COMMENTS OF ATTORNEYS GENERAL OF NEW YORK, NEW JERSEY, CALIFORNIA, CONNECTICUT, DELAWARE, ILLINOIS, IOWA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, NORTH CAROLINA, OREGON, PENNSYLVANIA, WASHINGTON, AND THE DISTRICT OF COLUMBIA, THE SECRETARY OF THE PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION, AND THE ATTORNEYS OF KING COUNTY, WASHINGTON AND THE CITIES OF CHICAGO, LOS ANGELES, NEW YORK, OAKLAND, PHILADEPHIA AND SAN FRANCISCO

August 16, 2018

By Electronic Submission to www.regulations.gov

Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
Washington, DC 20460

Re: Docket ID No. EPA-HQ-OA-2018-0259, Proposal to Limit Use of Scientific Evidence in Rulemaking, 83 Fed. Reg. 18,768 (April 30, 2018).

Dear Acting Administrator Wheeler:

The undersigned twenty-three State Attorneys General and County and City Attorneys respectfully submit the following comments on the U.S. Environmental Protection Agency's (EPA) April 30, 2018 proposal to limit the use of scientific evidence in rulemaking, 83 Fed. Reg. 18,768. The proposed rule would severely limit the scientific evidence that EPA can consider when adopting rules and standards to protect human health and the environment. It violates controlling federal law, is arbitrary and capricious, and contains clear errors in reasoning. The proposed rule was also issued without adequate review, most notably without *any* review from EPA's own science advisors. It will not "improve" the science relied upon by EPA, but will instead exclude much, if not most, of the science underpinning EPA action to protect the environment and our citizens from harm. Coupled with the former Administrator's directive prohibiting EPA grant recipients from serving on scientific advisory panels, the proposal reflects an effort to subvert well-founded agency practices for developing science-based regulations. This proposal is particularly troubling given EPA's critical mission and its significant responsibilities to the American people. EPA's change in leadership provides a unique opportunity to hit the reset button; we urge you to withdraw this harmful and deeply flawed proposal.

EXECUTIVE SUMMARY

While the proposal is worded vaguely, the intent is clear—in developing future regulations to protect human health and the environment, EPA would be precluded from considering relevant, probative scientific studies, models, or other information that have been

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validated through peer review, on the sole basis that the underlying data are not publicly available.

It is equally clear that the proposed rule would violate the very federal laws EPA is required to uphold. To cite just a few examples, in performing its duties, EPA must rely on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices," 42 U.S.C. § 300g-1(b)(3)(A)(i) (Safe Drinking Water Act); on the "best available science," 15 U.S.C. § 2625(h) (Toxic Substances Control Act); on "the latest scientific knowledge," 33 U.S.C. § 1314(a)(1) (Clean Water Act) and 42 U.S.C. § 7408(a)(2) (Clean Air Act); and on "generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies," 42 U.S.C. § 11023(d)(2) (Emergency Planning and Community Right-to-Know Act). Indeed, no federal environmental law so much as suggests that, in setting standards, EPA can ignore the "latest" or "best" or "appropriately designed and conducted" scientific studies whenever any portion of the underlying data is not public—which is often the case for important privacy reasons. The scientific community has made clear that such a limitation is *not* in accordance with best practices. This anti-science approach has stalled in Congress and been rejected by the courts; it has no place at EPA. Indeed, in rejecting an industry effort to impose the same strictures imposed here, the D.C. Circuit was persuaded by EPA's position that "requiring agencies to obtain and publicize the data underlying all studies on which they rely 'would be impractical and unnecessary,'" and agreed with EPA that such a requirement would mean "'much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment.'" *Am. Trucking Ass'ns, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002).

EPA's proposal would also violate the Administrative Procedure Act (APA), 5 U.S.C. § 501 *et seq.*, both because it is arbitrary and capricious, and because it flouts that Act's important procedural requirements. EPA claims that the entire basis for the proposed rule is to ensure that the "pivotal regulatory science" underlying EPA regulations is transparent. But EPA ignores existing laws and policies that already do exactly that and which also take into account the need to protect medical data and other confidential information. This proposed rule would promote transparency in name only; in truth, it would mean that EPA's important decisions would no longer be informed by the latest, best available, and generally accepted science. Disturbingly, the proposed rule's only failsafe is the EPA Administrator's sole discretion to determine on a case-by-case basis that compliance is "impracticable" when making data publicly available is "not feasible." But the proposal provides no standards to govern the Administrator's exercise of discretion in determining "impracticability or "feasibility"—a recipe for the very arbitrariness that the APA prohibits.

With respect to EPA's process, this proposal has been rushed, is vague, and creates more questions than it answers: it does not clearly state the actual parameters of the proposed rule, it is open-ended in terms of alternatives under consideration, and it fails to provide critical information such as projected costs. It is also completely unclear—or worse, contradictory—whether and how this proposed rule would apply to EPA's cost-benefit analyses. Still more troubling, EPA has failed to consult its own Science Advisory Board (SAB) about this proposed rule despite the SAB's assessment that "this rule deals with a myriad of scientific issues for

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which the Agency should seek expert advice."[1] Proposing a rule that limits the use of scientific data without even notifying, let alone consulting, the Agency's own expert scientific advisors is a text book example of an arbitrary and capricious failure to consider "relevant factors." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983).

