EARTHJUSTICE
BECAUSE THE EARTH NEEDS A GOOD LAWYER

May 18, 2020

Via Regulations.gov

Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: Comments on the Environmental Protection Agency's "Strengthening Transparency in Regulatory Science" Supplemental Notice of Proposed Rulemaking (EPA-HQ-OA-2018-0259)

Dear Administrator Wheeler:

More than two years have passed since the EPA's last administrator, E. Scott Pruitt, first proposed a regulation to "preclude … [the agency] from using" many of the scientific studies that have been critical in protecting our air, water, and food.[1] The response to Administrator Pruitt's proposal shouldn't have come as a surprise. In hundreds of thousands of comments, members of the public made clear that the proposed regulation was dangerous and unlawful—a reckless assault on science that prioritized industry profits over public health.[2]

Though the public urged the Environmental Protection Agency to abandon the proposed rule, its comments were apparently ignored. Rather than withdrawing the proposal, your supplemental notice has widened its reach, subjecting a larger set of studies to the regulation's prohibitions.[3] While Administrator Pruitt's proposal was focused on "dose response data and models[,]" yours would "apply broadly to data and models" of every kind.[4] And while Administrator Pruitt's proposal was directed at the studies used in making "significant regulatory

[1] EPA, Strengthening Transparency in Regulatory Science: Proposed Rule, 83 Fed. Reg. 18,768, 18,769 n.3 (Apr. 30, 2018) ("Original Proposal").

[2] *See, e.g.*, Kelsey Brugger, White House Spills Red Ink on 'Secret Science' Rule, E&E News (Mar. 10, 2020) (noting that "Pruitt's initial plan … was flooded with about 600,000 public comments, most negative"), *available at* https://www.eenews. net/stories/1062568573; Comments of 88 Environmental, Farmworker, Environmental Justice, Public Health, and Animal Protection Organizations on Science Proposal (Aug. 15, 2018) (EPA-HQ-OA-2018-0259-6137) ("August 2018 Coalition Comments").

[3] *See* EPA, Strengthening Transparency in Regulatory Science: Supplemental Notice of Proposed Rulemaking, 85 Fed. Reg. 15,396 (Mar. 18, 2020).

[4] Original Proposal, 83 Fed. Reg. at 18,770; Supplemental Notice, 85 Fed. Reg. at 15,399-400.

decisions[,]" yours would "expand the scope of th[e] rulemaking to apply … to the science underlying influential scientific information[.]"[5] As many of the scientific assessments prepared by the EPA have been identified as "influential scientific information," the new regulation promises to interfere with much of the agency's essential work.[6]

The proposed limits on the EPA's use of important scientific research are irreconcilable with the agency's fundamental mission and statutory duties. As the U.S. Court of Appeals for the D.C. Circuit recently affirmed, the "EPA operates pursuant to multiple statutory mandates requiring that its decisions rest on various formulations of 'the best available science.'"[7] Given these mandates, the EPA has no authority to disregard or devalue "high-quality studies" based on arbitrary data-availability requirements.[8]

On behalf of a coalition of organizations dedicated to protecting the health of the environment and communities across the country, we urge you to withdraw the proposed rule and renew the EPA's commitment to its critical mission.

I. The EPA Does Not Have the Authority to Adopt a Regulation that Limits Its Ability to Rely on the Best Available Science

Since first announcing Administrator Pruitt's proposal to limit its use of science, the EPA has made three attempts at identifying a congressional grant of authority that would allow for the adoption of such a rule. In its original notice, the agency asserted that it was acting "under authority of the statutes it administers"—specifically, the Clean Air Act, the Clean Water Act, the Safe Drinking Water Act, the Resource Conservation and Recovery Act, the Comprehensive Environmental Response, Compensation, and Liability Act, the Emergency Planning and Community Right-To-Know Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Toxic Substances Control Act.[9] When it later granted an extension of the comment period on Administrator Pruitt's proposal, the EPA declared that it was acting "under authority of 5 U.S.C. 301"—the federal "housekeeping" statute—"in addition to the authorities" it had previously named.[10] Now, the EPA seems to have concluded that it actually has housekeeping powers as the result of a congressional reorganization plan, and it has asked members of the public to comment on whether it should "use its housekeeping authority independently as authority or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rulemaking[.]"[11]

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[5] Original Proposal, 83 Fed. Reg. at 18,773; Supplemental Notice, 85 Fed. Reg. at 15,398.

[6] *See* EPA, Peer Review Agenda, *available at* https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

[7] *Physicians for Social Responsibility v. Wheeler*, 956 F.3d 634, 647 (D.C. Cir. 2020).

[8] Supplemental Notice, 85 Fed. Reg. at 15,399.

[9] Original Proposal, 83 Fed. Reg. at 18,769.

[10] EPA, Strengthening Transparency in Regulatory Science: Extension of Comment Period and Notice of Public Hearing, 83 Fed. Reg. 24,255, 24,256 (May 25, 2018).

[11] Supplemental Notice, 85 Fed. Reg. at 15,398.

The EPA's difficulties in finding a legal basis for the proposed rule are understandable. There isn't one. As explained at length in comments on the original proposal, the environmental statutes on which the agency has attempted to rely actually prohibit the proposed restrictions on science.[12] And the regulation can't be defended as a "housekeeping" measure. Given that the EPA has no authority to adopt a regulation that would limit its ability to use scientific research in protecting public health, the proposed rule must be withdrawn.

A. The Agency's New Standards for Evaluating Scientific Studies Are Not Internal "Housekeeping" Requirements

As the Supreme Court has noted, the federal housekeeping statute was originally "'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'"—documents "'pertaining to the day-to-day business of Government[.]'"[13] In its current form, which has been codified in Section 301 of Title 5, the statute provides that:

> The head of an Executive department or military department may prescribe regulations for the government of … [the] 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. This section does not authorize withholding information from the public or limiting the availability of records to the public.[14]

Both the terms of the housekeeping statute and its legislative history accordingly demonstrate that it is "simply a grant of authority to … agenc[ies] to regulate … [their] own affairs."[15] In the words of the Supreme Court, Section 301 "authoriz[es] what the … [Administrative Procedure Act] terms 'rules of agency organization[,] procedure[,] or practice' as opposed to 'substantive rules.'"[16]

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[12] August 2018 Coalition Comments at 17-31.

[13] *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 n.39 (1979) (quoting H.R. Rep. No. 1461, 85th Cong., 2d Sess., at 1 (1958)). *See also* Don Lively, Government Housekeeping Authority: Bureaucratic Privileges Without a Bureaucratic Privilege, 16 Harv. C.R.-C.L. L. Rev. 495, 498 n. 15 (1981) (noting that the housekeeping statute can be traced back to 1789, when "Congress enacted several statutes authorizing the heads of the various executive departments 'to have the custody and charge of all records, books and papers in the office'") (quoting Act of July 27, 1789, ch. 4, 1 Stat. 28).

[14] 5 U.S.C. § 301.

[15] *Chrysler Corp.*, 441 U.S. at 309.

[16] *Id.* at 310.

With its supplemental notice, the EPA has admitted that it is "not one of the 15 'Executive Departments'" Congress has identified in Title 5.[17] The agency argues, however, that it has "been granted full section 301 or equivalent authority" under Reorganization Plan No. 3 of 1970—and that this authority is sufficient, maybe, to support the proposed rule.[18] According to the EPA, the regulation "exclusively pertains to the internal practices" of the agency, as it merely "describes 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."[19] Because of this "internal" focus, the EPA contends, the proposed rule should be understood as an unremarkable exercise of the agency's housekeeping power.[20]

The EPA's half-hearted attempt to cast the proposed restrictions on science as nothing more than internal "housekeeping" measures that lack substantive significance cannot be sustained.[21] As a result, even if the agency has been granted "section 301 or equivalent authority[,]" that authority would not provide a foundation for the proposed rule.[22]

Under the proposed regulation, the EPA would be required to consider a new (and sometimes dispositive) factor when deciding if it should rely on a particular scientific study: whether "the data and models underlying … [the study] are publicly available[.]"[23] As the EPA admits in its supplemental notice, this assessment of data availability would be separate from—and subsequent to—the agency's evaluation of a study's "quality[.]"[24] It could accordingly result in the exclusion of "high-quality studies" from the agency's scientific analyses and rulemakings.[25] In the words of the notice, if the proposed rule is finalized, the EPA:

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[17] Supplemental Notice, 85 Fed. Reg. at 15,397.

[18] *Id.* at 15,397-98. *See also id.* at 15,397, 15,398, 15,399 (questioning whether the EPA's asserted "housekeeping" authority can be used "independently" in adopting the proposed rule, or whether it must be used "in conjunction" with other asserted powers).

[19] *Id.* at 15,398.

[20] *Id.* at 15,397-98.

[21] *See Columbia Broad. Sys. v. United States*, 316 U.S. 407, 416 (1942) (noting that "[t]he particular label placed upon … [an action by an agency] is not necessarily conclusive, for it is the substance of what the … [agency] has purported to do and has done which is decisive").

[22] Supplemental Notice, 85 Fed. Reg. at 15,397-98.

[23] *Id.* The fact that the EPA would be bound by the requirements of the proposed rule when it undertakes later rulemakings and analyses confirms the substantive nature of regulation. *See, e.g.*, *Pac. Gas & Elec. Co. v. Fed. Power Comm'n*, 506 F.2d 33, 38 (D.C. Cir. 1974) (noting that "[a] properly adopted substantive rule establishes a standard of conduct which has the force of law" in later agency proceedings).

