535110.

[179] Woodruff TJ, Sutton P, The Navigation Guide Work Group. An Evidence-Based Medicine Methodology To Bridge The Gap Between Clinical And Environmental Health Sciences. Health Affairs. 2011;30(5):931-7. doi: 10.1377/hlthaff.2010.1219; PMCID: 21555477.
Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. Environmental Health Perspectives. 2014;122(10):A283

To date, science-based methods for systematic review in environmental health have been demonstrated in case studies in the peer-reviewed literature, and adopted by the National Toxicology Program[180] and the U.S. EPA's Integrated Risk Information System (IRIS) program.[181]

The Institute of Medicine notes that it is critical to "assess the strengths and limitations of the evidence so that decision makers can judge whether the data and results of the included studies are valid,"[182] and developed standards for assessing the validity and relevance of individual studies with the following required elements:

- Systematically assess the risk of bias, using predefined criteria
- Assess the relevance of the study's populations, interventions, and outcome measures
- Assess the fidelity of the implementation of interventions[183]

The predefined criteria to assess risk of bias focus on elements of studies (design, conduct and analysis) that have been demonstrated to lead to bias in the study results, affecting the validity of the study conclusions. Risk of bias criteria have been developed for different types of studies (randomized controlled trials, observational studies, etc.) by authoritative organizations including Cochrane[l][184] the U.S. Preventive Services Task Force.[185] the U.S. Agency for Healthcare Research and Quality[186] and the U.S. National Toxicology Program.[187] Examples of elements to consider in risk of bias are below in Table 2; none of the existing, validated empirically-based systematic review methods has identified public availability or access to data as a factor that affects study validity or quality.

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[180] National Toxicology Program. Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration. In: U.S. Department of Health and Human Services, editor.: Office of Health Assessment and Translation, Division of National Toxicology Program, National Institute of Environmental Health Sciences; 2015.

[181] National Academies of Sciences, Engineering, and, Medicine. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, D.C.: The National Academies Press; 2018

[182] Institute of Medicine. (2011). Finding What Works in Health Care. National Academies Press. https://doi.org/10.17226/13059 pg. 123

[183] Institute of Medicine. (2011). Finding What Works in Health Care. National Academies Press. https://doi.org/10.17226/13059 pg. 137

[184] Sterne, J. A. C., Savović, J., Page, M. J., Elbers, R. G., Blencowe, N. S., Boutron, I., Cates, C. J., Cheng, H. Y., Corbett, M. S., Eldridge, S. M., Emberson, J. R., Hernán, M. A., Hopewell, S., Hróbjartsson, A., Junqueira, D. R., Jüni, P., Kirkham, J. J., Lasserson, T., Li, T., … Higgins, J. P. T. (2019). RoB 2: A revised tool for assessing risk of bias in randomised trials. The BMJ, 366, 1–8. https://doi.org/10.1136/bmj.l4898

[185] U.S Preventive Services Task Force (2015) Procedure Manual. Appendix VI. Criteria for assessing internal validity of individual studies. Available: https://www.uspreventiveservicestaskforce.org/uspstf/procedure-manual

[186] Viswanathan M, Patnode C, Berkman ND, Bass EB, Chang S, Hartling L, Murad HM, Treadwell JR, Kane RL. Assessing the Risk of Bias in Systematic Reviews of Health Care Interventions. Methods Guide for Comparative Effectiveness Reviews. (Prepared by the Scientific Resource Center under Contract No. 290-2012-0004-C). AHRQ Publication No. 17(18)-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality; December 2017. Posted final reports are located on the Effective Health Care Program search page. DOI: https://doi.org/10.23970/AHRQEPCMETHGUIDE2.

[187] National Toxicology Program. Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration. In: U.S. Department of Health and Human Services, editor.: Office of Health Assessment and Translation, Division of National Toxicology Program, National Institute of Environmental Health Sciences; 2015.

Table 2: Examples of required elements to consider for risk of bias evaluation of individual studies of different types. Public availability or access to data is not included for any type of study.

Cochrane	U.S. Preventive Services Task Force	U.S. National Toxicology Program
For randomized trials Randomization Deviations from intended interventions Missing outcome data Measurement of the outcome Selection of the reported result	For case control studies Accurate ascertainment of cases Unbiased selection of cases/controls, with exclusion criteria applied equally to both Response rate Diagnostic testing procedures applied equally to each group Measurement of exposure accurate and applied equally to each group Appropriate attention to potential confounding variables	For animal studies Selection Confounding Performance Attrition Detection Selective reporting

The body of evidence supporting systematic review methods is extensive and deep; EPA's proposal to use public data availability and access as a factor to give greater consideration to studies flies in the face of more than 40 years of scientific research and has no scientific support or precedent.

Because the proposal has no scientific basis, there is also no evidence-based approach to answer EPA's request for comment on how much consideration should be given to studies when there is limited or no access to the underlying data and models.[188] Any scheme that assigns different scores or weights to studies based on data availability would be arbitrary in nature, and moreover, EPA has not detailed such an approach in the Supplemental Proposal.

EPA should suspend this rulemaking in its entirety and use a validated, demonstrated approach based on empirical evidence to assessing science and making decisions such as systematic review methods recommended by the Institute of Medicine and National Academies of Sciences.

In the proposal, EPA expects to "give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because they are publicly available or because they are available through tiered access when the

[188] 85 FR 15396.

data includes CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects."

However, because the agency relies on scientific studies across a range of disciplines and for a range of activities (including, for example, regulatory impact assessments of proposed rules and integrated science assessments through the National Ambient Air Quality Standards), it is not clear how such variations in weight given to specific studies would actually be implemented.

Under the alternative approach in this supplemental proposal, EPA "would consider using all available high-quality studies but give greater consideration to those studies with data available for independent validation." Problematically, EPA has not defined "greater consideration" within the Supplemental Proposal, and not clarified whether making data "available" for independent validation is sufficient for such increased consideration, or whether such independent validation must have actually occurred prior to the EPA making such a decision.

Later on in the proposal, EPA says the agency "will identify those studies that are given greater consideration and will provide a short description of why greater consideration was given." EPA has not defined what "grater consideration" means in different contexts, and it has not clarified whether such a determination on degree of consideration would apply consistently across all EPA staff, science advisors, and subject matter areas relevant to EPA work.

Given the potential for such a decision on a single study to affect its application across a range of different agency activities (see Table 1), a "short description" is not nearly sufficient transparency from the agency in describing such a significant decision with potentially far reaching and long lasting consequences.

EPA does not explain what information could be included in such a "short description," nor how the agency would assess and confirm public availability or verify that data and models underlying pivotal science studies remained "publicly available" into the future. Furthermore, EPA does not clarify when such a description would be drafted or finalized by the agency within the context of its rulemaking responsibilities.

It is not clear whether such a description would be included in a central science data clearinghouse and potentially revisited and revised over time, or whether it would necessarily be included in individual science products published by EPA and potentially remain static. Moreover, it is not clear how EPA would explain and document its deliberations and decision-making around the waiver process in a way that accounts for the complexity of any endeavor to make all "data and models" underlying key scientific information publicly available.

The alternative approach offered in the Supplemental Proposal compounds, rather than the problems with weighing of studies in the original Proposal. Further, in both the Proposal and the Supplemental Proposal, the rationales for giving more consideration to certain studies over others entirely fail to grapple with the foundational fact that they, by their terms, run afoul of the various statutory mandates that the Agency is bound by. For these and all of the reasons noted

throughout this section, EPA's Supplemental Proposal is arbitrary, capricious, and an abuse of discretion. It must be withdrawn.

VII. EPA did not seek appropriate SAB consultation for the Supplemental Proposal

In a major deviation from standard process under the Environmental Research, Development and Demonstration Authorization Act (ERDDAA) of 1978, EPA did not seek consultation from the SAB on the full 2018 rule proposal or supplement. The supplement does not address numerous critical issues identified by the SAB including:

- the purpose of the rule;
- the costs and resources required to implement the proposal;
- the recommendation that application should not be retroactive;
- the need for tailored approaches to different types of data;
- and the protection of confidential business information (CBI) and personally identifying information (PII).

EPA did not consult with the SAB prior to publication of the original rule in 2018 nor the current supplement, despite the SAB's urging in June 2018 that EPA "request, receive, and review scientific advice from the SAB before revising the proposed rule."[189] This failure to consult is emblematic of a larger disregard for SAB input at EPA.[190]

To date, EPA has only asked the SAB for input on one issue related to this proposal-existing mechanisms for secure access to CBI and PII. Further, even on this narrow issue, EPA did not seek a consensus report but instead asked only for individual comments from members.[191]

Because of the significant scientific and technical issues raised in the rule, in June 2019 SAB identified the rule as a planned action that merited its review and elected to review the full proposed rule beyond EPA's narrow request on CBI and PII.[192]

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[189] EPA SAB (2019) Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science. EPA-SAB-18-003. Available: https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf

[190] Rice, Mary B., Thomas A. Burke, Deborah L. Swackhamer, and Jonathan M. Samet. 2020. "Threats to Science Advising at the Environmental Protection Agency." Annals of the American Thoracic Society 17 (3): 267–70. https://doi.org/10.1513/AnnalsATS.201909-724PS.

[191] EPA SAB (2019) Consultation on Mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) under the proposed rule Strengthening Transparency in Regulatory Science. EPA-SAB-19-005. Available: https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentBOARD/41042C652229CA398525848500595458/$File/EPA-SAB-19-005.pdf

[192] EPA SAB (2018) Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science. EPA-SAB-18-003. Available: https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf

Overall, EPA's SAB consultation on the transparency proposal and supplement is notable in its departure from standard ERDDAA process in that:

- EPA did not request SAB review of the full original rule proposal or supplement; and
- EPA did not request a consensus SAB review.