In light of these substantive and procedural infirmities, it is unsurprising that the proposed rule also makes little sense as a matter of science. Although EPA now claims that science is "better" only when both the underlying information is publicly available and the results reproducible, that position is contrary to the scientific consensus, and EPA provides no support for its assertion. The downsides of this proposal are significant: critical studies already designed and published on virtually all aspects of public health and environmental protection have relied on information for which complete disclosure is impossible for various reasons, including legally mandated confidentiality protections. This is particularly true of seminal and long-standing epidemiological studies that EPA has relied upon in setting air and other health-based standards. Therefore, the proposal would force EPA to ignore important peer-reviewed studies of health effects in future regulatory efforts. As our nation's leading scientists at the National Academies of Sciences, Engineering, and Medicine (NAS) warned in a July 16, 2018 letter to EPA, the proposal's overly stringent transparency requirements "pose a threat to the credibility of regulatory science."[2]

Although EPA stated in its proposal that this rule would not affect any states, and therefore has no federalism implications, nothing could be further from the truth. The adoption of this proposed rule would very likely affect the protectiveness of the standards that EPA sets, which would significantly impact federal and state efforts to protect the quality of our air, water, and land, and the health and welfare of the American people. Some states' environmental laws and regulations explicitly adopt EPA standards in all or some instances, or at the very least require an express justification for any deviation. So it is clear that a fundamental change in how EPA develops standards would most certainly affect state standards, and therefore would affect the health of our residents and our natural resources.

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[1] Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons, *Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)* 2 (May 12, 2018) [hereinafter SAB Work Group Memo], *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[2] Letter from Marcia McNutt, President, Nat'l Acad. of Sciences, C.D. Mote, Jr., President, Nat'l Acad. of Eng. & Victor J. Dzau, President, Nat'l Acad. of Med., to Andrew Wheeler, Acting Administrator, U.S. Envtl. Prot. Agency (July 16, 2018) [hereinafter NAS Letter], *available at* http://www.nationalacademies.org/includes/EPA%20Proposed%20Rule%20Docket%20EPA-HQ-OA-2018-0259%20NASEM%20Comment.pdf.

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For all these reasons, as discussed in detail below, we oppose this misguided proposal to limit the science on which EPA relies. EPA should withdraw this flawed proposal and return to its core mission of protecting human health and the environment.

LEGAL COMMENTS

I. EPA Lacks Statutory Authority to Promulgate the Proposed Rule, Which Conflicts with Statutory Requirements Regarding EPA's Consideration of Scientific Information

Agencies may not adopt or implement regulations that conflict with the statutes under which they are promulgated, and an agency's interpretation of those statutes must always at least be reasonable. *See Chevron, U.S.A., Inc. v. Natural Res. Defense Council, Inc.*, 467 U.S. 837, 842-44 (1984). Accordingly, an agency's regulations cannot be "arbitrary, capricious, or manifestly contrary to the statute," *id.*, or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. § 706. Further, agencies may not rely on general statutory grants of rulemaking authority to promulgate regulations that are otherwise inconsistent with more specific statutory directives. *Global Van Lines, Inc. v. Interstate Commerce Comm'n*, 714 F.2d 1290, 1293-97 (5th Cir. 1983).

In this case, the proposed rule is at odds with provisions of multiple statutes EPA is charged with implementing. For example:

- The Clean Air Act (CAA) requires that air quality criteria "accurately reflect *the latest scientific knowledge* useful in indicating the kind and extent of *all identifiable effects on public health or welfare*." § 108(a)(2), 42 U.S.C. § 7408(a)(2) (emphases added).

- The Safe Drinking Water Act (SDWA) requires that findings which support a determination to regulate a contaminant "be based on *the best available public health information*," and that, in developing the National Primary Drinking Water Regulations, "to the degree that an Agency action is based on science, the Administrator shall use *the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices*." §§ 1412(b)(1)(B)(ii)(II), 1412(b)(3)(A)(i), 42 U.S.C. §§ 300g-1(b)(1)(B)(ii)(II), 300g-1(b)(3)(A)(i) (emphases added).

- The Clean Water Act (CWA) requires that water quality criteria "accurately reflect[] *the latest scientific knowledge*." § 304(a)(1), 33 U.S.C. § 1314(a)(1) (emphasis added).

- The Toxic Substances Control Act (TSCA) requires the Administrator, in decisions based on science, to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed *in a manner consistent with the best available science*," and, in carrying out certain sections of the Act, to "take into consideration information relating to a chemical substance or mixture . . . that is

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reasonably available to [him or her]." § 26(h), (k), 15 U.S.C. § 2625(h), (k) (emphases added).

- The Emergency Planning and Community Right-to-Know Act (EPCRA) requires that a determination to add a chemical to the Toxics Release Inventory "be based on *generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, available to the Administrator*." § 313(d)(2), 42 U.S.C. § 11023(d)(2) (emphasis added).