[24] Supplemental Notice, 85 Fed. Reg. at 15,399.

[25] *Id.*

> would continue to use standard processes for identifying, evaluating, and reviewing available data, models, and studies. When the Agency has potentially identified multiple key studies or models of similar quality that could drive its subsequent decisions, the Agency will investigate the availability of the underlying data. If, for example, multiple high-quality studies exist but only two studies have data and models that are available for independent validation and reanalysis, EPA would only include those two studies as pivotal regulatory science and/or pivotal science in accordance with the 2018 proposed rulemaking. However, under the alternative approach in this supplemental proposal, EPA would consider using all available high-quality studies but give greater consideration to those two studies with data available for independent validation.[26]

As the supplemental notice makes clear, the proposed rule would alter the EPA's substantive standards for evaluating scientific research—undermining the agency's ability to protect public health and the environment in the process. The regulation accordingly can't be dismissed as a "housekeeping" measure that merely "govern[s] internal agency procedures."[27] Indeed, the rule is at odds with the scientific standards that Congress has itself imposed on the agency. As the D.C. Circuit recently emphasized, the "EPA operates pursuant to multiple statutory mandates requiring that its decisions rest on various formulations of 'the best available science'"—among them, the Clean Air Act's requirement that "'[a]ir quality criteria … accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all

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[26] *Id.*

[27] *Id.* at 15,398. *See, e.g.*, *Int'l Ry. Co. v. Davidson*, 257 U.S. 506, 514 (1922) (noting that the housekeeping statute "does not confer … any legislative power"); *United States v. George*, 228 U.S. 14, 20 (1913) (concluding that the federal housekeeping statute "confer[red] administrative power only" and did not authorize federal agencies to establish requirements beyond those imposed by statute as, "certainly, under the guise of regulation legislation cannot be exercised"); *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993) (holding that legislative rules, which "create new law, rights, or duties in what amounts to a legislative act[,]" do not fall within the APA's exlusion for "'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice'") (quoting 5 U.S.C. § 553(b)(3)(A)); *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047, 1051 (D.C. Cir. 1987) (noting that a rule is substantive when it "encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior[,]" and concluding that the defendant agency's challenged measures would have been substantive if they had established "a new standard of review" or "a presumption of invalidity" for the agency to apply); *City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1024 (N.D. Cal. 2019) (noting that rules that "add to the requirements of the underlying statutes" are "legislative[,]" and Section 301 does not provide authority for the adoption of legislative rules); *Pharm. Mfrs. Ass'n v. Finch*, 307 F. Supp. 858, 863-64 (D. Del. 1970) (holding that FDA regulations that "prescribe[d] in specific detail, for the first time, the kinds of clinical investigations … necessary to establish the effectiveness of existing and future drug products and which require that such evidence be submitted as a condition to avoiding summary removal from the market" could not be defended "as 'procedural and interpretative'").

identifiable effects on public health or welfare,'" and the Toxic Substances Control Act's demand that the EPA's administrator "'make decisions … based on the weight of the scientific evidence[.]'"[28] In summarizing its own mission, the EPA has therefor acknowledged that it is obligated to "ensure that 'national efforts to reduce environmental risks are based on the best available scientific information[.]'"[29] The proposed rule is an unlawful effort to amend these standards by requiring the EPA to disregard or devalue high-quality studies based on an extra-statutory evaluation of data availability.[30] As explained in comments on the original proposal, moreover, the regulation also promises to cause substantial harm to members of the public, who depend on the EPA to adopt safeguards based on the best available science.[31]

In short, while the EPA has declared that it has "the authority to establish policies governing its reliance on science in the administration of its regulatory functions[,]" this authority actually lies in Congress.[32] Because the proposed rule would require the EPA to make decisions based on a factor Congress omitted from the governing statutes, it is both arbitrary and unlawful.[33]

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[28] *Physicians for Social Responsibility*, 956 F.3d at 639, 647 (quoting 42 U.S.C. § 7408(a)(2) and 15 U.S.C. § 2625(i)).

[29] *Id.* at 639 (quoting EPA, Our Mission and What We Do (Feb. 7, 2018), www.epa.gov/aboutepa/our-mission-and-what-we-do).

[30] The proposed rule's disinterest in the quality of the studies used by the EPA is further confirmed by the fact that the rule doesn't care if anything's actually been done with publicly available data. According to the supplemental notice, "[a]lthough the ability to independently validate pivotal regulatory science or pivotal science is a key component of this rulemaking," nothing in the regulation "would require that EPA, a member of the public or [any] other entity must independently validate a study before it can be considered to be pivotal regulatory science or pivotal science." Supplemental Notice, 85 Fed. Reg. at 15,403. The notice also "clarif[ies] that independent validation is not required under proposed 40 CFR 30.7[,] which describes the role of independent peer review." *Id.* While Congress has required the EPA to identify and use the best available science, the proposed rule is focused—arbitrarily and unlawfully—on other concerns.

[31] *See, e.g.*, August 2018 Coalition Comments at 6-14 (summarizing the significant impacts on public health that could result from the rule as originally proposed); *Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 653 F.3d 1, 6 (D.C. Cir. 2011) (concluding that the challenged regulation was substantive in light of the "public concern" it had created regarding "issues of privacy, safety, and efficacy").

[32] Original Proposal, 83 Fed. Reg. at 18,769.

[33] *See, e.g.*, *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mutual Auto. Insurance Co.*, 463 U.S. 29, 43 (1983) (noting that "an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise"). *See also, e.g.*, *Flynn v. Comm'r*, 269 F.3d 1064, 1072 (D.C. Cir. 2001) (noting that internal housekeeping rules cannot "displace or

The EPA has itself confirmed the substantive nature of the proposed regulation by electing to pursue it through notice-and-comment rulemaking. As the Supreme Court has said, the only actions authorized under the federal housekeeping statute are "what the … [Administrative Procedure Act] terms 'rules of agency organization[,] procedure[,] or practice' as opposed to 'substantive rules.'"[34] And under the APA, "rules of agency organization, procedure, or practice" are exempt from the requirements of notice-and-comment rulemaking.[35] If the proposed rule were actually an internal housekeeping measure, in other words, notice and comment wouldn't have been required. The EPA was correct in concluding otherwise. Its efforts to reframe the proposal now as one that "exclusively pertains to the internal practices" of the agency cannot be taken seriously.[36]

During two recent briefings that were held at the request of the House Committee on Science, Space, and Technology, the EPA provided further confirmation that the proposed rule cannot be dismissed as an internal housekeeping measure.[37] According to a memorandum prepared by the committee's staff, the EPA indicated that "the bulk of the responsibility for instituting new methods for access to data and models" under the proposed rule will "fall[] on outside parties"—both researchers and the Centers for Disease Control.[38] These responsibilities, moreover, promise to be burdensome. Researchers, for instance, "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."[39] And the Centers for Disease Control would be tasked with "hosting the data and models on its own servers, with CDC personnel working at the secure data enclave reviewing research proposals submitted by members of the public seeking to conduct their own analyses of study data and determining the level of access to grant on a case-by-case basis."[40] In light of the significant burdens the rule would impose on

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override" substantive requirements); *New York v. U.S. Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 516 (S.D.N.Y. 2019) (rejecting the defendant agency's contention that a rule was "mere housekeeping" when it "relocate[d] the metes and bounds—the who, what, when, where, and how—of conscience protection under federal law").

[34] *Chrysler Corp.*, 441 U.S. at 310.

[35] 5 U.S.C. § 553(b)(A).

[36] Supplemental Notice, 85 Fed. Reg. at 15,398. *See, e.g.*, *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 172-73 (2007) (concluding that the Department of Labor had intended for one of its rules to be "a binding application of its rulemaking authority" as the agency, among other things, had "used full public notice-and-comment procedures, which under the Administrative Procedure Act an agency need not use when producing an 'interpretive' rule").

[37] Democratic Staff of the 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 (April 30, 2020) (attached).

[38] *Id.* at 2.

[39] *Id.*

[40] *Id.*

other agencies and private parties, the proposal cannot be defended as a housekeeping measure that governs the internal operations of the EPA.

B. The Environmental Statutes Cited in the Supplemental Notice Offer No Support for the Proposed Rule

In its original notice, of course, the EPA made no attempt to rely on any kind of "housekeeping" power.[41] Instead, the agency said it was "propos[ing] to take this action under authority of the statutes it administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conducting of and reliance on scientific activity to inform those functions[.]"[42] The EPA went so far as to list the specific statutory sections that it believed its rule could rest on, citing:

> Clean Air Act sections 103, 301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C. 1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C. 300j–1, 300j–9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660; Emergency Planning and Community Right-To-Know Act section 328, 42 U.S.C. 11048; Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w; and Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609.[43]

None of these provisions offered any support for the proposed rule—and many were at odds with it. As noted during the prior comment period, "restricting sound science is neither necessary nor consistent with the … goals" of the referenced environmental statutes.[44] A few of the citations, moreover, appeared to be entirely irrelevant.[45]

With its supplemental notice, the EPA appears to abandon its misguided effort to rely on the laws it had previously cited, stating that it no longer "propose[s] to interpret provisions of a

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[41] Original Proposal, 83 Fed. Reg. at 18,769.

[42] *Id.*

[43] *Id.*

[44] August 2018 Coalition Comments at 2-3, 17-30.