In response to its request for consultation on existing mechanisms for secure access to CBI and PII, EPA received comments from 22 individual SAB members in Sept 2019. Of these, seven (30%) noted serious concerns with this process:

> "An important policy such as this deserves more complete and explicit development of the proposed rule and its implementation by the EPA in written documentation available for public comment and should have complete consensus review by the SAB prior to the EPA taking further actions." - Hugh Barton

> "The information provided by U.S. EPA is insufficient for me to provide a complete answer… In addition, by narrowly focusing on the tiered approach in the charge question, other relevant considerations to the use of PII were not presented." -Barbara Beck

> "I think that avoiding the SAB in promulgating this rule was a serious mistake. In his comments during our last meeting in Washington, Administrator Wheeler suggested that he wanted to restart appropriate engagement with SAB as a step forward to work together. This rule was promulgated in such a way to leave SAB out of the consideration. I believe that a sound rule to improve transparency could be accomplished if EPA would dedicate to following Administrator Wheeler's offer to rebuild the appropriate relationship with this proposed rule." - Joseph Gardella

> "If the EPA wanted the SAB to provide substantive input to help address the current short comings then EPA should have requested a full review with an expert panel and not a consultation. One can only speculate that the Administrator and his representatives deliberately did not complete the required analysis of the implications or request substantive input from the SAB to avoid providing clarity about the rule and its implications." - Steven Hamburg

> "As explained in the Chartered SAB's April 25, 2019 memorandum on EPA's Planned Agency Actions and their Supporting Science in the Spring 2018 Regulatory Agenda, a consensus view was reached by the SAB in May 2018 concluding that this proposed rule warranted a full SAB review. This position was reiterated in a June 19, 2018 letter from SAB to the Administrator highlighting both the broad implications of the proposed rule on EPA's foundational policies related to the use of science in rulemaking and policy development and the essential need for a formal, deliberate review by relevant experts to logically inform a final regulation. The SAB's views were reinforced by a number of the public comments received on this proposed rule at the last SAB meeting held on August 27, 2019. The present consultation process is both limited in scope and in the relevant expertise that is available via the Charted SAB members for addressing the broad science challenges posed. Therefore, I would urge that the Administrator give

serious consideration to a more transparent evaluation of the science challenges that underpin the proposed rule by either constituting a dedicated SAB panel or supporting a focused National Academy of Sciences study. The output obtained from either of these options would in my view provide not only critical input prior to final rule-making but also promote public confidence in the regulatory outcome." - Thomas Parkerton

"My answer to both charge questions is that I do not feel that I have enough information to be able to formulate a specific response. The consultation asked of the SAB and charge questions seem to be a situation of 'putting the cart before the horse' which became very clear during the public meeting held on August 27, 2019… If the SAB could have a more thorough report as is typically done, it would likely lead to answers to these questions that are grounded in science and a foundational information base." - Tara Sabo-Attwood

"To directly reply to the charge questions out before us could be construed as the SAB having been consulted and then providing input on the proposed Science and Transparency rule, when in fact we have not been consulted on the core matters surrounding this proposed rule. Moreover, the process we are being asked to participate in represents a departure from the traditional practice of producing a consensus SAB statement." - Mark Wiesner

These comments raise significant concerns about the consultation process for the original proposal, yet EPA made no changes in the process with this supplement. EPA has not requested SAB review on the supplement.

Further, the SAB's reports, received by EPA in September 2019[193] and October 2019, identified critical issues which the supplemental proposal does not address.

VIII. EPA has not clarified the purpose of the rule and how its proposal will create improvements

The SAB's draft report notes that "In general, the SAB finds that the EPA has not fully identified the problem to be addressed by the Proposed Rule."[194] The supplement does not provide any additional problem statements, data or information describing the issue to be addressed or its current scope. Likewise, the supplement does not address how, and to what extent, the actions proposed will result in improvements. The supplement does not address these issues, and other related issues, raised in the SAB's draft report and individual member's comments to the Agency:

[193] EPA Science Advisory Board letter to Administrator Wheeler. 9AD. "Consultation on Mechanisms for Secure Access to Personally Identifying Information (PII) and Confidential Business Information (CBI) Under the Proposed Rule, Strengthening Transparency in Regulatory Science." https://yosemite.epa.gov/sab/sabproduct.nsf/41042C652229CA398525848500595458/$File/EPA-SAB-19-005.pdf.

[194] EPA SAB (2019) Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science (June 28, 2018). EPA-SAB-18-003. Pg. 6. https://yosemite.epa.gov/sab/sabproduct.nsf/cf0020ec3f99320a85256eb4006b6bd1/4ecb44ca28936083852582bb004ade54/$FILE/EPA-SAB-18-003%20Unsigned.pdf

"The lack of reference to and comparison with existing and evolving federal procedures to address the underlying purpose of the Proposed Regulation (increased transparency) within scientific studies supported and utilized by the federal government undermines the confidence that the proposed regulation will meet its objectives effectively and efficiently… The EPA's proposed policy of excluding from consideration any study for which underlying data are not made publicly available is not consistent with sound scientific practice. The EPA, the U.S. Office of Management and Budget, and scientific institutions have recognized…that such constraints on availability of data do not prevent studies from being validated in other ways - much less require that the studies be ignored in regulatory decisions." (draft report pp.16)

"There is no justification in the Proposed Rule for why EPA finds that existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate, and how the Proposed Rule will improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner." (draft report pg. 17)

"The SAB is concerned that the net effect of the proposed rule could be to inappropriately limit the science used by EPA and rigor of decision-making - impeding EPA's ability to protect the public. Evidence to support this concern has been presented by the editors of scientific journals and the Congressional Budget Office." (draft report pg.23-24)

"EPA's proposed transparency rule acknowledges the need to respect legal requirements and confidentiality, but I am concerned that that the intent is that studies subject to such restrictions will be excluded entirely, not exempted from the requirements. This will result in the exclusion of scientific studies that are potentially significant for rule making and that contain important scientific results. This could lead to de facto attempts to engineer particular conclusions by arbitrarily eliminating studies from consideration. Because I cannot support any type of confirmation bias I cannot support the proposed rule as it stands." -Joseph Gardella

"The proposed rule would limit the scientific information that EPA would be allowed to take into consideration in the regulatory process with potentially harmful implications for public health."- Mark Wiesner

As the SAB notes, it is highly problematic that, two years since the original Proposed Rule, EPA has not identified any reasons to introduce such drastic changes to the Agency's science activities through the Supplemental Proposal. Given the lack of any convincing rationale, EPA's Supplemental Proposal is arbitrary and should be immediately withdrawn.

IX. EPA has not addressed the significant costs and resources required to implement the rule

The SAB's draft report notes multiple times that for non-industry researchers, significant time and monetary resources would be needed to ensure their data meet the requirements of the rule. SAB recommends that EPA consult with library science and data management experts, as well as consider establishing a data sharing office to assist with rule implementation. The

supplemental proposal makes no mention of cost or resource issues, leaving the SAB's concerns of unreasonable burdens on researchers, and subsequent exclusion of their data, unaddressed:

"There will be costs associated with assessing and disseminating data as required by the Proposed Rule. The agency should consider seeking input from experts in library science, data curation, management and data retention to identify best practices and tools to ensure efficiency and utility of data that are made available." (draft report pg. 3)

"EPA should… discuss the level of effort required by the generator of the data to assist EPA in complying with this proposed mandate." (draft report pg. 9)

"The SAB suggests that EPA consider establishing an office (or virtual office) on data sharing. This group could identify standard data formats (data templates?), how to report methods/procedures used, uncertainty, when and how to implement greater data protections for PII/CBI, etc. It would be beneficial to build experience and expertise in a group charged to meet this goal. This office could work directly with laboratories/researchers to provide the necessary information in a "user friendly" format. This office also could build and manage data archives and pursue critical historical data sets if deemed important. There will be costs associated with the establishment of such an office as well as researchers' time to collate raw data and work with EPA to make these data publicly available. It is unclear how the EPA will manage these additional costs." (draft report pg. 14)

"Time and cost associated with formatting, curating and sharing raw data also may pose difficulties for laboratories." (draft report pg. 17)

"Additionally, the labor involved in resorting and recalculating the information from available raw data might be too time-consuming and cumbersome to be reasonable." (draft report pg. 18)

"I would include a comment as to the enormous cost and extended timeline implied by this rule change, an issue I feel has not been fully addressed, and which argues for limiting this rule's applicability to future studies… A further significant consideration is the financial burden on the research agencies. This rule would ask universities and institutes (some outside the U.S.) to find new funding for finished projects, long after the grants or institutional support has expired. This is a classic example of an unfunded mandate, where the burden is placed on a (usually) non-profit organization to provide funding so that the EPA can continue to meet their regulatory responsibilities. Even if the EPA provides a simple and efficient method for embedding raw study data into a public-facing repository, a significant burden will be placed on the research organizations to bring their data up to this threshold due to issues of media recovery and conversion, reformatting, quality control and a need to provide continuous support for the data, once embedded (as surely the repository will require the submitting organization to provide a contact to answer questions about the data).

Absent some (as yet unmentioned) commitment by the EPA to fund such costs, it is ridiculous to assume that most of these organizations will willingly shoulder this significant financial burden. Even if they do, they will have to shift funding from ongoing, vital new

research to fund this activity, at the net negative cost to the nation's health. A cynical observer might suggest that, absent EPA funding support for participants, only organizations producing results favorable to deep-pocketed industrial concerns will easily find funding to participate, which could be an underlying raison d'etre for the rule" -Robert Merritt

EPA did not consult with data management or library science experts, and in fact to date has not engaged with the research, scientific or medical community for input on the rule or supplement.

In recent briefings, EPA confirmed the SAB's concerns about an unmanageable workload for researchers triggered by the poorly conceived mechanisms partially outlined in the Supplemental Proposal (see section XIII.A). This major failure of EPA to describe the significant impacts of its plans on stakeholders outside of the Agency is unacceptable and the Supplemental Proposal should be withdrawn.

X. EPA has not addressed critical concerns with retrospective application and data handling in the Supplemental Proposal

A. Overarching concerns

The SAB raises multiple issues regarding data that would be subject to a retroactive application of the proposal, including lack of data retention, costs, informed consent agreements and peer review standards. The sheer scope of these problems led the SAB to conclude that "The Proposed Rule should be explicitly prospective and follow evolving norms developed by the scientific community as well as federal agencies (National Science Foundation, National Institutes of Health, National Oceanic and Atmospheric Administration)."[195]

"Historical data sets might not be available at the level of detail needed for recalculation. Some of the raw data or computational methods may have been discarded if they were deemed not necessary to maintain. Certainly IRB applications usually indicate when individual records can be discarded." (draft report pg. 14)

"The SAB notes that the retrospective application of modern transparency standards is a challenge. A large amount of work would be required to locate, curate and retrospectively make data sets available for public access. This requirement could adversely affect the ability to move this program forward in a meaningful capacity… Either way retrospective application of the requirement would be difficult to implement, could be expensive with no clear responsibility regarding who would cover the added costs and could impact the conclusions drawn arbitrarily." (draft report pg. 15-16)

"Having said that, epidemiological studies in the past were done with the consent agreements that were used at the time. I am concerned that "Strengthening Transparency" will unreasonably apply a contemporary standard to studies done in the past and inappropriately

[195] EPA SAB (2019) Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science. EPA-SAB-18-003. Pg. 15

make important information unavailable to EPA for regulatory purposes. I am aware of cases where pharmaceutical studies have been substantially impacted by the consent agreements used, leading to changes in agreement wording for future studies. There likely needs to be a similar differentiation of historical studies from future studies for EPA purposes as well." - Hugh Barton pg. 12

"For studies conducted in the past, EPA should rely on the standard of peer review that existed at the time the study was published. It is unrealistic for studies conducted long ago to provide all study data, but that does not make them any less valuable." -Deborah Bennet pg. 18

"However, I remain concerned about access to PII when participants in the study have not agreed to their information being shared with people outside the group of investigators who are conducting the study. I would think that many of the older epidemiology studies would not have considered this option in their Informed Consent Forms—we certainly did not in the ICF's that we developed for our epidemiological studies a few years ago. Certainly the option of PII being released to unknown people in the future would have caused some participants to decline participation. It is now unfair to them to put their PII at risk of disclosure without their knowledge and consent. If the rule only applies to studies going forward, then this possibility could be added to the ICF's, but there is no way to make this possibility retroactive to past studies." – Janice Chambers pg.19

Yet, EPA continues to request comment on a retrospective application of the rule while the supplemental proposal does not address the issues SAB raised.