Even statutory provisions that EPA chose to cite as authority for the proposed action prohibit the Agency from promulgating the proposed rule. For example, CWA § 104(l) explicitly requires that "[t]he Administrator shall . . . develop and issue . . . *the latest scientific knowledge available* in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in water." 33 U.S.C. § 1254(l) (emphasis added). It strains credulity to believe that a directive to issue the "latest scientific knowledge available" somehow imposes a requirement that the Administrator only issue knowledge based on publicly available data, and EPA has not supplied any substantive argument that it does. Similarly, although Section 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) directs that regulations "take into account . . . *the appropriate data* for evaluating [] risk," 7 U.S.C. § 136w (emphasis added), it would be arbitrary and capricious to define "appropriate" to exclude from consideration relevant and valid scientific studies, as EPA proposes to do in this rulemaking. Requirements to review the "latest" and "appropriate" scientific data are not carte blanche to impose new, unscientific limits on that data.

Because the proposed rule would run afoul of these provisions and potentially others,[3] EPA's citation to general rulemaking authorities such as CAA § 301(a), 42 U.S.C. § 7601(a), and CWA § 501, 33 U.S.C. § 1361, is unavailing. Such general provisions of rulemaking authority cannot override more specific statutory directives. *Global Van Lines*, 714 F.2d at 1293-97. Nor can EPA's reliance on 5 U.S.C. § 301 in the notice extending the comment period save its *ultra vires* proposal. 83 Fed. Reg. at 24,256. Known as the "housekeeping statute," 5 U.S.C. § 301 is "simply a grant of authority to the agency to regulate its own affairs," not a general, independent basis for deviating from a specific statutory directive or limiting the scope of other statutes. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 308-12 (1979).

Thus, as a general matter, EPA's obligation is clear: it must base its decisions on such criteria as the latest scientific knowledge, the best available, peer-reviewed science, and/or generally accepted scientific principles or laboratory tests. No statute suggests that EPA, in setting standards, can reject scientific evidence that meets those criteria solely because the underlying data are not public or because the evidence is based on models that otherwise follow long-accepted scientific guidelines. In short, EPA lacks sufficient legal authority to either adopt or implement the proposed rule, and its proposed action conflicts with the statutes it must follow.

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[3] For example, CAA § 184(d), 42 U.S.C. § 7511c(d), "require[s] that the best available air quality monitoring and modeling techniques be used" in setting the criteria for determining ozone contributions in nonattainment areas.

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II. The Proposal Does Not Meet Baseline Rulemaking Requirements and Should Be Withdrawn

a. EPA Failed to Obtain Input from Scientists in Developing a Proposal with Sweeping Impacts on Agency Use of Science

Common sense, good government, and the APA's fundamental requirement for informed decision-making all dictate that an agency developing a proposed rule should consult with persons having expertise regarding the subject matter of the proposal. EPA's Scientific Integrity Policy makes clear that these principles apply with great force here: "it is essential that the EPA's policymakers involve science experts on scientific issues and that the scientific information and processes relied upon in policymaking manifest scientific integrity, quality, rigor, and objectivity."[4] Indeed, Congress mandated in the Environmental Research, Development and Demonstration Authorization Act of 1978 that when EPA provides a proposed rule such as the one at issue here to another federal agency for formal review and comment, it must also provide that same proposal to the SAB: "the Administrator . . . shall make available to the [SAB] such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based." 42 U.S.C. § 4365(c)(1). Yet, as revealed in a June 28, 2018 letter from the SAB Chair to former Administrator Pruitt, EPA violated this fundamental requirement: although EPA provided the proposed rule to the Office of Management and Budget (OMB) for review on April 18, 2018, the SAB never had the opportunity to review it and instead learned of the proposal only from subsequent news reports and the April 30, 2018 *Federal Register* notice.[5]

Nor did EPA obtain input from the NAS or any other external science organizations or experts in developing the proposal. As the SAB work group noted: "Although the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community." SAB Work Group Memo at 3.

EPA offers no explanation for its inexplicable failure to consult with science experts, including the SAB, on this proposal, and it is beyond question that this highly consequential proposal demanded such consultation. Not only is this statutorily required, *see* 42 U.S.C. § 4365(c)(1), but as the SAB Work Group Memo states, "[t]he proposed rule deals with issues of scientific practice and proposes constraints that the [A]gency may apply to the use of scientific studies in particular contexts. As such, this rule deals with a myriad of scientific issues for

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[4] U.S. Envtl. Prot. Agency, *Scientific Integrity Policy* 3, *available at* https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf.

[5] Letter from Michael Honeycutt, Chair, Science Advisory Bd., to E. Scott Pruitt, Administrator, U.S. Envtl. Prot. Agency 2 (June 28, 2018) [hereinafter SAB June 28 Letter], *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf.

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which the Agency should seek expert advice from the [SAB]." SAB Work Group Memo at 2. Underscoring the importance of the issue, the full 44-member SAB followed up on the Work Group's Memo with a unanimous vote to review the proposal and urged EPA to proceed no further until EPA does what it should have done in the first place: "request, receive and review scientific advice from the SAB." SAB June 28 Letter at 1.