[45] *Id.* at 26-27 (noting that 42 U.S.C. § 9616 establishes goals for the EPA "to begin assessment and remediation of facilities on the National Priorities List, and is entirely irrelevant" to the proposal); *id.* at 30 (noting that 42 U.S.C. § 6979 "pertains to labor standards related to wages for laborers and mechanics[,]" and is accordingly "inapposite").

particular statute or statutes that it administers[.]"[46] At the same time, however, the notice declares that the agency is still "taking comment on whether to use its housekeeping authority independently as authority or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rulemaking[.]"[47] And it also corrects two of the citations included in the agency's earlier list, "clarifying that the citation to the Resource Conservation and Recovery Act … section 7009, 42 U.S.C. 6979, should be to … section 8001, 42 U.S.C. 6981[,]" and "the citation to the Comprehensive Environmental Response, Compensation, and Liability Act … section 116, 42 U.S.C. 9616, should be to … section 115, 42 U.S.C. 9615[.]"[48]

Given the EPA's inconsistent statements regarding the relevance of the statutory provisions it has cited, it is not at all clear what the public is being asked to comment on. What is clear, however, is that the agency's two new citations do nothing to support the proposed rule. As none of the environmental statutes the agency has cited provide a legal basis for the proposed action, the EPA would get nowhere in trying to use them "in conjunction" with the agency's asserted and inapposite housekeeping authority.[49]

1. *RCRA Section 8001 Does Not Provide the EPA with Authority to Adopt the Proposed Rule*

Section 8001 of the Resource Conservation and Recovery Act does not allow the EPA to issue the proposed rule.[50] Instead, the provision provides the agency with the authority:

- To conduct, and assist others in conducting, "research, investigations, experiments, training, demonstrations, surveys, public education programs, and studies" relating to solid-waste management;[51]

- To establish a management program or system to coordinate activities relating to solid-waste research, and to facilitate and accelerate the development of new technology;[52]

- To make grants to, and enter into contracts with, public agencies and authorities or private persons relating to solid-waste research;[53] and

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[46] Supplemental Notice, 85 Fed. Reg. at 15,398.

[47] *Id.*

[48] *Id.* at 15,397.

[49] *Id.* at 15,398.

[50] *See* 42 U.S.C. § 6981.

[51] *Id.* § 6981(a).

[52] *Id.* § 6981(b).

[53] *Id.* § 6981(c)(1).

- To detail EPA personnel to agencies eligible for assistance under Section 8001.[54]

Notably absent from the provision is any grant of authority for the EPA to fundamentally change its approach to reviewing scientific research by selectively disregarding or devaluing certain studies. The EPA has also failed to provide a citation to any particular paragraph or subsection of the provision, making it difficult to even understand what language the EPA believes does give it such authority. While Section 8001 does provide the EPA with authority to coordinate research activities, this is plainly intended to *increase* scientific knowledge in pertinent areas and ensure efficiency—not to *exclude* scientific information from consideration or to provide substantive limits on the science that can be used by the agency at the expense of public health. The proposed rule is thus at odds with Section 8001, which accordingly provides no support for the agency's action.

2. *CERCLA Section 115 Does Not Provide the EPA with Authority to Adopt the Proposed Rule*

There is also no plausible reading of CERCLA Section 115 that would provide the EPA with the authority to limit the science it relies on.[55] Section 115 provides that "[t]he President is authorized to delegate and assign any duties or powers imposed upon or assigned to … [the President] and to promulgate any regulations necessary to carry out the provisions of this subchapter."[56] This section accordingly allows the EPA—to whom the President has delegated implementation of CERCLA—to "promulgate any regulations *necessary to carry out*" the statute.[57] The EPA has not shown that the proposed rule is in any way *necessary* to carry out CERCLA. Nor could it. In other words, the EPA has not identified any problems in implementing CERLCA that have resulted from relying on all available scientific knowledge.

Indeed, courts have rejected the view that such general rulemaking provisions authorize the promulgation of any regulation that is "'reasonably related to the purposes of the enabling legislation[,]'" noting that "[a]n agency's general rulemaking authority does not mean that the specific rule the agency promulgates is a valid exercise of that authority."[58] A regulation promulgated under such a provision "cannot stand if it is arbitrary, capricious, or manifestly contrary to the statute."[59] The agency may not use such a provision "to contravene Congress' will[.]"[60]

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[54] *Id.* § 6981(c)(4).

[55] *See* 42 U.S.C. § 9615.

[56] *Id.*

[57] *Id.* (emphasis added).

[58] *Colo. River Indian Tribes v. Nat'l Indian Gaming Comm'n*, 466 F.3d 134, 139 (D.C. Cir. 2006).

[59] *Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 86 (2002) (internal quotations omitted).

[60] *Id.* at 92.

As explained elsewhere in these and previous comments, the proposed rule's restrictions on the use of scientific studies where underlying data is not available will prevent the EPA from considering sound science in its rulemakings and analyses. This is manifestly at odds with CERCLA's focus on protecting human health and the environment. Thus, the EPA cannot rely on Section 115 of CERCLA to support the proposal.

3. *Clean Water Act Section 501 Does Not Provide the EPA with Authority to Adopt the Proposed Rule*

In its supplemental notice, the EPA also points to Section 501 of the Clean Water Act, a provision that was first referenced in the agency's original proposal.[61] Like Section 115 of CERCLA, Section 501 grants general rulemaking authority, authorizing the administrator "to prescribe such regulations as are necessary to carry out" the agency's functions under the Clean Water Act.[62]

For the reasons explained above, and as previously noted, Section 501's general grant of rulemaking authority does not provide support for the proposed rule.[63] Once again, the EPA has failed to explain why the regulation would be "necessary" for implementing the Clean Water Act. It plainly is not, as it would rather undermine the EPA's ability to protect public health and the environment by limiting the scientific studies the agency could consider when setting critical limits for toxic pollutants. And the agency has failed to provide any evidence that its current process for reviewing scientific evidence has been failing it. Limiting the science the EPA can rely on would compromise, not help, the agency's ability to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters"—the very purpose of the Clean Water Act.[64] If the proposed rule is finalized, the EPA will undermine its ability to consider what may be the best or only scientific evidence available. The language of Section 501 does not provide authority for rules that are arbitrary and contrary to the statute—and it accordingly offers no support for the proposed rule.[65]

II. The EPA's Rulemaking Has Flouted the Procedural Requirements of the Administrative Procedure Act and Other Laws

In addition to being at odds with the environmental statutes the EPA is charged with implementing, the present rulemaking has fallen short of the requirements of the Administrative Procedure Act. Under the APA, a federal agency generally may issue a regulation only after providing members of the public with sufficient notice of the proposed rule and a meaningful

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[61] Supplemental Notice, 85 Fed. Reg. at 15,397; Original Proposal, 83 Fed. Reg. at 18,769.

[62] 33 U.S.C. § 1361(a). While the EPA has failed to identify the specific language in Section 501 that it means to rely on, none of the statute's other provisions appear to have any possible relevance to the proposed rule. *See id.* § 1361(b)-(f).

[63] August 2018 Coalition Comments at 24-25.

[64] 33 U.S.C. § 1251(a).

[65] *See Colorado River Indian Tribes*, 466 F.3d at 139; *Ragsdale*, 535 U.S. at 86.

opportunity to comment.[66] As "these procedural requirements are intended to assist judicial review … [and] provide fair treatment for persons affected by a rule[,]" they demand "an exchange of views, information, and criticism between interested persons and the agency."[67] An agency's notice of proposed rulemaking accordingly "must disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based."[68] The agency must also give members of the public sufficient time to respond.[69] The EPA has failed on both of these fronts. And its rulemaking has violated the procedural requirements of other statutes, as well.

A. The EPA Has Failed to Explain Why the Proposed Rule Is Necessary and What, Exactly, It Would Require

While the EPA has had more than two years, now, to explain why the proposed restrictions on science are necessary, it has yet to offer any evidence or substantial arguments in their defense. As the agency's own Science Advisory Board recently noted in its comments on the proposal, "[t]here 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."[70]

The EPA's continued failure to provide such "justification" has significant substantive and procedural implications.[71] Substantively, the agency's unwillingness to address the implications of its proposal has disguised the severe problems the regulation would cause. In the words of the Science Advisory Board:

> It is plausible that in some situations, the Proposed Rule will decrease efficiency and reduce scientific integrity, [and] 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.[72]

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[66] 5 U.S.C. § 553(b)-(c).

[67] *Home Box Office, Inc. v. F.C.C.*, 567 F.2d 9, 35 (D.C. Cir. 1977).

[68] *Id.*

[69] *See* 5 U.S.C. § 553(c).

[70] Science Advisory Board Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled "Strengthening Transparency in Regulatory Science" (Apr. 24, 2020) ("SAB Comments") (attached), at 18.

[71] *Id.*

[72] *Id. See also id.* at 1 (noting that "key considerations that could inform the Proposed Rule are not present in the proposal, or presented without analysis").