One important aspect of the retroactivity issue that EPA must consider is that it is not sufficient to apply the policy prospectively to new *agency actions*, because such actions may rely on *scientific products* that pre-date the new policy. An instructive example can be found in the Clean Water Act. That law's framework requires states to review their water quality standards every three years and update them as needed, after which EPA must approve or disapprove proposed changes. Under section 304(a)(1) of the Act, the water quality criteria that state standards include are commonly based on levels EPA determines to be safe enough to support various uses in reliance on available science.[196] As the Act provides:

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 ... 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….

EPA's criteria guidance is -- as the statute provides -- periodically updated, but any new update will be based on then-existing scientific studies (especially if there is no evidence to suggest that those studies should be ignored). Accordingly, EPA may be issuing revised criteria

[196] 33 U.S.C. § 1314(a)(1). State criteria may also be based on "[o]ther scientifically defensible methods." 40 C.F.R. § 131.11

documents and making approval/disapproval decisions on newly-submitted state standards that rely on science products that pre-date this rule for many years into the future. Any final rule must not limit EPA's ability to use these pre-existing studies for new agency actions.[197]

The approach enabled by the Supplemental Proposal to retroactively apply new public data release requirements is arbitrary and the Supplemental Proposal should be withdrawn.

B. EPA has not addressed the need to handle diverse data differently

The SAB comments that exclusion of particular kinds of data that don't meet the rule will bias EPA"s decisions, for example excluding data from laboratories that choose not to make data publicly available or from international studies where researchers are not based in the U.S.[198] These are specific examples of a more general principle noted by SAB- that there is an enormous diversity of data used in EPA decisions that would be subject to this rule, and there is not a one-size-fits-all approach to each of these data types. SAB urges EPA to consider how it could tailor approaches to varied data sets, including using a trusted third party like the Health Effects Institute, Data Use Agreements, certification processes, a data archive accessed with confidentiality agreements and others:

"Extensive work would be required, across a diversity of fields, data types and data of different ages, to understand the implications of adopting different definitions of raw data for the purposes of the Proposed Rule. Such an effort is beyond the scope of what the SAB can undertake with the resources and time available. However, the SAB finds that such an analysis is foundational to development of any transparency rule that goes beyond established norms and procedures." (draft report pg. 4)

"However, the breadth of studies with different designs, sizes of populations, reliance on geographic or other data that can make blinding challenging or impossible, the historical consent agreements that researchers signed, and many other factors make it impossible for a single approach to address all the needs to insure EPA access to the best possible science." -Hugh Barton

"i) WILL owners of independent human data be willing to release some subset of their data to public repositories, even such safe harbor data archives as used by NCHS. Related to this is ii) CAN owners of independent human data legally release these data to public repositories, given IRB and HIPAA requirements for informed consent. For example, a prospective epidemiology study may not have received participant informed consent to release their data in this way. Many key epi studies, such as the ACS second cancer cohort, are not able to go back and get this kind of informed consent since a large fraction of their cohort have either died are no longer are able to provide informed consent due to age-related illness…. Forcing Agency

[197] Thorp, H. Holden, Magdalena Skipper, Veronique Kiermer, May Berenbaum, Deborah Sweet, and Richard Horton. 2019. "Joint Statement on EPA Proposed Rule and Public Availability of Data (2019)." Science 366 (6470): eaba3197. https://doi.org/10.1126/science.aba3197.

[198] EPA SAB (2019) Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science. EPA-SAB-18-003. Pg. 12-13

decisions to be made only on analyses for which supporting data can be made "public," even if such data are within a safe haven archive, could produce biased decisions." - Kenneth Portier

"What alternatives to making data publicly available has the agency considered? An example of an alternative approach is reflected in the HEI [Health Effects Institute] analysis of the Harvard Six- City Study about 20 years ago. The use of expert outside scientists allowed for an independent analysis of the study, while protecting PII. Note that this multi-year and costly re-analysis emphasizes the need for EPA to give more consideration to practical questions of implementation." - Barbara Beck

"Death and birth certificate information is publicly available from organizations such as state departments of health or the National Death Index, and hospital admissions data is available from Medicare. To access this data, researchers sign Data Use Agreements prohibiting them from making public anything other than aggregate data summarizing statistics from large numbers of people.

Other researchers can, and have applied to the same organizations to obtain their own copies of the data, after signing their own Data Use Agreements. This approach could be considered an alternative to publicly available data. Although it is not truly publicly available, other scientists can apply to work with the data and test either the same hypothesis or alternative hypothesis." - Deborah Bennet

"We describe an approach that allows researchers who analyze confidential data to signal the reproducibility of their research. It relies on a certification process conducted by a specialized agency accredited by the confidential-data producers and which can guarantee that the code and the data used by a researcher indeed produce the results reported in a scientific paper." - Samuel Cohen

"EPA should conduct a more detailed evaluation of different de-identification protocols in use in other agencies and in the private sector and determine if such approaches could be practically implemented in supporting this rule. If de-identification is determined to be inadequate for managing disclosure risk for a given pivotal dataset, an interagency government or third-party data archive could be created to collect and manage data specifically used to support "significant regulatory actions." Researchers could access these data for independent evaluation after preparing a research plan and agreeing to confidentiality agreements subject to penalties for violating the agreement." - Thomas Parkerton

"So in summary, if by a "tiered approach" EPA means using the FSRDCs [Federal Statistical Research Data Centers] to allow access by researchers to individual-level datasets held by federal agencies, I believe that could be a viable approach…It does not solve the problem of PII data held by non-federal entities." - Richard Smith

"There are many avenues open beyond simple publication of data that others have mentioned. I will add one. The IRS keeps some of the most sensitive data from being made public but they have still found a way to allow researchers to use their data. Researchers create a model (in this case, use the existing model), come up with a dummy data set with random

numbers to test the model, and the IRS runs the model with actual data. As long as models are made available with a description of the statistics used, EPA or a trusted third party could run the replications so that the underlying private (PII) data would not be made public."- Richard Williams

But the supplemental proposal does propose a single approach for all types of data and EPA did not conduct analysis of how the likely exclusion of specific data types would affect its decisions.

The approach enabled by the Supplemental Proposal to retroactively apply new data handling requirements is arbitrary and the Supplemental Proposal should be withdrawn.

C. EPA does not ensure critical protections for CBI and PII

Finally, the SAB raises important points about the protections needed for CBI and PII beyond simply restricting access through a tiered system. Even if access is restricted, EPA needs to ensure that parties accessing the data (whether EPA staff, EPA consultants, or the public) are legally bound to protect the information, such as through a non-disclosure agreement, data use agreement or the like:

"EPA must also make certain that personally identifying information (PII) and confidential business information (CBI) are not available to persons/groups not properly vetted, approved, and trusted by those owning the CBI information. Without adequate protection, industry data generated by one company can be used by other companies to fulfill regulatory requirements in other geographies." (draft report pg. 7)

"The people or groups processing and handling the data (EPA staff or independent non-EPA consultants) would need to be identified, their credentials and any conflicts of interest with the particular case identified, and documentation secured that they will not reveal confidential information without appropriate permission from the owners of the CBI; PII should not be revealed." (draft report pg. 14)

"EPA must consider:… requirements the public will have to adhere to/agree to in order to access the data to ensure protection of relevant information (e.g., formal data transfer agreements between the agency and entity requesting access to the data, general electronic agreement and check box noting that the data user agrees to meet certain pre-established requirements)." (draft report pg. 17)

"EPA could…require additional information or data sharing agreements when access to confidential or copyrighted information is warranted. Copyright would protect the particular program or model from being used by others without permission. Signing a non-disclosure agreement would protect other CBI information." (draft report pg. 21)

"There are EPA laws protecting both CBI and PII and certainly there are Non-disclosure Agreements (NDA's) that are used in many situations to protect CBI, so there are mechanisms for this protection that have legal standing. EPA may need to obtain the protected information to

make regulatory decisions and EPA provides assurance that its staff will not divulge protected information; this should not change in the future. EPA will need to provide the same assurances of protection for any individuals in the public who are granted permission to access the protected information, and these members of the public need to be fully informed about the legality of maintaining the confidentiality and the legal ramifications if the protection is violated." - Janice Chambers

The supplemental proposal does not address how the confidentiality of CBI and PII would be protected for those granted access to data under a tiered approach. This lack of explanation from EPA is particularly troubling in light of recent research indicating major privacy risks from unsupervised sharing of environmental health research.[199]

Given these adverse impacts and insurmountable conflicts with existing privacy protections, the Supplemental Proposal should be withdrawn.

D. Problematic retroactive application of data requirements

In the Supplemental Proposal, EPA has not acknowledged that there are regular review cycles for different environmental rules, and that new requirements for all "data and models" to be considered by the agency in development of "influential scientific information and/or pivotal regulatory science" will substantially complicate existing science review processes at the agency. The supplemental makes no reference to the fact that EPA is constantly re-reviewing scientific evidence, and that the body of science remains relevant no matter when it is generated. EPA has not explained in the Supplemental Proposal why retroactive application of its expansive requirements is warranted, even as the agency proceeds with a number of influential science products that rely on underlying environmental studies that do not meet the Supplemental Proposal's vaguely presented public data release requirements.

Moreover, retroactive application of new data release requirements would newly allow industry lobbyists to petition the agency for rulemakings under EPA's Information Quality Guidelines[200] to review or refine rules on grounds that some subset of studies do not meet the Supplemental Proposal's public data release requirements.

As such, the Supplemental Proposal's retroactive application would directly undermine a wide range of influential scientific information already finalized and widely disseminated by the agency, despite no change in the types or quality of the underlying scientific information, data, and models upon which those products are based.

EPA has not explained or anticipated the impact of the Supplemental Proposal on other federal agencies that rely on similar types of scientific data and models to develop influential scientific information. For example, both EPA and the National Highway Traffic Safety

[199] Boronow, Katherine E., Laura J. Perovich, Latanya Sweeney, Ji Su Yoo, Ruthann A. Rudel, Phil Brown, and Julia Green Brody. 2020. "Privacy Risks of Sharing Data from Environmental Health Studies." Environmental Health Perspectives 128 (1): 017008. https://doi.org/10.1289/EHP4817.
[200] U.S. Environmental Protection Agency. 2017. "EPA Information Quality Guidelines." Collections and Lists. US EPA. December 12, 2017. https://www.epa.gov/quality/epa-information-quality-guidelines.

Administration recently published the Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021-2026 Passenger Cars and Light Trucks.[201]

The Supplemental Proposal does not explain how newly restrictive requirements introduced at EPA would affect significant scientific work underway at other federal agencies. Moreover, it appears that the misguided attempt underway at EPA is already informing similarly destructive anti-science efforts and attempts undermine longstanding scientific review processes at other federal agencies, including the Department of Interior.[202,203]

Because the Supplemental Proposal is such a blatant and sweeping attack on science, it should be immediately withdrawn.

XI. The Supplemental Proposal would inhibit EPA from responding quickly to environmental and health threats

On March 24, 2020, Senator Thomas Carper sent a letter[204] to the EPA Administrator outlining concerns about the adverse impact of the Supplemental Proposal on EPA's ability to respond quickly to environmental and public health threats.