Put simply, EPA's effort to rush this proposed rule out the door without any input from the SAB or other scientists violates basic principles of good government and policy-making as well as EPA's legal duty. We urge EPA to withdraw this ill-conceived proposal and to consult with the SAB, the National Academy of Sciences, and the broader scientific community before determining if any rule is needed.

b. The Proposal is Too Vague, Conclusory, and Conditional to Allow for Meaningful Public Participation

EPA's failure to solicit input from the SAB and other scientific groups is exacerbated by its failure to meet the fundamental legal requirements for a valid rulemaking proposal under the APA. The APA requires that "general notice of proposed rulemaking shall be published in the Federal Register," including the "terms or substance of the proposed rule." 5 U.S.C. § 553(b). The straightforward purpose of this requirement is to give the affected public an opportunity to provide meaningfully informed comment on an agency's proposal. *See Home Box Office, Inc. v. Fed. Commc'n Comm'n*, 567 F.2d 9, 35-36 (D.C. Cir. 1977). But here, EPA's notice of proposed rulemaking is vague as to the actual parameters of the proposed rule, is open-ended in terms of the alternatives under consideration, and fails to provide key information such as projected costs. Courts will not hesitate to strike down final rules based on proposals so lacking in specificity. *See, e.g.*, *Horsehead Res. Dev. Co. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) (noting that "general notice that a new standard will be adopted affords the parties scant opportunity for comment").

Far from meeting the requirement to "disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based," *Home Box Office*, 567 F.2d at 35–36, the proposal at issue here creates far more questions than it answers. Most fundamentally, the proposal fails to provide a rationale for EPA to act contrary to accepted scientific practice, i.e., to preclude consideration of probative scientific information that has been subject to rigorous peer review for the sole reason that underlying data are confidential and therefore not publicly available. The proposal states that "EPA believes the benefits of this proposed rule justify the costs," 83 Fed. Reg. at 18,772, but fails to provide any specific information, quantification, or analysis as to what EPA believes are the proposed rule's purported benefits or expected costs, including the significant costs from the loss of probative information that the proposed rule would work to exclude. For example, Section 30.7 of the proposed rule could be read to require EPA to undertake very costly independent review of "pivotal" science on which it relies, but Section 30.8, entitled "How is EPA to account for cost under this subpart?" states only that EPA will "minimize costs." *Id.* at 18,774. The absence of data and analysis in support of EPA's cost-benefit conclusion deprives the public of a meaningful opportunity to evaluate the proposal and thus violates EPA's duty under the APA.

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Further, the proposal says the rule is intended to apply prospectively, but also states that EPA "should be guided by this policy to the maximum extent practicable during ongoing regulatory action." *Id.* at 18,771. Yet it never explains how or why ongoing EPA actions would be subject to the proposed rule and which existing scientific studies are implicated by the proposed rule. It also fails to acknowledge the costs from delays in rulemaking proceedings while EPA performs the additional review called for above and beyond the extensive scientific peer review to which scientific studies have already been subjected. Other open-ended aspects of the proposal similarly fail to provide commenters with a sufficient guide as to what any final rule would look like or how it would operate if adopted. For example:

- The proposal defines "pivotal regulatory science" as "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions." *Id.* at 18,773. However, the proposal does not specify to what extent studies must support regulatory decisions to be considered a "driver," who will determine what qualifies as pivotal regulatory science, or at what stage of the rulemaking process such determinations will be made. The proposal is also unduly vague in its use of undefined terms that are subject to interpretation, such as the use of the term "uncertainty" in Section 30.6 of the proposed rule. *Id.* at 18,774.

- The proposal says EPA "should collaborate" with other agencies to identify strategies to protect private information (such as patient health records) when it is making information publicly available. *Id.* at 18,771. However, there is no timeframe for this process, no explanation of what will happen until such strategies are formed, and no indication of what these strategies will be.

- EPA asks "whether alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other policy vehicles on the programmatic or statutory level would be appropriate as alternative or additional steps." *Id.* It is EPA's job to identify and describe these alternatives, and to explain why it has put forward its particular proposal: it may not, at this late stage, ask amorphous questions on policy design.

- EPA seeks comment on criteria it should use to establish exemptions, whether case-by-case exemptions may be appropriate, whether the proposed rule should apply to a broader or narrower set of regulatory proceedings, and whether certain categories of regulatory actions should be exempt. *Id.* at 18,772. As written, the proposed rule would allow the Administrator to grant exemptions based solely on his or her own determination of what is "feasible" without offering any definition or bounds on that term. *Id.*

- EPA asserts that the proposed rule is generally consistent with a number of policies or reports by scientific groups or scientific journals, but it does not specify in what respects those documents support its proposal, nor does it identify any groups or reports that advocate precluding consideration of non-public data in regulatory decision-making. In fact, contrary to EPA's assertion, the Bipartisan Policy Center, a

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group with which EPA claims consistency, clarified that the proposed rule "is not consistent" with the Center's position "in substance or intent."[6] EPA's false assertion of consistency with the policies and positions of leading science groups thus misleads the public and inhibits their informed participation.