Procedurally, the EPA's silence has denied members of the public a meaningful opportunity to comment on the proposal. In the words of the D.C. Circuit, the EPA "has an obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible."[73] The agency's refusal to do this cannot be squared with the requirements of the Administrative Procedure Act.[74]

The inadequacy of the EPA's rulemaking notices, unfortunately, have not been limited to their omission of essential explanation and analysis. As explained more fully below, the EPA has also failed to articulate clearly what the proposed rule would even require, obscuring the implications of the regulation with vague language and broad grants of discretion. The Science Advisory Board repeatedly emphasized this problem in its comments on the proposal, noting, for example, that:

- "[C]ertain key terms and implementation issues have not been adequately defined or described" in the proposed rule;[75]
- "Given the relatively skeletal nature of the Proposed Rule, it is not possible to define the implications of the rule with confidence";[76]
- "To ensure that the rule is evidence-based EPA must provide greater clarity regarding details of the rule and how it will be implemented, as well as example analyses of how it would be deployed";[77]
- "The lack of specific criteria for what might satisfy the [proposal's availability] requirement makes it difficult for the SAB to understand the implications";[78]
- "Given the lack of clarity in the Proposed Rule, it is difficult to understand how this regulatory action could be accomplished in a standardized and consistent manner";[79]
- "[T]he lack of criteria for what data might satisfy the requirements of the Proposed Rule makes it difficult to understand the implications for protection of [personally identifiable information]";[80]

[73] *Home Box Office*, 567 F.2d at 36.

[74] *See id.*

[75] SAB Comments at 1.

[76] *Id.* at 2.

[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] *Id.*

- "[G]reater clarity is needed in definitions of 'data and models' and 'pivotal regulatory science[,]'" as "[t]he definitions provided in the Proposed Rule are not adequate";[81]

- "Case-by-case exceptions [to the proposal's requirements] without criteria may create public concerns about inappropriate exclusion of scientifically important studies";[82]

- "The requirement in the Proposed Rule that 'data' be made publicly available is vague and, as a result, can be interpreted in different ways";[83] and

- "More clarity is … needed to define the nature of the 'data' that must be publicly available."[84]

The inscrutability of the proposed rule is unacceptable. Under the APA, a rulemaking proposal "must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking."[85] Until the EPA has clarified the meaning and implications of its proposal for members of the public, it cannot move forward with this rulemaking.

B. The EPA Has Failed to Provide Members of the Public with an Adequate Opportunity to Review and Comment on the Proposed Rule

In addition to denying members of the public adequate notice regarding the terms and basis of the proposed rule, the EPA has failed to afford a sufficient amount of time for reviewing the proposal and preparing comments. Following the publication of Administrator Pruitt's original proposal in 2018, the EPA accepted written comments for more than a hundred days and invited members of the public to share their views at a hearing.[86] Now, after proposing a much broader regulation in the midst of a national health emergency, the agency has elected to

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[81] *Id.* at 3.

[82] *Id.* at 4.

[83] *Id.*

[84] *Id.* at 5.

[85] *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983). *See also, e.g.*, *Shell Oil Co. v. EPA*, 950 F.2d 741, 751 (D.C. Cir. 1992) (noting that "[i]nterested parties cannot be expected to divine the EPA's unspoken thoughts"); *Home Box Office*, 567 F.2d at 36 (noting that a federal agency "has an obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible").

[86] *See* Extension of Comment Period and Notice of Public Hearing: Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 24,255, 24,256 (May 25, 2018) (extending the comment period on Administrator Pruitt's April 30, 2018 proposal through August 16, 2018).

authorize a comment period of only 61 days—and to refuse to convene a public hearing.[87] The EPA's decision to limit the public's opportunity to comment was arbitrary and unlawful.

The Administrative Procedure Act requires federal agencies to ensure that members of the public have a "meaningful opportunity" to comment on proposed rules.[88] Given the nature of the pending proposal and the current public-health crisis, such an opportunity could not be afforded in only 61 days. Under the proposed rule, the agency could often be precluded from relying on scientific studies as the basis for public-health protections. In order for the EPA to understand the implications of the proposed restrictions on science, it needs to hear from the nation's scientists and public-health experts—the very people who are now on the frontlines of the pandemic. By refusing to hold the comment period open until the national health emergency has come to an end, the EPA has denied itself essential information on the implications of the proposed rule. And it has failed to provide members of the public with a meaningful opportunity to be heard.[89]

As previously explained, the current rulemaking process has also violated the requirements of other statutes the EPA may or may not be relying on in attempting to issue the proposed rule.[90] Under FIFRA, for instance, the EPA is required to provide the Secretary of Agriculture with a copy of any proposed rule for review and comment at least 60 days before a proposed rule is signed for publication in the Federal Register.[91] And under the Clean Air Act, the EPA is directed to "give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions[,]" and to "keep the record of such proceeding open for thirty days after completion of the proceeding to provide an opportunity for submission of rebuttal and supplementary information."[92] The EPA's refusal to satisfy these requirements cannot be allowed to stand.

III. The Expanded Reach of the Proposal Will Further Undermine the EPA's Ability to Protect Public Health and the Environment

With its original proposal, the EPA seemed to recognize that significant costs would result from a regulation that required only dose-response data and models to be made publicly

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[87] Supplemental Notice of Proposed Rulemaking: Extension of Comment Period, 85 Fed. Reg. 21,340 (Apr. 17, 2020).

[88] *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009). *See also* Executive Order 12,866, 58 Fed. Reg. 51,735 (Sep. 30, 1993) (directing federal agencies to "afford the public a meaningful opportunity to comment on any proposed regulation").

[89] *See* Request for Public Hearings and an Extension of the Comment Period on the "Strengthening Transparency in Regulatory Science" Supplemental Notice of Proposed Rulemaking (Mar. 25, 2020) (Docket ID No. EPA-HQ-OA-2018-0259-9493).

[90] *See* August 2018 Coalition Comments at 63-67.

[91] 7 U.S.C. § 136w(a)(2)(A) (cited in August 2018 Coalition Comments at 63-64).

[92] 42 U.S.C. § 7607(d)(5) (cited in August 2018 Coalition Comments at 43, 64).

available.[93] The agency accordingly claimed that it was carefully narrowing the reach of its rule. "By limiting the proposed rule to pivotal regulatory science[,]" the agency declared, "the proposed rule ensure[d] that … [its] standard for transparency [would] affect[] a smaller subset of regulations which are economically significant, create inconsistency for other federal agencies, alter budgetary impacts, or raise novel legal or policy issues."[94]

The supplemental notice discards the limitations of the original proposal, "expand[ing] the scope of th[e] rulemaking" so that it will apply to both "influential scientific information" and "data and models" of every kind.[95] This expansion promises to further undermine the EPA's ability to fulfill its statutory duties by protecting public health and the environment.

A. The Proposed Rule's Data-Availability Requirements Will Not Improve the Quality of the Science Used by the EPA

Throughout the proposed rulemaking, the EPA erroneously conflates the public availability of underlying data with the accuracy of a study. This conflation is contrary to well-established standards of scientific practice, in which the process of peer-review ensures that studies are vetted for accuracy. While many scientific journals are starting to make more data publicly available, it is important to note that the availability of data underlying published studies has no bearing on evaluating the accuracy of the studies. In fact, access to unprocessed data at the stage described in the supplemental notice is typically not a requirement even for peer-review, as scientists can evaluate the robustness and accuracy of findings based on the presentation of processed data and the articulation of the methods and analysis used.[96]

Less than 30 percent of scholarly literature is open-access, and only a small fraction of these include access to underlying raw data.[97] Journal-specific transition plans to increase access involve long timeframes to accommodate these changes, which are often voluntary opt-ins for participating researchers.[98] Notably, these open-access programs typically refer only to public

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[93] Original Proposal, 83 Fed. Reg. at 18,772.

[94] *Id.*

[95] Supplemental Notice, 85 Fed. Reg. at 15,397, 15,398, 15,399-400.

[96] Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel, and Deborah Sweet, Joint Statement on EPA Proposed Rule and Public Availability of Data, Nature (Apr. 30, 2018) (attached), *available at* https://www.nature.com/articles/d41586-018-05026-y.

[97] *See* Piwowar, *et al.*, The State of OA: A Large-Scale Analysis of the Prevalence and Impact of Open Access Articles (2018) (attached), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5815332/. *See also* Lisa M. Federer, *et al.*, Data Sharing in PLOS ONE: An Analysis of Data Availability Statements, PLOS ONE (May 2, 2018) (attached) (about 20 percent of articles in the open-access journal *PLOS* follow practice of including data in publicly available repository), *available at* https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0194768.

[98] *See* Richard Van Noorden, *Nature* to Join Open-Access Plan S, Publisher Says, Nature (Apr. 9, 2020) (attached), *available at* https://www.nature.com/articles/d41586-020-01066-5.

access to the published studies themselves rather than to underlying raw data as required in the proposed rule, which is contrary to standard scientific practice.

Given this, it is not surprising that a group of scientists and the editors-in-chief of leading scientific journals, including *Science, Nature*, *Proceedings of the National Academy of Science, Public Library of Science*, and *Cell*, denounced the proposed rule. In a 2018 joint statement, the group noted that "the merits of studies relying on data that cannot be made publicly available can still be judged." The group further noted that scientific studies typically contain all the information required to judge the accuracy and robustness of their findings without access to raw data. "[A]s a core skill, scientists are trained in assessing research publications by judging the articulation and logic of the research design, the clarity of the description of the methods used for data collection and analysis, and appropriate citation of previous results."[99]

While the EPA argues the proposed rule will strengthen the quality of the agency's science, it points to no evidence to support that statement. Instead, the evidence shows that the rule's misguided emphasis on data availability rather than accuracy will actually weaken the body of evidence available to the agency. While full consideration of the range of observations reported in peer-reviewed scientific literature provides a method for comprehensively estimating trends, means, and variances in data, arbitrarily omitting studies can result in skewed interpretations.[100] Furthermore, as explained above, failing to consider all available science based on arbitrary exclusion criteria explicitly violates established guidelines and statutory mandates in several contexts.