Specifically, the letter explains that the Supplemental Proposal's "time-consuming barriers to the use of scientific information could in some cases be more than a mere annoyance or ministerial task; it could be fatal" because it could significantly delay EPA's ability to make timely use of critical public health research. *Id.* The letter notes that

If EPA's rule was in place, before these studies could be used by EPA decision-makers there would, at minimum, be a time-consuming review needed in order to determine a) whether they meet the rule's requirements and/or b) whether they require independent validation or a case-by case exemption from the rule's applicability before they could be used for EPA decision-making purposes. Even if these and other relevant studies were ultimately deemed to be eligible for use under this rule, this rule would clearly establish barriers and delays to using available science to inform EPA's response.

Id. at 2. Within the text of the Supplemental Proposal, EPA has not explained what safeguards are in place so that new public data release requirements do not inhibit EPA's response to public health emergencies. The letter also notes that

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[201] Environmental Protection Agency and National Highway Traffic Safety Administration. 2020. "The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021-2026 Passenger Cars and Light Trucks." Federal Register. https://www.govinfo.gov/content/pkg/FR-2020-04-30/pdf/2020-06967.pdf.

[202] Peacher, Amanda. 2018. "DOI Policy Will Increase Transparency, Officials Say. Conservationists Are Dubious." October 3, 2018. https://www.boisestatepublicradio.org/post/doi-policy-will-increase-transparency-officals-say-conservationists-are-dubious.

[203] U.S. Office of Management and Budget. 2019. "Promoting Open Science in the Regulatory System (RIN 1090-AB20)." Fall 2019. https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=1090-AB20.

[204] Carper, Thomas R. 2020. "Letter to EPA Administrator Andrew Wheeler Regarding 'Strengthening Transparency in Regulatory Science,'" March 24, 2020. https://www.epw.senate.gov/public/_cache/files/8/a/8ab0f66e-d9d3-49a9-9896-cc0d18c2decc/511AC0DD395D5F8A08B642B2A42F0A5E.03-24-20-tc-secret-science-letter-to-epa.pdf.

it is also possible that studies that could be usefully relied upon during a pandemic or other crisis would be systematically excluded from being used in EPA's scientific and regulatory efforts well before the next pandemic or other crisis occurs if this rule is finalized.

Id. at 3. Indeed, the Supplemental Proposal includes a provision that gives the EPA Administrator the ultimate authority to decide which studies are exempt from new public data release requirements, as we describe in section XV. As applied to the current crisis, the Supplemental Proposal's requirements for public data release conflict with the Executive Branch's approach to releasing data and models within the context of the current COVID-19 response. For example, a White House representative recently told reporters that the COVID-19 task force "has not publicly released the models it drew from out of respect for the confidentiality of the modelers, many of whom approached the White House unsolicited and simply want to continue their work without publicity."[205]

In attacking the foundations of sound science and research through this rule, EPA runs the risk of discouraging researchers from working with the Agency to quickly and safely meet the challenges presented by the COVID pandemic. EPA's failure to explain how the Supplemental Proposal would not obstruct the Agency in responding to emergencies is further evidence that the Supplemental Proposal is arbitrary and capricious, an abuse of discretion, and otherwise unlawful.

XII. Science Advisory Board letter on April 24, 2020 raises additional concerns

On April 24, 2020, the Science Advisory Board delivered a letter to EPA with its review of the Proposal and Supplemental Proposal.[206] That letter identifies numerous glaring problems and significant implementation issues that remain unaddressed.

A. Scope

In the letter, the SAB notes that the application of data requirements to include studies relied upon in influential scientific information "could be complex and/or impractical because some studies could be considered when integrating evidence but not directly used to determine specific regulatory standards or levels." Indeed, EPA has not explained in any way how the consideration of different types of research studies would be made in the context of specific agency work.

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[205] Wan, William, Josh Dawsey, Ashley Parker, and Joel Achenbach. 2020. "Experts and Trump's Advisers Doubt White House's 240,000 Coronavirus Deaths Estimate - The Washington Post." Washington Post, April 2, 2020. https://www.washingtonpost.com/health/2020/04/02/experts-trumps-advisers-doubt-white-houses-240000-coronavirus-deaths-estimate/.

[206] EPA Science Advisory Board letter to Administrator Wheeler. EPA-SAB-20-005. 2020. "Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled Strengthening Transparency in Regulatory Science," April 24, 2020. https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/44DDFBB49B6E46AD852584430056804E?OpenDocument&TableRow=2.3#2.

It is not practical for EPA to arbitrarily screen specific studies, and EPA has not articulated in the proposal how such requirements will be implemented without significant interference in the agency's work. The proposal does not engage with the complexity and cascading ramifications of the requirements it spells out and should be withdrawn.

The letter notes that the "lack of criteria for satisfying the requirement to "make all such studies available to the public to the extent practicable" makes it difficult to understand the implications of the requirement. Criteria are needed to define the requirement."

As the SAB notes, EPA has not explained in the proposal how the requirement to make the studies publicly available could be practically achieved. It does not identify any phasing-in period for the requirement, which would significantly complicate EPA's science review process. No criteria have been established by EPA to understand. The lack of criteria at this stage in the process is problematic because it does not allow researchers--whose work can take many years to plan, fund, conduct, and publish-- adequate opportunity to understand the proposed requirements and submit comments to EPA.

This problem is magnified by the significant expansion of the supplemental proposal to consider all research data and models that cumulatively comprise pivotal regulatory science at EPA. Moreover, this lack of clarity places significant burden on researchers to understand the proposed requirements. If such requirements are not understood at this stage, it would be difficult for researchers to meet them for many years into the future-- potentially preventing EPA from fulfilling its mandate to consider the best available science. The Proposal does not address these difficulties and should be withdrawn.

B. Definition of "publicly available"

The letter notes that "A question to be answered is whether making the scientific papers reporting these studies available without charge makes the studies "available," or whether all data from every measurement taken as part of the study need to be available to anyone to analyze. At one end of this range of interpretation the requirement is easily implementable.

On the other end of the spectrum, meeting the requirement would be enormously expensive and time consuming at best and could be expected to result in the exclusion of much of the scientific literature from consideration (the machine data may no longer be available and/or the researchers may no longer be alive or in a position to assemble the data). The net effect could be minimal or complex."

Many peer-reviewed scientific studies are made available online on scientific journal portals, but those portals offer different levels of access depending on individual and/or institutional-level subscription status. How will EPA ensure that studies are considered in perpetuity if it does not constantly verify and re-verify that underlying data and models remain publicly available (e.g., if journal open-access policies were to change)? Who at EPA will certify that a study's underlying data and models have been made "available" so as to satisfy the requirements of the rule? When will such a determination be made, since weeks and months can elapse between when a paper is accepted to when it is formally published? What contingency has

EPA planned in the case that there arises a need to verify that all (rather than a portion) of a study's underlying data has been made, and who at EPA would be qualified to make that determination? The proposal does not include consideration of any of these questions and should be withdrawn.

The letter notes that "The SAB finds that requiring the identification of all studies and regulatory science supporting regulatory actions and making them available for reanalysis will be a complex process. As previously discussed, identifying and making "pivotal science data or studies" available could present challenges if some studies were considered in the regulatory decisions but were not used to determine the point of departure (POD) or reference dose (RfD) or other regulatory/technical level. It is not clear how much information and which studies should be included in the requirement to identify and make studies available.

As further discussed in Sections 3.2 and 3.3 of this report, if the intent of the rule is to make available for reanalysis "all underlying pivotal science supporting influential scientific information and/or pivotal regulatory science" that contributed to the ultimate regulatory decision, then practical procedures must be established for an independent validation."

As the SAB notes, the proposal does not make it clear how EPA would parse the relative portion of scientific information from peer-reviewed studies that is used in regulatory decisions. In some cases, a single study examining several distinct health endpoints is consulted in different ways. Would EPA make a single determination on such a study, regardless of its application in specific regulatory decisions? If so, then the proposal would arbitrarily prevent a study from being considered different ways for different contexts and regulatory decisions. (e.g., in the case where a study examines both commonly and less-commonly studied health endpoints)?

Moreover, will EPA publish a regularly updated database indicating its determination about how much weight each study is given? If so, how will the public be able to access this information? Will the decisions made by other federal agencies using the same studies be necessarily affected by the determinations that EPA makes? Will these determinations be final, or changeable? If final, will there be opportunities for the study authors or researchers to dispute the determination? If changeable, what is the process by which such a determination could be changed, and who within EPA would have that authority? The proposal does not include consideration of any of these questions and should be withdrawn.

The letter notes that "When PII and CBI data or methods are made available, "the public" receiving the information should be a small group of people who have provided assurance that they will keep such information confidential and protected. EPA could consider developing tiers of public access that may provide a base level of information (e.g., a robust summary or final study report which is devoid of confidential protected information) for the general user or member of the public and then restrict the availability of additional information to a smaller group when access to confidential or copyrighted information is warranted. In matters of public health, it is common to require disclosure to a trusted third party. In the case of environmental epidemiological studies, microaggregation of data can be used to protect personal identity. The SAB notes that the supplemental proposal indicates the Agency will only use studies containing CBI and PII if there is tiered access to the data or if the data can be sufficiently de-identified."

C. Data confidentiality

With regards to the SAB's suggestion to protect data confidentiality, it is not clear that EPA will be able to ensure that such data remains "confidential and protected." EPA has not indicated any plan for this important data protection mechanism in the Supplemental Proposal. The EPA does not define a level to which study data can be "sufficiently" de-identified in the proposal, which leaves this determination open to arbitrary influence. The Proposal should be withdrawn.

The SAB letter notes that "It may not be practical for EPA to make all studies or other regulatory science used in a final regulatory action available to the public. Many studies are included as part of a regulatory evaluation, but some studies or data may not drive the final regulatory decision (e.g., because of insufficient sample size or doses that are too high). The EPA could consider producing a list of study data considered in an evaluation and then strive to provide data for critical studies driving regulatory limits (e.g., "pivotal studies").

The SAB letter suggests that the Proposed Rule could benefit from use of the term "analysis dataset" to define data that should be made publicly available. This term refers to data that have been collected and processed (e.g., cleaned and transformed) for analysis. In this way, the public could understand which studies/data were considered and used without expending the resources to gather and disseminate all available data. The level of detail required to allow the public to transparently reach the same conclusion(s) as the Agency will differ among individuals who seek the data. Some people may wish to verify that the EPA has selected the right "pivotal studies." However, a more expansive scope would increase the reporting burden in a way that may make the Proposed Rule untenable."

It is not clear how EPA could construct such a "list of study data" nor when and how such a list would be produced. EPA has not indicated whether or not the agency would provide the underlying data or simply link to it. EPA has not made it clear whether any agency-initiated cleaning or transformation of the data would be publicly available. The Proposal does not address these difficulties and should be withdrawn.

The SAB letter notes that "emerging technologies . . . raise new challenges, including dealing with "big data" (i.e., extremely large datasets to be analyzed computationally). It may also be very challenging to identify pivotal studies if holistic judgments and weight-of-evidence frameworks are used."

D. Data sharing

The proposal does not engage with the idea of "big data" and large datasets that may not lend themselves to data sharing, nor does it reckon with the consequences of public users potentially merging multiple big data sets in order to identify individuals. Such a prospect for data misuse and abuse could violate patient privacy. The Proposal does not address this challenge and should be withdrawn.