- EPA seeks comment as to "whether the disclosure requirements . . . should be *expanded* to cover other types of data and information, such as, for example, economic and environmental impact *data and models that are designed to predict the costs, benefits*, market impacts and/or environmental impacts of specific regulatory interventions." 83 Fed. Reg. at 18,772 (emphasis added). However, EPA also states that the "pivotal regulatory science" to which the proposed rule would already apply includes "studies, models, and analyses that drive the magnitude of the benefit-cost calculation." *Id.* at 18,770. It is thus unclear whether and how EPA intends the proposed rule to apply to the cost-benefit determinations that it performs.

- The proposal provides no analysis of its environmental impacts and fails to explain how EPA has addressed the requirements of the National Environmental Policy Act, 42 U.S.C. § 4321 *et seq.*

- The proposal fails to meet EPA's obligations under Executive Order 12898, which requires the Agency to address the proposal's "disproportionately high and adverse human health or environmental effects" on "minority and low-income populations." 59 Fed. Reg. 7629 (Feb. 16, 1994). Section IV.K of the proposal incorrectly asserts that Executive Order 12898 does not apply since the proposal "does not establish an environmental health or safety standard," 83 Fed. Reg. at 18,773. But the Executive Order by its own terms applies to the "effects of" all federal agency "programs, policies, and activities," 59 Fed. Reg. at 7629, and thus plainly applies here. While the proposal would jeopardize the health of all Americans, it would have increased impacts upon the nation's most sensitive populations—such as children, those with chronic illnesses, and environmental justice communities.

- The proposal likewise fails to meet EPA's obligations under Executive Order 13045, which requires the Agency to identify and assess environmental health risks that may disproportionately affect children. 62 Fed. Reg. 19,885 (Apr. 23, 1997). That Executive Order also requires each federal agency to "ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks," *id.* at 19,885, and thus applies here.

- EPA states in conclusory fashion that the proposed rule "does not have federalism implications" and "will not have substantial direct effects on the states." 83 Fed. Reg. at 18,772-73. However, the proposal fails to explain whether or how the proposed rule would apply to EPA's review and approval of state standards, and, accordingly,

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[6] Letter from Jason Grumet, President, Bipartisan Policy Center, to E. Scott Pruitt, Administrator, U.S. Envtl. Prot. Agency (May 22, 2018), *available at* https://www.eenews.net/assets/2018/05/31/document_gw_01.pdf.

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deprives commenters of a full and fair opportunity to assess and comment on the proposal's federalism implications.

In sum, EPA's skeletal outline falls far short of the APA's notice requirements and fails entirely to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Natural Res. Defense Council, Inc. v. U.S. Envtl. Prot. Agency*, 859 F.2d 156, 209 (D.C. Cir. 1988). EPA should withdraw the proposal on these grounds alone.

c. EPA Failed to Identify Legal Authority for the Proposed Rule

The APA further requires that a notice of proposed rulemaking contain "reference to the legal authority under which the rule is proposed." 5 U.S.C. § 553(b)(2). "'[T]he required specification of legal authority must be done *with particularity*,'" and "'must be sufficiently precise to apprise interested persons of the agency's legal authority to issue the proposed rule.'" *Global Van Lines*, 714 F.2d at 1298 (quoting H.R. Rep. No. 1980, at 24 (1946) and U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 29 (1947)). EPA has also failed to meet this requirement.

In both the April 30, 2018 notice of proposed rulemaking and the May 25, 2018 notice extending the comment period, EPA discusses statutory authority for the proposed rule, citing to a number of provisions, largely from statutes it implements. 83 Fed. Reg. at 18,769; 83 Fed. Reg. 24,255, 24,256 (May 25, 2018). In particular, EPA invokes the CAA, CWA, SDWA, EPCRA, FIFRA, TSCA, Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and Resource Conservation and Recovery Act (RCRA). 83 Fed. Reg. at 18,769.

But rather than identify legal authority with particularity, the cited statutory provisions mainly set forth EPA's broader authorities to conduct research and promulgate regulations. Few of the cited provisions actually address EPA's ability to pick and choose amongst valid scientific information, studies, and techniques in its formation of environmental standards and modeling, and none authorize the wholesale preclusion of probative, relevant studies, as EPA proposes here. Tellingly, in the proposal itself, EPA requests assistance to determine "whether additional or alternative sources of authority are appropriate bases for the proposed regulation." *Id.* at 18,771. EPA's inability to identify specific statutory authority for its proposed action falls far short of the APA's standard for notice and comment rulemaking, as would any ultimate reliance on statutory authority EPA has failed to cite. *See Global Van Lines,* 714 F.2d at 1297-99.

III. The Proposed Rule Arbitrarily and Capriciously Requires EPA to Exclude Relevant Studies and Models, and is not Saved by Exemption Provisions

The proposed rule opens the door for arbitrariness, bias, and selectivity in its application, in contravention of the factors that Congress has required EPA to consider in setting standards, such as the best available science or latest scientific knowledge.