In its assessment of the proposed rule, the EPA's own Science Advisory Board warned against the introduction of bias by selectively excluding data. According to the SAB:

> 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

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[99] Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel, and Deborah Sweet, Joint Statement on EPA Proposed Rule and Public Availability of Data, Nature (Apr. 30, 2018) (attached), *available at* https://www.nature.com/articles/d41586-018-05026-y.

[100] *See, e.g.*, Hans C. van Houwelingen, Lidia R. Arends, and Theo Stijnen, Advanced Methods in Meta-analysis: Multivariate Approach and Meta-regression, Statistics in Medicine (Feb. 28, 2002) (attached), *available at* https://onlinelibrary.wiley.com/doi/abs/10.1002/sim.1040; Matthias Egger, *et al.*, Meta-analysis: Principles and Procedures, BMJ (1997), *available at* https://www.bmj.com/ content/315/7121/1533; Koricheva, J., Gurevitch, J., and Mengersen, K., Handbook of Meta-analysis in Ecology and Evolution, Princeton University Press (2013).

> containing the mechanisms for exclusions based on criteria defined by EPA and provide constructive considerations.[101]

In 2018, a group of scientists and editors-in-chief at leading scientific journals raised similar objections in a second joint statement in response to the proposed rule:

> It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.[102]

The expanded scope of impacted science in the supplemental proposal only exacerbates this problem by allowing the EPA to arbitrarily exclude studies for factors unrelated to their accuracy across all scientific disciplines. The new proposal's arbitrary expansion of the scope of what science could be excluded cannot survive scrutiny for precisely the same reasons that doomed the original proposal. There is simply no need to limit consideration of reliable science simply because the underlying data is not publicly available—and it would be unlawful to do so.

B. The Expansion of the Proposal to Data and Models of Every Kind Would Have Significant Impacts the EPA Has Failed to Consider

The expansion of the proposal from dose-response data and models to all data and models represents a major departure from the original rule, and the EPA has failed to adequately consider the wide-reaching implications of this expansion on the scope of impacted science. Numerous comments submitted in 2018 in response to the original proposed rulemaking called for greater clarity on the use of the terms "dose response data and models," which were themselves used inconsistently and viewed as too broad in scope.[103] Rather than addressing these concerns by providing greater specificity, the EPA has moved entirely in the opposite direction by expanding the breadth of impacted studies in the supplemental notice.

In describing the new scope of its proposal, the EPA lists a wide range of data and models that include, but are not limited to, "environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on environmental releases, exposure estimates, quantitative structure activity relationship data, and environmental

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[101] SAB Comments at 16.

[102] Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel, and Deborah Sweet, Joint Statement on EPA Proposed Rule and Public Availability of Data, Nature (Apr. 30, 2018) (attached), *available at* https://www.nature.com/articles/d41586-018-05026-y.

[103] Supplemental Notice, 85 Fed. Reg. at 15,399.

studies."[104] Each of these types of data and models involves unique challenges related to feasibility, privacy, and sensitivity that the EPA fails to acknowledge. The EPA fails to explain why independent analysis and validation is necessary to assess the integrity of any of the types of data and models now included within the scope of the proposal, and whether access to the underlying data is at all feasible.

1. *The Expanded Scope of Impacted Data and Models Jeopardizes Privacy and Sensitivity for a Wider Range of Studies*

Rather than fixing the problems inherent in the original proposal, the supplemental notice instead expands the scope of the rulemaking to encompass an even broader array of scientific data and models, thereby jeopardizing privacy and sensitivity for an even wider range of studies. Each subdiscipline of scientific research impacted by the expansion of the proposal involves unique challenges related to privacy. Epidemiological and public-health studies often involve confidential data related to people, and researchers must protect the privacy of study participants, rendering disclosure of the underlying data impossible and in some cases unlawful.[105] Many of these concerns were raised in detail in comments in response to the 2018 proposed rulemaking in relation to dose-response data and models. The supplemental notice attempts to address some of these concerns through potential mechanisms for tiered access to private data or by weighting studies based on the availability of underlying data. As explained below, both of these approaches are misguided and insufficient to address the problems with the original proposal. And the expansion of the rulemaking to apply to all data and models introduces new types of privacy and sensitivity concerns for a broader set of public-health and epidemiological studies, and an entirely new set of concerns for many types of environmental data.

In particular, the supplemental notice lists environmental-fate studies and models as an example of the types of studies included in its new, broader scope. These data and models are critical for the EPA's assessments of the environmental risks of pesticides, for example, and the agency has relied on well-established studies that were conducted before mechanisms existed for sharing data publicly. Furthermore, as described in our earlier comments, this requirement would place an uneven burden on data requirements for pesticide restrictions compared to that required for pesticide approvals, especially if implemented retroactively. The EPA also mentions bioaccumulation data as an example of the types of studies included in the new expansion, which could unjustifiably undermine established science on the accumulation of mercury, lead, and other metals in aquatic systems and wildlife, as well as models used by the EPA for decades to

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[104] *Id.* at 15,400 (acknowledging that the agency has identified "[s]ome, but not the only, examples of information that would be considered to be data and models" under its new proposal).

[105] For example, the "Common Rule" for research involving human subjects prohibits the EPA from relying on research that is "deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm … or impaired their informed consent." *See* 40 C.F.R. §§ 26.1704(b)(2), 26.1705(b); *see also* Leslie Wolf, *et al.*, Certificates of Confidentiality: Protecting Human Subject Research Data in Law and Practice, J. Law Med. Ethics (2015) (attached), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4636332/.

describe accumulation.[106] The requirement for publicly available data underlying all model parameters would be particularly problematic and potentially impossible for models developed iteratively over decades, in which model parameters and structure evolve with growing science without the need for publicly available documentation of all the underlying parameters' source data.

2. *The Expanded Scope of Impacted Data and Models Would Result in Significant Logistical Challenges for Many Newly Impacted Types of Studies*

It would be extraordinarily difficult if not impossible for the agency and external researchers to provide open access for all data and models underlying pivotal regulatory science and pivotal science. In particular, the size and storage practices for many large datasets and model outputs may not be suited for open sharing, and this should not exclude them from consideration. For example, studies involving continuous monitoring of air or water pollutants, greenhouse-gas emissions, or any other type of time-series data require sizable infrastructure and data-handling considerations to accommodate the vast size of these datasets.[107] Similarly, models often utilize specialized software to run, and outputs of model simulations are often not stored permanently, are challenging to distribute, and may be impossible for the agency to reanalyze independently.[108]

The EPA's own Science Advisory Board has warned that "[f]or studies published many years ago, it may not be feasible to deliver public access to data and analytic methods[,]" and "[t]here are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate."[109] Furthermore, the rule could have the effect of removing valid, credible, peer-reviewed studies of health effects as sources to support the agency's regulatory efforts. "The proposed rule does not acknowledge that the epidemiologic science community, for example, has been making significant efforts to make data available where possible and to develop studies based on publicly available data where appropriate."[110] Excluding studies where it is not possible

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[106] *See* EPA, Bioaccumulation and Aquatic System Simulator (BASS), *available at* https://www.epa.gov/ceam/bioaccumulation-and-aquatic-system-simulator-bass#History.

[107] Noel Cressie, Massive Data Sets: Problems and Possibilities, with Application to Environmental Monitoring (1996) (attached), *available at* https://www.nap.edu/read/5505/chapter/17.

[108] Gordon Blair, *et al.*, Data Science of the Natural Environment: A Research Roadmap, Environ. Science (Aug. 2019) (attached), *available at* https://www.frontiersin.org/articles/10.3389/fenvs.2019.00121/full.

[109] Science Advisory Board Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science (June 28, 2018) at 3 (attached), *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/cf0020ec3f99320a85256eb4006b6bd1/4ecb44ca28936083852582bb004ade54/$FILE/EPA-SAB-18-003%20Unsigned.pdf.

[110] *See* Memorandum from Alison Cullen, Chair, SAB Work Group, to Members of the Chartered SAB and SAB Liaisons, Preparations for Chartered Science Advisory Board

to make the underlying data publicly accessible would unnecessarily and irrationally exclude reliable science for no legitimate reason.

These challenges are particularly problematic given the expansive definition of "data," which requires the disclosure of data at a raw, unprocessed stage. Without advance notice and creation of the infrastructure required to securely support the storage and transfer of large volumes of data, the EPA cannot require researchers to categorically accommodate publicly available data and models for all types of pivotal regulatory science and pivotal science.

C. The Expansion of the Proposal to Include All "Influential Scientific Information" Will Further Undermine the EPA's Ability to Protect Public Health and the Environment

The supplemental notice further expands the scope of the proposed rule by broadening the applicability of the regulation to include all studies and analysis that the EPA considers "influential scientific information"—that is, "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[.]"[111] According to the EPA, this "information" includes integrated review plans, integrated science assessments, risk and exposure assessments, policy assessments, peer reviews, health models, and economic models.[112] The new rule would apply to any study that is relied upon in such assessments and may exclude many credible health studies from consideration. Environmental advocates, health scientists, and the EPA's own advisory board have accordingly expressed concerns that the rule will impede agency scientists from relying on the best available science while also compromising scientific integrity.[113]

Importantly, the SAB outlined a number of concerns with respect to the treatment of influential scientific information in the supplemental notice, stating that:

> The EPA's Supplemental Notice of Proposed Rulemaking expands the scope of this requirement to include studies relied upon in influential scientific information (i.e., scientific information that will or does have a clear and substantial impact on important public policies or private sector decisions). In some cases, this requirement could be complex and/or impractical because studies could be

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Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science (May 12, 2018) (attached), at 3.