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 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."[207]

Another explained that "87% (216 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]."[208] Finally, another explains that "any data that is even minutely useful can never be perfectly anonymous."[209] The Proposal does not acknowledge these issues and should be withdrawn.

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.[210]

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.

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[207] 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.

[208] 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.

[209] Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. Rev. 1701, 1755 (2010). https://www.uclalawreview.org/pdf/57-6-3.pdf.

[210] 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.

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."[211] 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 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.

The letter notes that "[i]t may not be feasible to identify and make available data in epidemiological studies that arise from small datasets or targeted geographic areas, especially if the Informed Consent Form indicated that only the particular researchers who conducted the study would have access to the information and data. If the participants agreed to grant only a select group of researchers access to their personal information, then that consideration should be respected, and such information should not be supplied to additional people for validation. It would probably be impractical, to go back to the participants and request their approval to provide additional people access to personal information."

The proposal does not explain how such permissions will be obtained from study authors and research participants. This shortcoming raises numerous questions, including the length of time that will be allowed for study participants to consider and respond to any requests for data release. The Proposal does not address this difficulty and should be withdrawn.

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

[211] U.S. EPA, Integrated Science Assessment (ISA) for Particulate Matter (Final Report, Dec 2009), 1–16, Washington, DC, EPA/600/R-08/139F, 2009.
https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=494959.

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 and should be withdrawn.

The Proposal's requirement for the public sharing of underlying data of these studies contradicts HIPAA's legal protections for private medical data and requirements researchers adhere to under Institutional Review Boards (IRBs), 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 letter notes that "Some of the major cohort studies, such as the Women's Health Initiative (WHI) (National Heart, Lung, and Blood Institute, 2020) or the Atherosclerosis Risk in Communities (ARIC) Study (ARIC Investigators, 1989), require researchers to write a manuscript proposal, study design or protocol – in effect, a document describing the study they intend to conduct, including data that are required and the rationale behind the study (Prentice et al., 1998; ARIC Investigators, 1989). The proposal is reviewed by a committee and, in most cases, is either approved without modification or returned to the investigators to address specific issues. It is possible that the EPA could work with holders of private datasets to develop such study designs or protocols or a similar system of broader applicability. That approach would provide a mechanism for interested researchers to access datasets for reanalysis under appropriate controls where relevant for EPA regulations."

This approach raises numerous serious questions. It is not clear who would staff such a committee and draft protocols. Moreover, the protocols themselves are likely to conflict (or at the very least, intersect) with existing, signed agreements for many studies, including major cohort studies that involve large participation. As a result, such a proposal for an added layer of federal scrutiny and approval over academic studies introduces unwieldy and impractical restrictions on already well-functioning systems. The Proposal does not address these difficulties and should be withdrawn.

E. Definitions of "data and models" and "pivotal regulatory science"

The SAB recommends that "the EPA clarify the definitions of "data and models" and "pivotal regulatory science." It would be useful to develop a guidance document that includes examples of the types of data and models of interest and requirements for reporting this information. It would be particularly useful to clarify specific requirements for reporting information from animal toxicity and/or environmental epidemiology studies. The Proposed Rule indicates that pivotal regulatory science refers to studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions. Although this definition is adequate for some practical purposes, the EPA should clarify whether this includes all the hazard characterization and dose response models that the Agency evaluated and captured in its analysis or only the final model ultimately selected."

Through these comments from the SAB, it is clear that EPA has adequately defined even the most basic terms within the supplemental proposal. It is not clear exactly which "data and models" are ensnared by this proposal, and therefore difficult to ascertain the effects of such burdensome new restrictions. The Proposal does not address these difficulties and should be withdrawn.

The letter notes that "When defining these terms, the following questions should be considered with regard to dose-response data. Are there any requirements for the number of dose levels or dose spacing? Does this mean that single dose studies will be excluded? If not, under what circumstances would these studies be included? What types of models are "in scope?" What type of information is needed for each model type – animal toxicity or epidemiological data? Is the goal to provide equations, allowing the public to replicate the math or to provide models with assumptions that the public can evaluate in detail? Are there standard approaches for modeling dose-response relationships (benchmark dose? other?) If so, under what conditions are different dose-response approaches implemented? Can a framework be prepared to outline the EPA's approach? To make the Proposed Rule more practical, pivotal regulatory science could be defined as the study (or studies if necessary) on which the regulatory limit is based. Ideally, the EPA should provide a brief explanation of why the selected study is the pivotal study and why other studies were not selected."

Beyond these questions, it is not clear when and how EPA would provide such a brief explanation, and what specific criteria would be used in order to make that decision. The Proposal does not address these difficulties and should be withdrawn.

The letter notes that "As previously discussed, protecting privacy and confidentiality must be taken into consideration when data and models underlying pivotal regulatory science are made available to the public. Although the Proposed Rule suggests that privacy and confidentiality issues can be addressed through anonymization or de-identification, this is not always the case."

EPA's proposal does not clarify how fundamental patient privacy and confidentiality issues can be overcome, and the SAB rightfully points out that such hurdles will prove insurmountable in some cases, depriving EPA of the best available science to inform critical safeguards to limit pollution and protect public health. The Proposal does not address these difficulties and should be withdrawn.

F. Unexplained impacts on researchers

The letter notes that "There is a need to know what information was used in models (e.g., whether all data points were used, how confounders were handled in epidemiological studies, what statistical models were used, what predictive models were used, the fit of the model to the data). Independent validation requires sufficient information about how the original data were collected and analyzed in order to know whether the validation procedures are likely to yield the same result as the original calculations.

The SAB notes that there are legitimate legal, ethical, professional and financial reasons why researchers may be unable or unwilling to fully share "data" - including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data. The EPA, the U.S. Office of Management and Budget, and scientific institutions have recognized these legitimate concerns, and recognized that such constraints on availability of data do not prevent studies from being verified in other ways - or preclude those studies from being considered in regulatory decisions.

Under the Proposed Rule, EPA would require that data underlying any proposed rule be made publicly available. The SAB finds that the requirement in the Proposed Rule that "data" be made publicly available is vague and, as a result, can be interpreted in different ways. The term "publicly available" is also vague and should be better defined. If "data" includes all machine output associated with analysis it would create demands on researchers that would be very onerous and could significantly slow down science-based decision-making. Even if the "data" were accessible, making it publicly available in a usable form would be costly and could be of limited utility based on past experience of the scientific community relative to the interpretation of the derivative data. If the data required to meet the "data" requirement is no more than the current standard of most journals (and in most cases provided in supplementary information) then the implications prospectively are minimal. Either way retrospective application of the requirement would be difficult to implement, could be expensive with no clear responsibility regarding who would cover the added costs, and could arbitrarily impact the conclusions drawn.

The Proposed Rule should be explicitly prospective and follow evolving norms developed by the scientific community as well as federal agencies (e.g., National Science Foundation, National Institutes of Health, National Oceanic and Atmospheric Administration, Department of Energy). The Proposed Rule should state and/or compare its objectives with existing and evolving federal procedures to address the underlying purpose of the Proposed Rule, which is to increase transparency of scientific studies utilized in regulatory actions. This additional explanation will enhance the characterization of the proposed regulation and will help EPA meet its objectives effectively and efficiently."

EPA's proposal does not clarify how such information necessary for independent validation could be made available in a consistent, thorough, and equitable way to the public---while also not placing significant new burdens on researchers and investigators. The Proposal does not address these difficulties and should be withdrawn.

The letter notes that "it would be useful for the EPA to specifically define 'independent validation.'" EPA's supplemental proposal indicates that independent validation means the reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced.

However, the specific definition of independent validation drives the feasibility of whether EPA can make data and models available for independent validation. For example, the EPA should consider the following questions: How much information is sufficient for

independent validation? Will this information consist of equations where reviewers can verify the math, more detailed models where assumptions and limitations are described, or code to allow the public to evaluate and run the models if desired? Is this information simply the dose-response data for the endpoint of concern driving a regulatory limit, or is it availability of all data from a pivotal study to allow reviewers to examine the potential contributions of other variables on the primary endpoint of concern? Endpoint data are seldom evaluated in isolation so providing sufficient study information to allow an independent assessment seems important to meet the goals of the Proposed Rule.

For example, an effect on pup body weights in a toxicology study should be examined with knowledge of maternal gestational body weight gains, litter size, food consumption, maternal/litter clinical signs, etc. Sample size and variability also play a key role in data interpretation. The SAB notes that EPA Data Quality Guidelines include definitions of replication and validation; this information must be included in the "analysis dataset" with guidance on how to read/interpret it."

It is highly problematic that EPA has not adequately defined "independent validation" within the proposal nor outlined clear criteria for assessing whether or not a study can be independently validated. For meta-analyses and other studies that rely on multiple component studies, it is not clear what threshold would have to be met for the overall study to qualify as one that can be independently validated. The Proposal does not address these difficulties and should be withdrawn.

The letter notes that "How will the EPA manage international studies where there is no requirement for laboratories to provide data to EPA? EPA may have little to no leverage in these situations. Again, the inability to use "pivotal studies" from other geographies could bias risk assessment decisions."

EPA commonly relies on studies conducted outside of the United States, including environmental epidemiology studies of air pollution and health in Canada. Such studies provide relevant information to EPA but are unlikely to meet stringent data requirements in the proposal. The proposal does not engage with this issue at all or identify any ways in which the significant reduction in research input from international community would affect EPA's science activities. The Proposal does not address these difficulties and should be withdrawn.

G. Meta-analyses

The letter asks "How will the EPA manage conclusions drawn from a meta-analysis? Do all studies included in the analysis become "pivotal" studies? This could markedly increase the number of datasets that must be publicly available."

Meta-analysis studies are powerful tools that allow EPA to make sense of multiple independent studies. The proposal does not make any mention of such studies despite their importance for informing pivotal regulatory science,. It is not clear whether all component studies included in a meta-analysis (which may span both domestic and international research) would be subject to the requirements of the proposal in order for the meta-analysis study itself to

be fully considered by EPA. The Proposal does not address these difficulties and should be withdrawn.

H. Determining "pivotal" nature of research

The letter asks how EPA will "justify identification of a "pivotal study" and dose-response without clarifying why other studies were not pivotal? This will require transparent evaluation and reporting of data quality/reliability for available studies that allows reviewers to understand EPA's selection of the "pivotal" study."

The proposal does not explain how such a determination will be made nor how it will be communicated to the public. It is not clear whether EPA itself or an independent group will conduct this assessment. Will such a determination be considered final, or will there be opportunity to revisit the determination if underlying circumstances change (e.g., if some or all of the underlying study data and models are made publicly available)? The Proposal does not address these difficulties and should be withdrawn.

I. Proprietary software models and code

The letter notes that "Some data and models may rely on proprietary software that may not be readily accessible or available and scientists may need to develop their own proprietary code, while other software may be accessible but require considerable data storage or download that may limit utility and availability."