The proposed rule disregards the APA's bedrock requirement that an agency's decision-making be based on a consideration of the relevant factors and data. *See Motor Vehicle*

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Mfrs., 463 U.S. at 42-43 (articulating standard and citing numerous cases). An agency's action is arbitrary and capricious not only if the agency "entirely fail[s] to consider an important aspect of the problem," but also if it "relie[s] on factors which Congress has not intended it to consider." *Id.* at 43. The proposed rule would call for EPA to do both. First, in excluding studies and models from its consideration based only on whether the underlying data are publicly available or have been subject to additional independent review by EPA, EPA would be excluding studies and models that Congress has instructed it to consider by requiring it to use, for example, the "best available science" or "latest scientific knowledge." Second, because none of the statutes EPA administers specify that, in setting standards, it shall consider whether the studies and models it uses have publicly available data or have been independently reviewed by EPA, EPA would be using factors that Congress did not intend it to rely on in deciding to exclude studies and models based on the proposed rule. *See Am. Trucking*, 283 F.3d at 372 (finding that the CAA does not require EPA to "obtain and publicize the data underlying the studies on which the Agency relies"). EPA's failure to consider otherwise relevant studies and models that do not meet the proposed rule's requirements would therefore be arbitrary and capricious. *See Motor Vehicle Mfrs.*, 463 U.S. at 42-43.

In apparent recognition of the overly limiting nature of the proposed rule's requirements, the proposal also includes a provision that would allow the Administrator to grant case-by-case exemptions based on his or her subjective determination that compliance is "impracticable" because making data publicly available or conducting independent peer review is "not feasible." 83 Fed. Reg. at 18,774. However, allowing the Administrator to make ad-hoc exemptions for specific studies or models does not cure the proposed rule's fatal defect of requiring EPA to consider factors other than those specified by Congress. *See Alltel Corp. v. Fed. Commc'n Comm'n*, 838 F.2d 551, 561 (D.C. Cir. 1988) (holding that an agency "cannot save an irrational rule by tacking on a waiver procedure" because the "essence of waiver is the assumed validity of the general rule"). Rather, because the proposed rule contains no standards requiring the exemptions to be based on the relevance, importance, or scientific validity of the study or model at issue, the Administrator's ability to arbitrarily include certain studies at his or her discretion simply compounds the extent to which the proposed rule would allow EPA to deviate from the requirements of the statutes it is charged with implementing.

In addition, because the proposed rule offers no definition or standards to guide the Administrator's determination of what is "practicable" or "feasible," the exemption provision gives the Administrator broad discretion in making such determinations.[7] Without any

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[7] The exception to the proposed rule's requirement of additional independent peer review, unlike the exception to the transparency requirement, does instruct the Administrator to look at Section IX of the OMB Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005), when making those determinations. *See* 83 Fed. Reg. at 18,774. However, this direction makes little sense because Section IX of the Bulletin primarily discusses situations in which peer review is not *needed* rather than not feasible. *See* 70 Fed. Reg. at 2667 (providing exceptions for individual adjudications, agency regulatory impact analyses, routine information, and accounting and other financial information). The use of Section IX as a guidepost is not only inappropriate but is also unhelpful because almost all of the situations described therein are outside the category of "pivotal regulatory science" that the proposed rule addresses. Notably, although

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standardized and objective criteria, the exemption process could, for example, allow biased determinations by the Administrator that provide an exception for confidential business information in studies submitted by chemical and pesticide manufacturers, while excluding academic toxicology or epidemiology studies. The NAS also highlighted this concern, noting that "[d]ecisions about exemptions should be based on formal agency guidance and not according to criteria established by a single EPA employee." NAS Letter at 3. Given how severely the proposed rule would limit the scientific evidence available for EPA's use, the proposed exemption provisions could become the basis upon which *most* of the science relied on by EPA in its rulemaking is admitted. The exceptions could thus largely swallow the rule, resulting in greater arbitrariness in EPA regulatory actions rather than greater transparency.

IV. Existing Statutes, Policies, and Procedures Already Provide for Transparency and Ensure Scientific Reliability, Rendering the Proposed Rule Unnecessary

a. Existing Laws and Policies Promote Transparency

EPA's proposal is unnecessary because existing laws and policies already fulfill its stated purpose. EPA claims that the rule will ensure that the "pivotal regulatory science" underlying "significant" EPA regulations is fully transparent, and will ensure that underlying data and models are publicly available in a manner sufficient for independent validation. 83 Fed. Reg. at 18,770. Notwithstanding its stated purpose, the proposed rule would not add anything useful to the existing body of policies and laws already in place, which include mechanisms to provide for maximum transparency while taking into account the need to protect the privacy of medical data, confidential business information, and the like. These existing laws and policies include the following:

- A directive issued on February 22, 2013, by the White House Office of Science and Technology Policy directing federal agencies with more than $100 million in annual research and development expenditures (which includes EPA) to develop plans for increasing public access to the results of the research they support, specifically scholarly publications and digital data.[8]

- OMB Memorandum 13-13,[9] which mandates, among other things, broader public access to federal and federally funded data and information, and provides that

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there is an exemption for time-sensitive disseminations when the findings of a study have already been adequately peer-reviewed, there is no general exception for situations in which independent EPA review would be duplicative of external peer review that has already been performed.