[111] Supplemental Notice, 85 Fed. Reg. at 15,398 n.5.

[112] *See* EPA, Peer Review Agenda, *available at* https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

[113] *See* August 2018 Coalition Comments at 14; Comments of the Int'l Society for Environmental Epidemiology on EPA's Proposed Rule on Strengthening Transparency in Regulatory Science (EPA-HQ-OA-2018-0259-1973).

> considered when integrating the evidence but not directly used to determine specific regulatory standards or levels.[114]

The SAB goes on to state:

> 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).[115]

Commenters have similar concerns, particularly with respect to the practicability of requiring all information to be made available, given unequivocal statutory deadlines embedded within environmental statues.[116] In 2018, commenters provided detailed examples of influential human-health studies that necessarily relied on sensitive human data.[117] Such studies have led to the crucial strengthening of public-health protections by, for example, linking exposure to chemicals to the risk of disease.[118] Disturbingly, the supplemental proposal vastly expands the scope of studies that might be subjected to the rule, which could greatly weaken public-health protections. The EPA's Peer Review Agenda describes different types of highly influential scientific assessments developed by the agency.[119] It states, "[a] scientific assessment is an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple

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[114] SAB Comments at 2-4.

[115] *Id.* at 17.

[116] *See* August 2018 Coalition Comments at 85-87 (discussing potential delays in the implementation of critical public-health protections).

[117] *Id.* at 10. Epidemiological studies have been foundational to understanding critical connections between exposure to toxic chemicals and public-health harms. For example, links between certain occupations and incidences of cancer were discovered through the precursors to epidemiological studies. *See* Dana Loomis, Neela Guha, Amy Hall, and Kurt Straif, Identifying Occupational Carcinogens: An Update from the IARC Monographs, Occup. & Envtl. Med. (2018) (attached), *available at* http://oem.bmj.com/content/early/2018/05/16/oemed-2017-104944.

[118] August 2018 Coalition Comments at 10-14 (outlining specific studies that have been relied upon to show how certain chemicals pose a danger to health, particularly for vulnerable populations like children).

[119] *See* EPA, Peer Review Agenda, *available at* https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information."[120] The agenda includes a list of influential assessments, including the Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Office of Research and Development), the Peer Review of EPA's Biologically Based Dose-Response Model for Perchlorate (Office of Water), and the EPA's Draft Risk Evaluation for 1-Bromopropane (Office of Chemical Safety and Pollution Prevention), all of which rely on studies that may be arbitrarily excluded if the proposed rule is finalized.[121]

The EPA's Office of Research and Development is the internal scientific-research branch that often conducts research and develops internal scientific assessments used to inform "[a]gency decisions and support the emerging needs of EPA stakeholders, including the Agency's state, tribal, and community partners."[122] The office conducts research across many scientific disciplines, including health and environmental-risk assessments, chemical safety, safe and sustainable water resources, and air and energy research.[123] The office's scientific assessments often rely on critical epidemiological studies (for example, exposure studies, occupational-cohort studies, and case-control studies), as well as toxicological studies, to support its findings. Under the proposed rule, the best available science, which may include studies that involve personally identifiable information, may be restricted from use by the very EPA scientists tasked with "delivering research products to better protect human health and the environment"—the Office of Research and Development's foremost goal."[124]

The EPA's assertion that the proposal would simply be a rule of internal agency procedure cannot be taken seriously.[125] Instead, it will dramatically alter the scientific foundation of the agency's rulemakings under a number of environmental and public-health statutes, leading to dire consequences. Importantly, many other federal and state agencies rely on the scientific assessments developed by EPA scientists in order to make sound environmental and public-health decisions. The continued integrity of the EPA's published assessments is greatly consequential to ensuring environmental and health protections, especially for the commenters' members and the public who will lose effective health protections if the EPA ignores key science.

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[120] *Id.*

[121] *Id.*

[122] EPA, About the Office of Research and Development (ORD), *available at* https://webcache.googleusercontent.com/search?q=cache:9R6AFNYYRBgJ:https://www.epa.gov/about epa/about-office-research-and-development-ord+&cd=1&hl=en&ct=clnk&gl=us.

[123] *Id.*

[124] EPA, Office of Research and Development Strategic Plan, 2018-2022 (2018) (attached), at 3 ("The science and research results that ORD provides form the foundation for the environmental policies that are a precursor to achieving the best possible public and environmental health."), *available at* https://www.epa.gov/sites/production/files/2018-10/documents/ord_strategic_plan_2018_to_2022.pdf.

[125] Supplemental Notice, 85 Fed. Reg. at 15,398.

IV. The Proposed Tiered-Access Option Would Suppress Important Science and Fail to Protect Private Medical Information

As an update to the original proposal, the supplemental notice offers what the EPA describes as an "alternative" approach that would allow for "tiered access" to data and models.[126] Under this approach,

> [w]hen promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will only use pivotal regulatory science and/or pivotal science if the data and models are available in a manner sufficient for independent validation. This includes studies with data and models that are publicly available as well as studies with restricted data and models (i.e., those that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects) if there is tiered access to these data and models in a manner sufficient for independent validation. Tiered access includes the appropriate techniques used to reduce the risk of re-identification and therefore, mitigate certain disclosure privacy risks associated with providing such access.[127]

Not only does the EPA fail to adequately define and explain what "tiered access" means, it fails to describe who will have access to the information and what type of information they will have access to. The alternative approach offered in the supplemental notice does not remedy the grave problems with the original proposal, as it will still arbitrarily exclude sound science. The supplemental notice also admits that under a tiered approach, the EPA will not fully protect confidential information.[128] The EPA should abandon the tiered-access approach, along with the rest of the proposal, as it would not provide additional transparency to the public and the agency has not explained how it will safeguard private information. The tiered-access approach introduced in the supplemental notice problematically and arbitrarily relies on an approach to be developed in the future without providing commenters with the opportunity to comment on the exact tiered-access methodology it will use.

A. The Tiered Access Approach Will Not Be Adequate to Protect Personal Information

While the EPA claims that its tiered-access approach will allow for a reduction in the risk of re-identification, it cannot guarantee that it can fully prevent all such data from being re-identified. An analysis published in 2019 assessed the risks associated with the sharing of data within environmental-health studies, including genetic and medical records, and found an

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[126] *Id.* at 15,399.

[127] *Id.*

[128] *Id.*

increased likelihood of re-identification.[129] There is little discussion as to the criteria the EPA will rely upon to develop such an approach and even then, the EPA can only guarantee a reduction of risk—which means there would remain individuals whose private medical information is at risk of being disclosed. The proposed tiered-access approach is arbitrary and unexplained, as the EPA has failed to provide any analysis to justify the approach. Furthermore, the EPA has not adequately responded to concerns previously raised in comments to substantiate how its tiered approach would remedy existing concerns.[130]

The supplemental notice states that "risk reduction techniques include creating multiple versions of a single dataset with varying levels of specificity and protection[,]" and that "[t]he benefit of tiered access is that data users who wish to conduct activities with a statistical purpose without first obtaining special authorization have access to the versions of the data in the least restricted tiers, allowing them to conduct research while protecting confidentiality."[131] While the notice is unreasonably short on specifics, this suggests how the tiered-access approach might operate, with tiers that are less or more restricted than others. Yet the EPA does not describe which users would be granted access to the vague "higher restricted tiers" and, importantly, what type of information would be made available at each tier. Nor is there any indication of who would be responsible for reviewing access requests and otherwise managing the large databases the revised proposal would require. Based on the agency's recent statements to the House Committee on Science, Space, and Technology, it appears the EPA intends for this burden to be shouldered by other agencies and private institutions.[132]

The EPA asserts that "[u]nder a tiered approach to accessing data and models that include CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects, access is more restricted for more sensitive data and models. Thus, the amount of information available for analysis is dictated by the tier. The greatest amount of information is made available at the most restricted access tier."[133] Again, this fails to describe what criteria must be met or what grounds any member of the public—including researchers or advocates—must have in order to access potentially sensitive information.

Environmental-health research at times requires researchers to collect highly sensitive information, including individual exposure measurements and biomonitoring in personal spaces. Some research may even rely on "wearable sensors (e.g., smartphones and devices like Fitbit)

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[129] Katherine Boronow, *et al.*, Privacy Risks of Sharing Data from Environmental Health Studies, Environmental Health Perspectives (Jan. 10, 2020) (attached), a*vailable at* https://ehp.niehs.nih.gov/doi/10.1289/EHP4817.

[130] *See* August 2018 Coalition Comments at 8.

[131] Supplemental Notice, 85 Fed. Reg. at 15,402.

[132] Democratic Staff of the 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 (April 30, 2020) (attached), at 3.