For many studies, proprietary software and/or proprietary code is necessary in order to effectively work with underlying study data. However, these models are generally not freely available to the public, and many require advanced technical training and considerable technical resources to operate. EPA has not discussed this issue in the proposal, even though it presents a major obstacle to the goals of the proposal. For already burdened researchers, it is not feasible to expect them to provide underlying code (which may be subject to other release requirements and advance permissions) to the agency. It is not clear that such code, even if provided, could be navigated by anybody not intimately familiar with the underlying data, models, and methodological approaches applied in specific studies. The Proposal does not address these difficulties and should be withdrawn.

The letter notes that "The SAB finds that assessing the validity of epidemiological studies for the purposes of the Proposed Rule poses particular scientific and technical challenges. In general, for the purposes of the Proposed Rule, validation should be defined to include both internal validity and external validity, in the senses defined by Campbell and Stanley (1963). Issues to be addressed include understanding bias, confounding factors, measurement errors and exposure characterization. All of these factors will play a role in defining what would be appropriate for access and validation purposes. Specifically, one would need the following information: how measurements were taken; how confounders were assessed and dealt with; the institutional review board (IRB) application and subsequent approvals or concerns; the Informed Consent Form (or assent process for children capable of providing assent) or the consent of parents or guardians for information collection on children; the qualifications of the researchers

obtaining personal or health information and the consistency of multiple researchers for collection of PII; how truncated datasets for longitudinal studies were handled when participants dropped out of the study or missed sampling times; how environmental samples or human blood samples were taken, handled, stored and analyzed; criteria for how any data points were deemed outliers and eliminated from the dataset; how participants were selected and what the selection/exclusion criteria were. As previously discussed, to address some of these issues, the SAB recommends using approaches such as conducting independent analysis by a third party, e.g., Health Effects Institute (HEI), where risk of personal identification is high, and/or adopting the term analysis datasets as described below."

The SAB's criticism underscores EPA's failure to adequately define terms in the Supplemental Proposal within the context of its scientific activities. The Supplemental Proposal makes no mention, for example, of internal and external validity.

J. Impracticality of Supplemental Proposal

Later, the letter notes that "Another aspect to consider is the practical aspect of actually conducting a reanalysis of a major epidemiological study. Such an enterprise requires an enormous amount of work even for a well- qualified researcher. The Health Effects Institute (HEI) established a model for conducting such a reanalysis in its 2000 reanalysis of the Six Cities and American Cancer Society datasets (HEI, 2000). However, HEI has not repeated this kind of exercise. EPA could consider using the HEI model for funding its own reanalysis for datasets that are deemed critically important for regulation."

The proposal does not make any mention of the need to assess study validity, nor does it distinguish between internal validity (reduction of error and bias) and external validity (applicability of results to other populations, exposure settings, or time periods). The information that the SAB suggests be made publicly available is not easily assembled by researchers, and is well beyond the common scope of information required from researchers in order to submit their work for peer-review in scientific journals. While independent third parties have historically had some limited capacity to conduct targeted analyses at EPA's request, the sheer volume and complexity of the scientific information that would fall under the scope of the new proposal represents a major obstacle to any independent organizations that could possibly assist EPA. The proposal does not discuss any of these issues and should be withdrawn.

The letter notes that "There will be technical, scientific and resource challenges associated with assessing and disseminating data as required by the Proposed Rule. Costs of processing and documenting data will be difficult to assess in advance until EPA has developed a system for dealing with the requirements of the rule. However, the SAB notes that the Agency should consider seeking input from experts in library science, data curation management and data retention to identify best practices and tools to ensure efficiency and utility of data that are made available. Obtaining data in a usable format with adequate documentation may be difficult. Funding agencies may have different time limits for retaining data. It is likely that not all data will be in a format suitable for public data sharing. Data problems may include: nontraditional data formats, PII, CBI, and inadequate documentation of data or methods. The SAB notes that there may be solutions for some of these data issues, but not for others. Historical datasets might

not be available at the level of detail needed for recalculation. Some of the data or computational methods may have been discarded if they were deemed not necessary to maintain. IRB applications usually indicate when individual records can be discarded."

K. Significant costs of Supplemental Proposal

Later, the letter notes that "There will be costs associated with the establishment of such an office as well as researchers' time to collate data and work with EPA to make these data publicly available. It is unclear how the EPA will manage these additional costs. In the future, it might be possible for EPA to develop a reporting framework for laboratories so that study data are collected in a format that requires less rework if a study is subsequently judged to be a "pivotal study." Some laboratories/researchers may not want to organize historical data for public release as they may see this activity as a diversion from their research priorities. There would likely also be additional costs that occur at an institutional level (i.e., Institutional Review Boards) that would be substantial. The EPA may need to find creative ways to offset the expense associated with data submission for pivotal studies."

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.[212] 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. Other cost projections are staggering: when EPA staffers in 2017 considered the potential effects of the failed HONEST Act[213] that mirrors the approach of the Proposal, they calculated[214] that efforts to anonymize health data and confidential business information could top $250 million annually[215] (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.[216] 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

[212] 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.
[213] 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.
[214] EPA Internal Analysis of HONEST Act (2017), *available at* https://www.scribd.com/document/344731162/EPA-analysis-of-Honest-Act-to-CBO.
[215] 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.
[216] 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.

analyses (according to a Congressional Budget Office evaluation of the HONEST Act[217]), 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.

L. Conflicts of Interest

The letter notes that "The people or groups processing and handling the data (EPA staff or independent non-EPA consultants) would need to be identified, their credentials and any conflicts of interest with the particular case identified, and documentation secured that they will not reveal confidential information without appropriate permission from the owners of the CBI or PII. The processing might include ways to strip some of the PII of potential identifying information or aggregating the information if these methods would still allow for the validation to be performed. Similarly, the people or groups who would maintain the datasets and provide them to independent public people or groups for validation processes would need to be identified and provide assurance that the data would be maintained as confidential PII or CBI and only released to authorized people or groups. A mechanism would need to be developed for public requests for data access and for approval or disapproval of the requests."

M. Managing public requests for data

The proposal does not identify or explain such a mechanism for managing public requests for data access, nor does it make it clear whether such a platform would itself be open for public inspection. If requests for data access are granted, would study data be provided only to the requestor, or made available to a broader group? How would EPA ensure that anyone with access to the data make appropriate use of it, and not share it with other individuals or groups? None of these issues are confronted by EPA in the supplemental proposal and it should be withdrawn.

N. Retroactive applicability of Supplemental Proposal

In the letter, the SAB notes that "processing and documenting data and models developed prior to the effective date of the rule will pose challenges. It is likely that some flexibility is going to be required as the standards on transparency are evolving, and data collection expectations do not apply to historical studies or investigations completed 10 or 20 years ago.

It may be reasonable in some cases to apply modern standards of transparency and public availability to a subset of current and future studies, but it will not always be possible to apply these same standards retrospectively, especially for studies involving human subjects. It is not clear: (1) how many of the studies EPA currently relies upon to take important regulatory actions would meet the public disclosure standards stated in the Proposed Rule, and (2) whether EPA has assessed the feasibility of making underlying information from the studies publicly available, or what the impact of precluding those studies would be on EPA's decision making and its ability to

[217] 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.

protect public health/environment. The SAB could advise EPA on how to use data from historical studies in regulatory decisions. This may require case-by-case approaches."

It is true that retroactive application of this proposal does not make any scientific or practical sense, but EPA has not reckoned with the serious complications of applying stringent data requirements on studies that were completed many years ago. Any proposed "case-by-case" approach posited by the SAB for allowing individual studies to circumvent the proposal's new requirements has not been included by EPA in the original proposal, and this idea introduces substantial probability for arbitrary interference in pivotal regulatory science at EPA.

As previously noted, the retrospective application of suddenly applied data transparency standards is a monumental challenge. A large amount of work would be required to locate, curate and retrospectively make datasets available for public access. This requirement could adversely affect the ability to move this program forward in a meaningful capacity.

For example, EPA could decide not to apply the Proposed Rule and its specific requirements retrospectively given the potential difficulty accessing, reviewing and making data available that were not originally intended to be disseminated in such a manner as defined in a future rule. The EPA could consider designating a "start date" and begin collecting and releasing pivotal study data at that time. When the EPA updates an existing risk assessment after the start date, the EPA could collect and release pivotal data.

It is true that a substantial amount of work would be required in order to make any data and models underlying studies available to the public, but EPA has not identified a responsible party for this work, nor has it made clear the timelines, electronic data sharing mechanisms, or public reporting of such availability would be achieved, archived, and maintained over time. It is not clear how such a "start date" for future applicability of data requirements could be determined or fairly applied, and in many cases such as the National Ambient Air Quality Standards science reviews, the assessments rely on a foundation of scientific evidence that stretches back many years, if not decades. As a result, determination of any "starting date" would be arbitrary and deprive EPA of the best available science.

O. Potential for arbitrary influence from EPA Administrator in granting exemptions from proposal through waivers

The SAB notes that "The Proposed Rule indicates that the EPA Administrator may grant exceptions to the requirements of the Proposed Rule on a case-by-case basis if it is determined that compliance is impracticable because: (1) it is not feasible to ensure that all pivotal regulatory science is publicly available in a manner sufficient for independent validation, consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or (2) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions. The SAB understands the need for exceptions and recommends that EPA develop specific criteria for such exceptions as part of the Final Rule. Although it may be difficult to develop criteria for exceptions, outlining such criteria would benefit EPA and help ensure that the principles of transparency outlined in the Proposed Rule are accomplished.

The SAB notes that the proposal to use a case-by-case "waiver" may not be an effective mechanism for ensuring that the EPA can appropriately consider important studies, including those that rely on confidential data. Without pre-defined criteria for such waivers, a case-by-case waiver may create concerns about inappropriate exclusion of scientifically important studies. Reference to a vague "feasibility" standard suggests that such waiver decisions are to be made solely by the Administrator. In the absence of clear guidance, such waivers might appear to be inconsistent or lacking objectivity. A framework and/or guidance document could also help EPA to clarify how current scientific review procedures will be affected by this rule. It might be useful for the EPA to consider recommendations from a scientific advisory committee when making waiver decisions.

The SAB finds that exclusion of segments of the scientific literature, with the possibility of inclusion of other selected information without pre-defined criteria, could allow systematic bias to be introduced with no easy remedy. The proposed exception process applies no constraints on how this mechanism could be used or that it be restricted to the issue of confidential data. Such a proposal is inconsistent with the scientific method that requires all credible data be used to understand an issue and to allow systematic review to evaluate past research. It may be useful for the SAB to peer review documentation containing the mechanisms for exclusions based on criteria defined by EPA and provide constructive considerations.

Although it would be difficult to develop, the EPA could benefit from preparing a framework and/or guidance that outline criteria to specify exceptions. While the EPA cannot address all circumstances and scenarios that could limit data sharing, the SAB recommends that EPA explore and document some reasonably anticipated scenarios that could be described, perhaps with case studies from previous risk assessments (e.g., What information would fall in scope based on past risk assessments? What data would have to be released to support a given risk assessment? Is it feasible to release this information? Why or why not?)."

The provision for the Administrator to issue case-by-case "waivers" injects 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.

P. No justification for Supplemental Proposal or original Proposal

The SAB notes that "There is minimal justification provided in the Proposed Rule for why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate, and how the Proposed Rule will improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner. It is plausible that in some situations, the Proposed Rule will decrease efficiency and reduce scientific integrity, determining if in fact that will be the case requires a thorough and thoughtful examination that is currently absent in the Proposed Rule. Moving forward with altered transparency requirements beyond those already in use, in the absence of such a robust analysis, risks serious and perverse outcomes."