[8] Memorandum from John P. Holden, Director, Executive Office of the President, Office of Science and Technology Policy, to Heads of Executive Departments and Agencies, *Increasing Access to the Results of Federally Funded Scientific Research* (Feb. 22, 2013), *available at* https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf.

[9] Memorandum from Sylvia M. Burwell, Dir., Steve VanRoekel, Fed. Chief Info. Officer, Todd Park, U.S. Chief Tech. Officer &Dominic J. Mancini, Acting Administrator of the Office of Info.

ED_002389_00029319-00012

information collection should be done in a way to support information dissemination. This includes building redaction, slicing, and exporting into how data are collected to reduce the cost of public access later on. The memorandum also requires agencies to create data catalogs to include datasets "that can be made publicly available but have not yet been released." *Id.*

- The Data Quality Act, also known as the Information Quality Act, which is designed to improve the quality, objectivity, utility, and integrity of data released by the federal government. 44 U.S.C. § 3501. Pursuant to this act, EPA issued *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*.[10] These Guidelines, which apply to rulemaking, among other things, provide that "EPA intends to ensure reproducibility according to commonly accepted scientific, financial, or statistical standards. . . . [I]f access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken." *Id.* at 21.

- The Data Access Act (attached as a rider to the Omnibus Appropriations Act of fiscal year 1999, P.L. 105-277), which requires federal agencies, including EPA, to ensure that all research data produced under a federal award be made available to the public under the Freedom of Information Act. The law promotes public access while protecting privacy by excluding medical and business-related confidential data from disclosure. *See* 2 C.F.R. § 200.315 (which superseded OMB Circular A-110).

- EPA's November 2016 public access plan,[11] which covers publications and digital data and requires those seeking EPA research and development funding to develop data management plans that describe the data to be collected in their studies and approaches for preserving and providing access to that data. For publications, the plan requires researchers to make peer-reviewed journal articles resulting from federally funded research publicly accessible in designated repositories no later than a year after the official date of publication.

& Regulatory Affairs, Exec. Office of the President, Office of Mgmt. and Budget, *Open Data Policy—Managing Information as an Asset* (May 9, 2013), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2013/m-13-13.pdf.

[10] U.S. Envtl. Prot. Agency, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (Oct. 2002) [hereinafter *Information Quality Guidelines*], *available at* https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf.

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

ED_002389_00029319-00013

In sum, while EPA should encourage making data available to researchers and the public where lawful and appropriate, existing laws and policies applicable to federal agencies already do that, while protecting the scientific integrity of the "pivotal regulatory science" considered by EPA in promulgating standards and weighing the various factors that impact those standards. EPA's proposal ignores these established transparency laws and policies in service of excluding relevant science, thereby undercutting the environmental laws that EPA enforces by limiting the use of best available science.

b. Existing Policies and Procedures Provide for a Robust and Transparent Peer Review Process That Ensures the Validity of Scientific Information Relied Upon by EPA, and EPA Provides No Explanation for Why an Additional Level of Review Is Required

EPA has a long history of peer review of scientific studies supporting its regulations, relying on independent analyses of studies while also giving respect to those privacy protections required by law or non-disclosure agreements. As the NAS has pointed out, the National Academies "have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data." NAS Letter at 2. And as several scientific journal editors have noted, scientists conducting peer review "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."[12] This peer review process ensures the reliability and validity of the scientific information relied upon by EPA in the regulatory process.

Existing policies and procedures for peer review include the following:

- EPA's *Peer Review Handbook* provides that if a regulation is supported by a scientific and technical work product, the underlying work product should be peer reviewed unless it meets listed exemption criteria.[13] The Handbook explains that a critical element in ensuring that decisions are based on sound and defensible science is to have an open and transparent peer review process. *Id.* at xiii.

- EPA vets scientific studies through several independent expert panels, including the SAB, the EPA Clean Air Scientific Advisory Committee, the EPA FIFRA Scientific Advisory Panel, and the EPA Chemical Assessment Advisory Committee. The Clean Air Scientific Advisory Committee routinely reviews and

[12] Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel & Deborah Sweet, *Joint Statement on EPA Proposed Rule and Public Availability of Data*, Science, Apr. 30, 2018 [hereinafter *Joint Statement*], *available at* http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.full.pdf.

[13] U.S. Envtl. Prot. Agency, *Peer Review Handbook* 28, 44-45 (4th ed. 2015), *available at* https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.

ED_002389_00029319-00014

evaluates epidemiological and toxicological studies that are the basis for dose response relationships used in risk and exposure assessments for air pollutants regulated under the National Ambient Air Quality Standards (NAAQS); the Chemical Assessment Advisory Committee reviews toxicological assessments of various chemicals for inclusion in EPA's Integrated Risk Information System database;[14] and the NAS has reviewed EPA risk assessment practices numerous times.[15]

- Each of these independent committees or panels is required to be staffed by a "fairly balanced" mix of regulators, academics, and industry/consultant representatives who bring a well-balanced perspective to the process. *See* Federal Advisory Committee Act, 5 U.S.C. App. 2 § (5)(b)(2), (c).