[133] Supplemental Notice, 85 Fed. Reg. at 15,402.

that continuously collect data such as location, exposure, and biometrics," which creates additional vulnerability.[134] Other researchers have found that the potential consequences of re-identification are severe, noting that:

> Loss of privacy from re-ID could result in stigma for individuals and communities; affect property values, insurance, employability, and legal obligations; or reveal embarrassing or illegal activity…. It could damage trust in research, harming the study and research more generally. Because … [environmental-health] studies often focus on groups with the highest exposures, privacy risks potentially compound harms faced by the most vulnerable communities. Entities that might be motivated to re-identify … [environmental-health] data include, for example, employers or insurance companies (who may wish to discriminate against individuals or properties on the basis of environmental exposures) and corporations affected by environmental regulations (who may wish to discredit litigants or studies demonstrating … [environmental-health] harms, or to discourage participation in … [environmental-health] research). Other parties might leverage the environmental variables to gain access to other parts of the data set, such as sensitive health information.[135]

As the authors note, there may be a number of adverse consequences due to re-identification—consequences that have not been addressed by the EPA. The study goes on to discuss how even limited information made available from multiple studies involving the same dataset allowed researchers to successfully re-identify study participants.[136] Furthermore, researchers in the study were able to re-identify study participants despite the exclusion and redaction of information that could not be shared under the safe-harbor provision of the U.S. Health Information Portability and Accountability Act.[137] In short, the EPA's proposal poses significant threats to personal privacy—threats the EPA has yet to acknowledge and address.

B. The Supplemental Notice Fails to Provide Sufficient Detail about the Tiered-Access Approach

In the original notice, the EPA mentioned "[o]ther federal agencies [that] have developed tools and methods to de-identify private information for a variety of disciplines" as examples of

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[134] Katherine Boronow, *et al.*, Privacy Risks of Sharing Data from Environmental Health Studies, Environmental Health Perspectives (Jan. 10, 2020) (attached), a*vailable at* https://ehp.niehs.nih.gov/doi/10.1289/EHP4817.

[135] *Id.*

[136] *Id.*

[137] *Id.*

approaches to de-identify and protect confidential medical information.[138] However, the Health and Human Services guidance referenced by the EPA acknowledges that de-identification does not fully protect patient information, stating that "[b]oth methods, even when properly applied, yield de-identified data that retains some risk of identification. Although the risk is very small, it is not zero, and there is a possibility that de-identified data could be linked back to the identity of the patient to which it corresponds."[139] As commenters noted in 2018, de-identifying personal information has thus far proven to be ineffective.[140] The supplemental proposal does not offer a resolution that would fully prevent de-identified information from being re-identified.

The supplemental notice states that,

> [a] model of tiered access for data involving PII is the Research Data Center (RDC), National Center for Health Statistics (NCHS), Centers for Disease Control (CDC). 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…. EPA is currently conducting a pilot study using the RDC's secure data enclave to host EPA datasets in a restricted use environment.[141]

The EPA goes on to acknowledge that:

> [d]evelopment of standard data repositories is still ongoing. For example, the White House Office of Science and Technology Policy recently solicited public comments on a draft set of characteristics of data repositories used to locate, manage, share, and use data resulting from federally-funded research. The effort is intended to help federal agencies provide more consistent information on desirable characteristics of data repositories "for data subject to agency Public Access Plans and data management and sharing policies, whether those repositories are operated by government or nongovernmental entities." Information received during this public

[138] Original Proposal, 83 Fed. Reg. at 18,771.

[139] *See* U.S. Dep't of Health and Human Services Office for Civil Rights, Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (Nov. 26, 2012) (attached), at 6, *available at* https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/De-identification/hhs_deid_guidance.pdf.

[140] *See* August 2018 Coalition Comments at 8.

[141] Supplemental Notice, 85 Fed. Reg. at 15,402.

> comment period will, among other things, help inform improved guidance and best practices related to preserving and providing access to data.[142]

The EPA suggests that the RDC is a viable model for its tiered-access protocol. As the protocol has yet to be fully developed, however, members of the public have no way of providing sufficient review or comment on the possible model. At the time of publication of the supplemental notice, there was no indication as to how long this evaluation will take and if it will be a successful model for implementation. Furthermore, the EPA still has not provided a sufficient explanation as to how the agency will consider all information available within a published study as well as an analysis of the costs and resources associated with the implementation of its approach (for example, monetary costs and in-house staff time).

The supplemental notice states the "EPA is proposing a modified version of the 2018 proposed rulemaking regulatory text at 40 CFR 30.5. 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."[143] Importantly, relationships with hospitals and other medical facilities rely on the confidentiality agreed upon by both researchers and the medical network. In instances where the EPA is requiring private medical information to be disclosed in order for scientific studies to be used for decision-making purposes, the risk of breach of contract is not addressed in the supplemental notice. Such agreements cannot be easily renegotiated, especially for existing published studies and data.[144] The alternative proposal provided in the supplemental notice does not address situations where researchers would be contractually precluded from releasing confidential information and does not offer a solution for data that cannot be contractually released. Indeed, even under a tiered-access approach, the EPA could effectively ignore such data and the EPA fails to provide a solution for considering such studies and underlying data under the tiered-access scenario.

Finally, the EPA states that "the Agency does not intend to make all data and models underlying pivotal regulatory science and pivotal science publicly available. There may be instances where EPA does not own the data and models, lacks access to part or all of the data and models or does not have the authority to provide access to part or all of the data and models."[145] Importantly, this explanation fails to consider how the EPA plans to assess which studies and underlying data will be made publicly available, or how it plans to prevent potential bias in its decision to make certain data and models publicly available as opposed to other data and models.

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[142] *Id.*

[143] *Id.*

[144] Owen Dyer, US Rule Would Strip Science from Environmental Policies and Increase Premature Deaths, Warn Scientists, BMJ (Nov. 15, 2019) (attached), *available at* https://www.bmj.com/content/367/bmj.l6544.

[145] Supplemental Notice, 85 Fed. Reg. at 15,402.

V. The Proposal's Weighted-Consideration Alternative Would Undermine the EPA's Ability to Protect Public Health and the Environment

The EPA is also taking comment on "how much consideration should be given to studies when there is limited or no access to the underlying data and models."[146] Even with the limited details on the proposed approach, the EPA's proposal is incredibly discretionary and does not outline any parameters or reasonable discussion as to why a study should be given differential consideration simply because the underlying data and models are unavailable. Under the EPA's alternate approach for weighted consideration, the protocol could be applied to "studies when there is limited … access to the underlying data and models" without considering the quality of the study and the type of data that is available.[147] If the EPA gives less weight or decides not to consider studies with limited underlying data availability, the consequence will likely be harm to public health.[148] The EPA's staff may fail to fully consider and include credible and valuable studies in its policy recommendations, which would greatly inform decision-making and health outcomes.

Indeed, the EPA states that "[i]n developing … [a] significant regulatory decision or influential scientific information, the EPA will identify those studies that are given greater consideration and provide a short description of why greater consideration was given. However, the Agency may still consider studies where there is no access or limited access to underlying data and models."[149] The EPA must use the best available science and it cannot exclude or down-weight a study that has undergone rigorous peer review that sufficiently analyzed the quality of the study. In their joint statement regarding the proposed rule, the editors-in-chief of six highly regarded journals voiced disagreement with the EPA's proposal by noting that "[d]iscounting evidence from the decision-making process on the basis that some data are confidential runs counter to the EPA stated mission 'to reduce environmental risks … based on the best available scientific information.'"[150]

The supplemental notice states that, "[w]hen promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will, other things equal, give greater consideration to studies where the underlying data and models are publicly available in a manner sufficient for independent validation."[151] The EPA cannot arbitrarily give greater or lesser weight to studies solely because of the public availability of underlying data. The agency has failed to articulate a rational connection between the availability of underlying data and the quality, significance, and scientific soundness of a study. Nor could it. By reducing the weight

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[146] *Id.*

[147] *Id.*

[148] *See* August 2018 Coalition Comments at 88-90.

[149] Supplemental Notice, 85 Fed. Reg. at 15,402.

[150] H. Thorp, *et al.*, Joint Statement on EPA Proposed Rule and Public Availability of Data, Science (Dec. 6, 2019) (attached), *available at* https://science.sciencemag.org/content/366/6470/eaba3197.

[151] Supplemental Notice, 85 Fed. Reg. at 15,402.

given to studies on the basis of data availability, the EPA would wrongly downgrade the importance of study findings, which would ultimately affect the EPA's ability to address well-documented health harms.[152]

The EPA's approach would also limit older studies arbitrarily. There are studies for which the availability of information is limited and cannot be replicated.[153] Furthermore, as acknowledged by the SAB, reanalysis of older studies involving large amounts of data would require "an enormous amount of work," and the supplemental notice does not provide an estimate of the cost and time required to sufficiently review the underlying data of such a study. Instead, an older yet critical study that, for example, examined blood-lead levels in children in the 1990s may be unnecessarily and arbitrarily down-weighted.[154] The EPA has indicated that it could use its exemption authority under section 30.9 of the proposed rule to allow reliance on older studies for which data, codes, and models are no longer available. Such exemption authority offers no assurance, however, that older studies will be considered because the exemption rests solely on the discretionary judgment of the EPA's administrator. Moreover, the exemption option adds yet another layer of arbitrariness to the proposal as the rule would still allow the EPA to deny an exemption even if a study is old and the data no longer available. The rule provides no meaningful limits on the degree of EPA discretion here. As such, the weighted approach and the exemption provision would allow the EPA to arbitrarily decide what to include and exclude, with no real accountability.

The supplemental notice states that:

> EPA is requesting comment on how to ensure that, over time, more of the data and models underlying the science that informs significant regulatory decisions and influential scientific information are available to the public for independent validation in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification". … [And] EPA is interested in comments about how to provide sufficient incentives and support to researchers to increase access to the data that may be used as pivotal regulatory science or pivotal science.[155]

This is a request for solutions to a problem that doesn't exist. The EPA has not shown that its regulatory decisions and scientific analyses have been at all compromised due to the public not having access to the models and data underlying scientific studies. Seeking to require or promote greater public accessibility to models and data underlying studies is not the EPA's role; the agency was established to protect public health and the environment using the best available

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[152] *See* August 2018 Coalition Comments at 14-17.