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.

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.[218] 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.[219] 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.[220]

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.[221]

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.

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[218] *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.
[219] *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.
[220] Scott Waldman, "Meet the man helping Pruitt reshape science," *Climatewire*, (May 23, 2018), https://www.eenews.net/stories/1060082467.
[221] 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.

The term “data” was not defined in the Proposed Rule and the nature of the data that must be made publicly available to fulfill the requirements of the Proposed Rule is not clear. It is difficult to develop a singular definition of “data” that would meet EPA’s objectives in the Proposed Rule. The SAB notes that EPA has further defined “data” in the supplemental proposal and, as previously discussed, the SAB finds that EPA could benefit from using the term “analysis dataset” (i.e., data that have been collected and processed for analysis) to define data.

However, the definition of data would likely differ based on available datasets. For example, the original data for an in vivo study could include all the individual animal body weight or individual pathology data while a dataset for an in vitro study may include multiple samples and assays assessed, and for epidemiology data it may include individual exposure monitoring data or biological samples.

“Raw” data (also known as original or primary data) could include individual sample values collected on individual study subjects or various instruments and include each measurement on sampled endpoints (and each time it is sampled) in a given study. The original or “raw” data would not be manipulated in any fashion (e.g., removing outliers - data would appear in the raw data with a scientific rationale on why a data point was removed from subsequent analysis).

Notably, in 40 CFR part 792 -TSCA which describes Good Laboratory Practices (GLP), raw data is defined as “any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study.” All or none of this original information may or may not be needed to adequately understand the results of the study or EPA's use of the information. Thus, making all this information publicly available may be resource intensive and provide limited utility. The SAB recommends that EPA use the term “analysis dataset.”

Q. Unrealistic expectations of Supplemental Proposal and potential for inconsistent and biased application

In its letter, the SAB notes that “the requirement to make data available for public inspection will be more easily implemented for some datasets than others (e.g., GLP studies include individual sample data as part of standard reporting). The expectation that data and methods will be available for all endpoints may be unrealistic. EPA could consider designating scores for information availability with the highest tier assigned to studies that define methods (e.g., protocol) as well as raw (individual sample level) data. Additional scores could be driven by sharing data on other related endpoints in the pivotal study to facilitate data interpretation. Scores could subsequently be used to evaluate data utility, uncertainty, etc. Ultimately, there are some datasets where CBI and/or PII data will require more onerous steps to protect data confidentiality. Based on EPA responses to SAB questions, it appears that the Agency is seeking approaches to manage these data issues.”

Any such scoring method has not been detailed by EPA in the Supplemental Proposal and could be biased given the unclear definitions and lack of evaluation criteria. While EPA may be

"seeking approaches" to manage data issues, those issues should have been resolved by EPA before issuing the Supplemental Proposal.

Any such approaches determined by EPA itself in preparation of a Proposed Rule must be set forth for robust public inspection and comment because they are central to the ultimate impact of the Supplemental Proposal within the agency and on stakeholders outside of the federal government. The SAB comment identifies "data utility, uncertainty, etc." as potential components of a scoring tool, but this is a poor representation of the complexity and depth of information available in scientific studies that would require consideration.

It is inappropriate for EPA to be "seeking approaches" to manage the fundamental flaws and implementation issues presented in the Supplemental Proposal. EPA should not use its poor degree of SAB consultation and a brief public comment period on an incomplete proposal to solicit input on fundamental components of the inappropriate and unjustified restrictions outlined in the Supplemental Proposal. For these reasons, the Supplemental Proposal must be withdrawn.

In its letter, the SAB suggests that in defining data, "it might be reasonable to consider the initial compilation of data (original data) in a spreadsheet as "raw" data. While this might still require some interpretation, e.g., abbreviations used in spreadsheet column headings, and footnotes about missing data points (if they were discarded because of legitimate reasons, such as known mistakes or statistically determined outliers), the spreadsheets are still very close to the initial raw data coming out of an instrument or written by a researcher when working with a subject in an epidemiological study."

This comment overly simplifies the different types of data used by the agency in its science interpretation activities, because in many cases researchers are not working from simple spreadsheets. The SAB comment appears to focus on environmental epidemiology studies, despite the fact that EPA's Supplemental Proposal now encompasses a much wider scope than the original Proposal (see section IV).

Moreover, It is unreasonable that EPA did not include an adequate definition of "data" in the Supplemental Proposal and any proposed definition for "raw" data must be published by EPA for public inspection and comment.

Later, the SAB letter notes that "there is extensive work required to understand the implications of different definitions across a diversity of fields, data types and data of different ages. Such an effort is beyond the scope of what the SAB can undertake with the resources and time available.

However, the SAB finds that such an analysis is foundational to the development of any transparency rule that goes beyond well-established norms and procedures." In this statement, the SAB identifies the radical nature of the Supplemental Proposal to undermine well-established practices within the scientific community. This comment from the SAB also confirms that this group did not have an adequate opportunity to understand the implications of the Supplemental Proposal because EPA did not allow for adequate time or make adequate resources available for the SAB to do so, despite the sweeping nature of the Supplemental Proposal.

The SAB letter notes that the Supplemental Proposed Rule "requires the EPA to describe and document any assumptions and methods that pertain to the use of data and models underlying pivotal regulatory science and to describe variability and uncertainty. The SAB notes that high quality scientific studies identify the assumptions used in models and methods, the variability of the replications, and any other confounders that add to the uncertainty of the final dataset, so these are not unusual or inappropriate factors to be addressed."

It is not clear that the Supplemental Proposal requires EPA itself to document assumptions and methods, and EPA has recently indicated in briefings to Congress that this burden may fall on researchers themselves (see Section XIII). The vague process as described in the Supplemental Proposal would significantly burden researchers to assemble this information, and EPA has not developed any criteria or guidance for that process. It is inappropriate for EPA to require that such information be made available as a prerequisite for any study's consideration by the agency, regardless of whether or not similar types of information are available to study authors.

The SAB letter declares that "it is good practice to identify: (1) testable assumptions (e.g., that residuals in a regression model are normally distributed with constant variance); (2) results of tests of assumptions; and (3) any untested assumptions made in deriving conclusions from data (e.g., that there are no unmeasured confounders, or that dose-response functions are linear below the lowest dose for which data are available). Results of tests should be presented where they are available, and assumptions that have not been tested, or that have been tested but not supported, should be identified."

Here, the SAB offers criteria for EPA to evaluate research studies, but these "good practices" are not offered or defined by the EPA in the Supplemental Proposal and they do not encompass the range of complexity involved in study design and analysis. The SAB comment appears to focus on environmental epidemiology studies, despite the fact that EPA's Supplemental Proposal now encompasses a much wider scope than the original Proposal (see section IV). The information offered in the SAB comment is indicative of the lack of detail in EPA's Supplemental Proposal. Given these shortcomings, the Supplemental Proposal should be withdrawn.

The SAB letter notes that "[a]ssumptions are often made about (a) error distributions for exposure estimates (most commonly, that they can be ignored); (b) model specification errors and uncertainties; and (c) causal interpretations of modeling results. These assumptions should be explicitly stated, and results of tests presented. Epidemiologists (e.g., Sander Greenland), statisticians, and risk analysts have written at length over several decades about how to test, validate, and document assumptions and methods for dose-response modeling and uncertainty and variability characterization, and these modern methods should be applied to make the factual and assumption-based foundations of pivotal studies as clear as possible. However, the SAB finds that there are scientific and technical challenges to be overcome and provides suggestions to implement this requirement."

Again, the SAB confines its comment to environmental epidemiology studies, despite the significant expansion of scope within the Supplemental Proposal (see section IV). No consideration for other types of "data and models" outside of that field is made in the letter, reflective of EPA's Supplemental Proposal that does not substantively engage with the scope and complexity of scientific information that would be ensnared by the Supplemental Proposal.

The "scientific and technical challenges" that are highlighted here are fundamental to the Supplemental Proposal's impracticability and arbitrary nature, especially in light of the fact that EPA has not offered any convincing rationale for the Supplemental Proposal nor the original Proposal (see section VI).

As the SAB notes, the specific assumptions and methods utilized in high quality studies are already included in published, peer-reviewed studies. EPA has not given any rationale for this requirement in the proposal, nor has it identified any systematic deficiency in the peer-reviewed literature that prevents a reasonable ascertainment of study assumptions and methods. Given these numerous deficiencies, the Proposal should be withdrawn.

XIII. Additional concerns raised by the House Committee on Science, Space, and Technology

On May 6, 2020 Eddie Bernice Johnson, Chairwoman of the Committee on Science, Space, and Technology sent Administrator Wheeler a letter[222] identifying key concerns with the Supplemental Proposal in follow-up to briefings to Committee staff on April 2, 2020 and April 14, 2020.

A memo describing information obtained from EPA during those briefings included with the letter includes new implementation details that EPA did not provide in the original 2018 Proposal nor the Supplemental Proposal. The memo serves to spotlight critical problems relating to vagueness and implementation that persist within the Supplemental Proposal and from the original Proposal.

The information contained in this memo, covering Congressional conversations and a report summarizing EPA briefings, released less than two weeks before the May 18, 2020 public comment deadline for the Supplemental Proposal, is no substitute for actual fair notice by EPA to the public. This fact alone is further indication that the rule is arbitrary and capricious and fails to provide fair notice or any reasoned explanation about key aspects of the Proposal and Supplemental Proposal.

A. EPA fails to inform researchers that they would bear the burden of implementing EPA's "tiered access" regime.

In particular, the Staff memo elaborates on the Supplemental Proposal's concept of "tiered access." The memo notes that in the briefings, "EPA provided far more detail on the so-

[222] *See Supra,* n. 21, House Staff Memo.

called "tiered access" approach than what was presented in the Supplemental Proposal. For the first time, EPA told Committee staff that the burden of implementing this proposal would be on researchers."[223]

Within the Supplemental Proposal text, EPA has not made that burden clear or explained how it would be implemented by the already-burdened research community without any additional resources or guidance from EPA. This failure to identify a significant burden imposed by the Supplemental Proposal on stakeholders outside the federal government is alarming, as is the fact that EPA did not make this burden apparent within the Supplemental Proposal itself.

According to the memo, "EPA's envisioned implementation – absent from the text of the Supplemental Proposal – would be as follows:

- EPA staff would reach out to the researchers involved in a study that the Agency wants to consider during the development of significant regulatory actions or Influential Scientific Information.
- The researchers would be responsible for managing the logistics of making the data and models publicly available in a manner that complies with the rule, in consultation with EPA staff.
- The researchers would be responsible for judging the sensitivity of the study's data and models and what information can or cannot be made publicly available through tiered access.
- The researchers would decide what tier of access should be designated for different types of information.[224]

These implementation details (none of which are included in the Supplemental Proposal), raise a number of glaring problems. First, EPA regularly consults thousands of scientific studies for influential scientific information like the Integrated Science Assessments for criteria air pollutants under the Clean Air Act's NAAQS program (see section IV.A.1). It is not feasible for EPA staff to contact research authors in such a way, particularly because many studies involve multiple authors and conceivably permission would need to be obtained from all co-authors for any new plan to share data with EPA or the public.