[153] *See* Marianne Lavelle, Trump EPA's 'Secret Science' Rule Would Dismiss Studies that Could Hold Clues to Covid-19, Inside Climate News (April 8, 2020) (attached), *available at* https://insideclimatenews.org/news/07042020/epa-secret-science-coronavirus-covid.

[154] *See* August 2018 Coalition Comments at 10-11, 89-90.

[155] Supplemental Notice, 85 Fed. Reg. at 15,403.

science, not to attempt to tell scientists how to do their jobs. Finally, there is no way to ensure that the EPA's approach would honor "legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification[,]" nor does the EPA offer any explanation as to how it would address these issues.[156]

VI. The New Definitions Included in the Supplemental Notice Are Inadequate

The supplemental notice includes definitions for several terms which were previously ambiguous or used inconsistently throughout the proposed rulemaking. However, the proposed definitions for *capable of being substantially reproduced* and *reanalyze* remain poorly defined, with wide margins for personal interpretation and judgement to introduce manufactured uncertainty into robust scientific findings. The proposed definition of *data* requires clarification and justification related to the degree of processing acceptable. These definitions impact all aspects of the proposed rulemaking as they are used throughout, and the EPA must either revise these definitions or provide greater specificity in context at each mention, with consideration of the specific implications for all types of data and models.

A. "Capable of Being Substantially Reproduced"

According to the proposal, "[c]apable of being substantially reproduced means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error."[157]

Capable of being substantially reproduced is poorly defined, as it is ambiguous and relies on personal judgement. The EPA should specify what an "acceptable degree of imprecision or error" means for specific types of data and models. Without greater specificity, the degree of imprecision or error found to be *acceptable* will vary between decision-makers. C*apable of being substantially reproduced* could be defined, for instance, relative to the impact of reproducing data on directional outcomes or by providing specific quantitative thresholds for acceptable degrees of imprecision or error.

B. "Data"

The 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."[158]

The selected definition of *data* describes data in a raw format, with only the removal of obvious errors. In using this definition throughout the proposed rulemaking, the EPA poses a major feasibility challenge for many types of data, as described above. This standard also carries

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[156] *See id.*

[157] *Id.* at 15,405.

[158] *Id.* at 15,401

the least protection of sensitive or private data compared to more processed data. This definition would be particularly problematic if the rulemaking were applied retroactively, as raw data is less likely to be available over time compared to more processed data. (The proposal, again, should be withdrawn altogether—not retroactively applied.) Additionally, this stage of data is not required for the purposes of reanalysis as defined by the EPA. For example, most frequentist statistical tests can be reproduced with summary statistics of the data (*e.g.*, means and variances) without requiring access to the underlying unprocessed data. Evaluation of the methods, statistical approach, and results presented in peer-reviewed literature is typically sufficient to assess the validity, accuracy, and robustness of findings without direct handling of raw data at the stage described in the agency's definition.

Even the EPA's own Science Advisory Board has indicated that it requires greater time and resources to evaluate the implications of this definition of *data* for the myriad types of data included under the broader scope of the supplemental notice:

> 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.[159]

The EPA fails to provide justification for requiring this most stringent stage of data at all times. Independent validation and reanalysis—neither of which are actually necessary for the EPA to assess the robustness of published studies—can often be conducted with more processed forms of data. Rather than categorically requiring the rawest form of data across all contexts, the EPA must attempt to justify the rule's requirements in specific contexts and for specific types of data and models to avoid eliminating studies where access to less processed data would jeopardize privacy or lead to logistical challenges for data sharing. In short, the EPA has failed to justify why this stage of data is required when its proposed reanalyses may be conducted with more processed data in several contexts, which would reduce the burden on researchers, improve feasibility, and avoid unnecessarily jeopardizing privacy and sensitivity concerns.

C. "Reanalyze"

The EPA defines *reanalyze* as meaning "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."[160]

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[159] SAB Comments at 19.

[160] Supplemental Notice, 85 Fed. Reg. at 15,405.

The EPA's definition of reanalysis should not include the use of *different* statistical software, models, and methodologies, as it should limit the definition to only the use of the same methods. The use of different statistical tests to assess the same data is a new analysis rather than a reanalysis. The EPA has failed to specify the stage of data required for reanalysis and has not considered the implications of this definition on all types of data and models expected to be impacted by the expanded scope of this rulemaking. In the absence of specifying a consistent framework for the types of statistical analyses required for specific types of data to ensure consistency across reanalyses, the ambiguity in the definition of reanalysis invites opportunities for manufacturing uncertainty through conflicting results from alternative statistical tests. This approach inherently violates standard scientific process as attempts for reanalysis will disproportionately be targeted towards findings some would like to undermine.[161] Notably, several examples exist within public-health and epidemiological studies where reanalysis funded by industry groups resulted in the emergence of less protective results related to toxicity or mortality estimates for different compounds.[162] Without consistent guidelines for when reanalysis is required and what statistical tests are utilized, the proposal risks introducing bias through "statistical fishing expeditions."[163]

VII. Applying the Proposed Rule Retroactively to Data and Models Generated Prior to the Rulemaking Would Be Arbitrary and Contrary to Established Scientific Practice

The proposed rule must not be applied retroactively to existing data, models, and studies—indeed, it must not be applied at all. Complying with the requirements of the proposed rule would represent a significant departure from standard scientific practices, as data availability typically has no bearing on the accuracy or robustness of scientific findings.[164] If it finalizes the proposed rule—which it should not do—the EPA must provide adequate notice to allow researchers to attempt to comply with the rule's requirements, which will impact not only data

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[161] Raymond Richard Neutra, *et al.*, Toward Guidelines for the Ethical Reanalysis and Reinterpretation of Another's Research, Epidemiology (May 2006) (attached), *available at* https://journals.lww.com/epidem/Fulltext/2006/05000/Toward_Guidelines_for_the_Ethical_Reanalysis_and.21.aspx.

[162] Levy, *et al.*, Beryllium and Lung Cancer: A Reanalysis of a NIOSH Cohort Mortality Study, Inhal. Toxicol. 14:1003-15 (2002) (attached); Paustenbach, *et al.*, Reevaluation of Benzene Exposure for the Pliofilm (Rubberworker) Cohort (1936–1976), J. Toxicol. Environ. Health. 36:177-231 (1992) (attached); Paustenbach, *et al.*, Benzene Toxicity and Risk Assessment, 1972–1992: Implications for Future Regulation, Environ. Health Perspect. 101(Supp. 6):177-200 (1993) (attached); Michaels, *et al.*, Selected Science: An Industry Campaign to Undermine an OSHA Hexavalent Chromium Standard, Environmental Health 5:5 (2006) (attached).

[163] *See* Dimitri Christakis and Frederick Zimmerman, Rethinking Reanalysis, JAMA (Dec. 18, 2013) (attached), *available at* https://www.vumc.org/socks/sites/vumc.org.socks/files/public_files/Rethinking%20Reanalysis.pdf.

[164] Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel, and Deborah Sweet, Joint Statement on EPA Proposed Rule and Public Availability of Data, Nature (Apr. 30, 2018) (attached), *available at* https://www.nature.com/articles/d41586-018-05026-y.

reporting but privacy agreements for data collection. Furthermore, without ensuring that infrastructure exists to make such data sharing feasible, the EPA cannot expect previously generated data and models to be able to be shared. The EPA's Science Advisory Board has rightly warned that "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."[165]

Retroactively applying the proposed rule to existing science would arbitrarily and unjustly eliminate a large collection of established, peer-reviewed, and verified science generated prior to the establishment of the rule's expectations. The proposed rule would impose new challenges for researchers related to data handling, storage, and the protection of sensitive information, and studies conducted prior to this rulemaking would likely not have made arrangements to allow for sharing of sensitive data publicly in the ways required by the proposal. For example, retroactive application would have uneven impacts on the science underlying pesticide approvals by favoring industry-backed science conducted for new permitting while imposing extra challenges for pesticide restrictions which may rely more heavily on previously conducted studies.

Retroactive application of the proposed rule would conflict with the practice of building scientific studies and models iteratively over time in the context of existing literature, as it would essentially wipe out consideration of older and established studies conducted prior to the establishment of mechanisms for sharing data publicly. Effectively excluding older studies based on this arbitrary criteria would undermine the most critical and foundational studies and impose tremendous challenges for more recent studies to re-establish foundational findings for acceptance under the guidelines described in the rulemaking.

[165] SAB Comments at 17.

VIII. Conclusion

The proposed rule is an arbitrary and unlawful effort to prevent the EPA from using important, peer-reviewed studies when establishing protections for public health and the environment. It must be withdrawn.

Earthjustice

On Behalf Of

Asbestos Disease Awareness Organization (ADAO)
Alaska Community Action on Toxics
Alianza Nacional de Campesinas
American Meteorological Society
Breast Cancer Action
Breast Cancer Prevention Partners
Center for Environmental Health
Clean Cape Fear
Farmworker Association of Florida
Food & Water Watch
Government Information Watch
Greenpeace USA
Healthy Building Network
Humane Society of the United States
Humane Society Legislative Fund
North Carolina Conservation Network
Ocean Conservancy
Oregon Environmental Council
Pesticide Action Network
Sierra Club
Toxic Free NC
Vermont Conservation Voters
Waterkeeper Alliance