Second, EPA burdens researchers with the obligation for managing complicated and costly logistics of making underlying data and models available to the public. It is not clear how EPA would assure that these researchers actually carried out these logistical details, and no hint of this major burden to researchers is mentioned in the proposal. The logistics themselves are nowhere spelled out in the Supplemental Proposal.

Third, EPA evidently expects researchers to assess the sensitivity of study data but provides no criteria for doing so. The expectation that researchers evaluate their own data and models conflicts with the agency's plan to independently assess whether the research has indeed been made publicly available or whether EPA should grant a waiver from the requirements identified in the Supplemental Proposal. Similarly, in the fourth bullet, EPA now says that it expects researchers to ascertain what data access tier is important for the underlying data and

[223] *Id.*, at 4.
[224] *Id.*

models used in their studies. No details are provided to assist researchers in making such important determinations. Further, EPA's inability "to say how conflicts between the researcher's judgment and the Agency's judgment would be handled" is further indication that the rule is arbitrary and capricious and fails to provide fair notice or any reasoned explanation about this key implementation concern.

This pervasive lack of detail about new and substantial burdens on outside researchers is troubling. The House Committee rightly notes that "it is concerning that EPA has decided internally that key implementation responsibilities will fall on the research community" without alerting that community nor the public at large to that expectation. *Id.* Further, "[t]he research community cannot be expected to meaningfully comment on this proposal and its imposition on their research practices without such detail." *Id.*

B. EPA fails to inform the Public and the CDC that it expects CDC to administer critical parts of the rulemaking

The Agency also fails to provide notice to other agencies within the federal government of new obligations placed on them as a result of the Supplemental Proposal's tiered access regime. The memo notes that EPA evidently envisions that the U.S. Centers for Disease Control and Prevention (CDC) will play a major role in implementation the Supplemental Proposal—a role which goes essentially unmentioned in the rulemaking. The memo notes that EPA staff were "inconsistent concerning how the data and models would be managed," and discussed a pilot project the Agency is conducting with the CDC. *Id.* The memo notes that EPA "raised the possibility that the data could be stored on multiple outside "secure enclaves," managed by CDC or another third party, who would also be responsible for reviewing research proposals" and that "this is the first time the Agency has described an implementation scenario that would potentially place such a large responsibility on an outside agency." *Id.*

Given this information, it is clear that EPA itself does not understand how the Supplemental Proposal would be implemented. EPA's apparent plans impose a significant and new compliance burden on researchers and CDC without adequate clarity, guidance, or resources. The Supplemental Proposal fails to mention or engage with any of these substantial implementation issues, is arbitrary in assigning such responsibilities to researchers and an outside federal agency, and should be withdrawn.

These "clarifications" provided to House staff by EPA all but guarantee the arbitrary effect of the Proposal. Researchers, scientists, and fellow executive agencies are certainly entitled to receive notice that EPA intends the burden of compliance with the Proposal to fall on them and to incorporate their concerns about that approach into their comments on the rule. EPA's failure to disclose these elements of the Proposal has foreclosed that possibility. The fact that these details were provided to congressional staff during closed-door briefings, and memorialized in a non-binding House staff memorandum, is certainly insufficient to allow for statutorily-required public comment, and Agency consideration of those public comments.

Neither the research community (nor the CDC) can be expected to meaningfully comment on this proposal and its imposition on their research practices without such detail. And

of course, the fact that this emerging element of the Proposal imposes requirements on third parties—researchers, scientists, as well as the Centers for Disease Control—makes clear that the Proposal is not merely a "a proposed internal rule of agency procedure," to which the so-called Housekeeping Statute on which EPA relies might apply.

Finally, under the current iteration of the Supplemental Proposal, the public is left with gaping questions about how the Supplemental Proposal will be implemented. For example, how would EPA would handle a reanalysis conducted by a third party? What procedures will EPA follow for assessing a reanalysis during a rulemaking? How might the absence of peer-review for a reanalysis influence the incorporation of those findings into influential scientific information or a rulemaking? How would EPA balance the timeline of a rulemaking with the timeline of a reanalysis, given that a reanalysis of a major study can take years and may not be completed before a regulatory deadline? All of these critical questions have not be raised, let alone addressed, by the Agency.

EPA seemed to acknowledge as much in its meeting with House staff, where the Agency "was largely unable to address these issues and frequently declined to answer questions, admitting that the Agency had simply not considered the issue this far into the rulemaking process." *Id.* Not only are the substantive aspects of the rulemaking arbitrary and capricious, but also EPA's glaring failure to notify parties and include information on the content of the rulemaking in the Supplemental Proposal text renders the Proposal arbitrary and capricious and a truly egregious abuse of discretion. As the memo notes, "the public comment period is no substitute for a well-reasoned, deliberative policymaking process. EPA's inability to answer basic questions about the rule's operation and implementation reflects the ill-conceived nature" of the Supplemental Proposal. *Id.* The Supplemental Proposal must be withdrawn.

XIV. Supplemental Proposal enables arbitrary interference from EPA political leadership

The Supplemental Proposal expands on the problematic "exemption" option presented in the Proposal. In proposed § 30.9, the 2019 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." 83 Fed. Reg. at 18,774. This provision injects additional arbitrariness into the rule, in that it ensures that the Proposal may be applied unevenly—for certain rulemakings the "rules" of the Proposal can be discarded or ignored where desired. The Supplemental Proposal compounds this arbitrariness by adding in the consideration of "technological barriers" such as the age of the data as a factor in weighing whether or not data can be made available. 85 Fed. Reg. at 15,403.[225]

EPA's Science Advisory Board noted numerous problems with EPA's plan to issue waivers from the Supplemental Proposal's public data release requirements, and additional problems with this plan are readily apparent. For example, EPA states in the Supplemental

[225] Allison, David B., and Harvey V. Fineberg. 2020. "EPA's Proposed Transparency Rule: Factors to Consider, Many; Planets to Live on, One." Proceedings of the National Academy of Sciences 117 (10): 5084–87. https://doi.org/10.1073/pnas.1922721117.

Proposal that an "exemption may be given if compliance is impracticable because technological barriers render sharing of the data or models infeasible." *Id.* In making this option available, EPA has not indicated which individual(s) at the agency would be authorized to make a decision, nor any criteria for assessing whether or not compliance is "impracticable." *Id.* Nor is it clear how, when, or by whom such claims of technological barriers would be submitted to the agency. It is not clear from the Supplemental Proposal whether such "barriers" would be independently confirmed, or what efforts might be required in order to attempt to surmount any such barriers. EPA has not accounted for non-technological barriers (e.g., legal ones) that would prevent sharing of data and models, and it is unclear whether such barriers would qualify for an exemption or not.

Further, in the case of some scientific studies, an underlying data set is built upon and expanded over time, serving as the basis for multiple publications. It is not clear from the waiver process identified in the Supplemental Proposal whether a waiver would apply to the study publication itself, the underlying data and models, or both. The lack of clarity from EPA on this point only compounds the potential for chaos in the Supplemental Proposal.

Moreover, EPA has made no acknowledgement that institutional, legal, and other practical barriers (to public data releases, for example) may also preclude specific studies from complying with the proposal. EPA has not clarified when in the process of reviewing pivotal regulatory science such an exemption would be granted, for how long such an exemption would apply, whether an exemption would only apply to the application of specific data or models in specific regulatory context(s) or not, and whether any proposed exemption could be challenged or reviewed.

In 40 CFR 30.9(a) of the supplemental proposal, EPA proposes to use the "age of data and models as a factor in the determination that compliance with the rule is impracticable." Later, "EPA requests comment on this consideration of the age of data and models in determining the feasibility of making underlying data and models publicly available." It also "requests comment on whether there are aspects other than the year the data or model was collected, completed or updated that EPA should consider in determining whether to grant an exemption in order to evaluate the technological barriers to sharing."

It is clear from the Supplemental Proposal that EPA has failed to meaningfully engage with our previous criticisms of the original Proposal, because here EPA has set forth no set of criteria for evaluating the vast array of ethical, legal, and technical reasons why underlying data and models cannot be publicly distributed. In restricting its request for input to strict "technological" feasibility issues, EPA attempts to obscure the major legal, institutional, and moral reasons that prevent key scientific information from being made available through the burdensome requirements of this radical proposal. We note these myriad reasons throughout both these comments and our 2018 comments. EPA's failure to meaningfully engage with these profound issues reveals yet again that the entire rulemaking is arbitrary, capricious, and an abuse of the Agency's discretion.

The Supplemental Proposal grants the Administrator the ability to grant an exemption to data availability requirements "if compliance is impracticable because technological barriers

render sharing of the data or models infeasible." In not detailing the criteria for judging what is "impracticable" or not, this provision injects additional arbitrariness into the rule, in that it ensures that the Supplemental Proposal may be applied unevenly—for certain rulemakings the "rules" of the Supplemental Proposal can be discarded or ignored where desired, and standards can shift over time depending on vague assessments of what is "infeasible" or not. This shortcoming, in addition to and with other sections of the Proposal, underscores that it is arbitrary and capricious and must be withdrawn.

XV. Conclusion

It is clear from the above that the Supplemental Proposal violates the law and must be withdrawn, like its predecessor Proposal. There is no support for either the Proposal or the Supplemental Proposal in any of the environmental statutes EPA cites, and in fact, those statutes conflict with the Proposal and the Supplemental Proposal.

Further, EPA's announcement in the Supplemental Proposal of 5 U.S.C. § 301, of the Federal "Housekeeping authority" as the source of authority for the Proposal and Supplemental Proposal, when the statute on its face does not apply to the Agency, serves to underscore the extent to which the entire rule is arbitrary, capricious, and an abuse of discretion.

The idea that this rulemaking is simply an internal, administrative one that would *not* dramatically and "directly affect the rights and obligations of private parties" nor regulate the "citizenry at large" by rewriting how science is considered, used and ignored in the Agency's substantive rulemakings does not even pass the laugh test. The Agency proves the expansiveness of the Proposal and Supplemental Proposal's reach time and time again in the rulemaking, and specifically designed it to strike at the heart of the most foundational scientific studies used by the Agency to support public health protections.

The Supplemental Proposal also suffers from a host of problems additional to and compounded by the issues plaguing EPA's initial Proposal: it expands the reach of the proposal to arbitrarily apply to even more types of data and models used by the Agency; its definitions are vague and incomplete; reversals from prior agency policy go entirely unexplained; it treats other types of agency actions inconsistently; it sets up but does not explain how it would implement a "tiered access" regime, and it attempts to empower the Administrator to make "exemptions" from the proposed regulatory text based on vague undefined concepts.

Basic justifications or notice to stakeholders for EPA's numerous departures from past practices and from the plain language of its statutory authorities are entirely absent. Just like the Proposal, the Supplemental Proposal fails to grapple with (because it cannot) the serious legal, technical, and ethical obstacles that preclude cannibalizing scientific study at the Agency in the way the rulemaking proposes. The Supplemental Proposal, like the Proposal, is arbitrary and capricious, an abuse of agency discretion, and must be withdrawn.