- OMB bulletin entitled "Final Information Quality Bulletin for Peer Review," 70 Fed. Reg. 2664-02 (Jan. 14, 2005), is applicable to all federal agencies, including EPA, and establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents. The bulletin was subject to extensive public and agency comment on two prior draft versions. It includes guidance to federal agencies on what information is subject to peer review, the selection of appropriate peer reviewers, opportunities for public participation, and related issues. The bulletin also defines a peer review planning process that provides for public participation whenever possible and permits the public and scientific societies to comment about which scientific reports and studies merit especially rigorous peer review.

The proposed rule ignores this existing robust peer review process and its role in independently validating scientific information and ensuring that published information meets the standards of the scientific community.

In addition, despite the existing peer review process, EPA apparently proposes to require that EPA itself conduct an additional "independent" review. *See* 83 Fed. Reg. at 18,774. Yet the proposal nowhere discusses how EPA would vet reviewers to identify persons who are purportedly more competent than those already used in past or current peer review processes, or the level of EPA staffing and associated costs that would be needed for additional review—only stating that EPA will implement the proposed rule in a manner "that minimizes costs." *Id.* at 18,774. But any requirement for EPA to conduct additional review would entail additional significant costs, contrary to the proposal's assertion. *Id.* at 18,772. The practical outcome of

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[14] *See, e.g.*, U.S. Envtl. Prot. Agency, *IRIS Assessment Development Process (2015)*, *available at* https://www.epa.gov/sites/production/files/2015-09/iris_process_figure_2015.jpg (providing a graphical listing of all the rounds of review in the existing IRIS process, which includes internal review, intra-agency review, external review (public comments), and peer-review (SAB)).

[15] *See, e.g.*, Nat'l Research Council, *Science and Decisions: Advancing Risk Assessment* (2009), *available at* https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.

ED_002389_00029319-00015

the proposal is that EPA may end up relying on a much smaller number of studies and/or on a less robust subset of relevant available studies, thus undermining the regulatory decision-making process.

In sum, EPA fails to acknowledge the rigor of existing processes in statutes, policies and federal procedures, or to explain how its proposal would provide any added value and minimize costs. EPA should abandon this unnecessary and counterproductive exercise.

V. Obtaining Private Data May Not Be Practically Possible and, Even When it is Possible to Make Data Available, the Proposed Rule Would Unnecessarily Impose Substantial Costs to Do So

The proposal's suggestion that concerns about access to confidential or private data can simply be addressed through the application of tools used by other federal agencies, *id.* at 18,770-71, will be unworkable or impracticable for many past and even future studies. For example, the proposal cites to guidance regarding methods to de-identify protected health information under the privacy rules of the 1996 Health Insurance Portability and Accountability Act (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936. *Id.* at 18,771 n.17. That guidance document is 28 pages, contains detailed instructions for de-identification, including how experts are to assess the risk of identification of information, and emphasizes the importance of data-sorting systems to manage protected health information for the de-identification process, including use of a one-way cryptographic function to obscure personally identifiable information.[16] Among other things, the guidance provides that various identifiers of individuals—including all names, geographic subdivisions smaller than a state (with one exception), dates directly related to an individual, telephone numbers, biometric identifiers, and so forth—must be de-identified. *HIPAA Guidance* at 4-5. The guidance thus highlights that, in fact, it is not easy to address confidentiality concerns: the de-identification process is complex and must be designed into the overall study process, something that cannot be done for historic studies. Moreover, to the extent that one of the purposes of the proposal is to enable persons to replicate studies, this may not be possible where the de-identified data is critical to the studies' findings and conclusions.

And even if it were possible, EPA's proposal ignores the large costs that would be associated with the complex process of de-identifying data and fails to identify who would pay for these procedures. As scientists from the Union of Concerned Scientists have pointed out, redacting confidential data from large studies "isn't just blocking out a line," it is a huge job that can take thousands of hours, at commensurately high cost.[17] Similarly, a Work Group of the SAB, EPA's external scientific advisors charged with evaluating EPA's science and regulatory

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[16] *See* U.S. Dept. of Health & Human Servs., *Guidance Regarding Methods for De-Identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule* 6 (Nov. 26, 2012) [hereinafter *HIPAA Guidance*], https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

[17] *See* Ed Yong, *The Transparency Bills That Would Gut the EPA*, The Atlantic, March 15, 2017, https://www.theatlantic.com/science/archive/2017/03/how-to-gut-the-epa-in-the-name-of-honesty/519462/.

ED_002389_00029319-00016

actions, explained that there are considerations associated with the cost and effort that would be involved in making large and complex existing datasets available within Institutional Review Board (IRB)[18] requirements, including the issue of who would be responsible for shouldering this burden. *See* SAB Work Group Memo at 3.

Indeed, those anticipated costs are well-documented, albeit not in EPA's proposal. In 2017, Congress proposed the Honest and Open New EPA Science Treatment Act, H.R. 1430, 115th Cong. (2017), which, like the proposed rule, provided that EPA could only rely on studies whose data were open and accessible. In assessing that legislation, the Congressional Budget Office (CBO) estimated that costs to EPA associated with redacting confidential information to comply with this act would be at least $100 million per year.[19] These costs would encompass obtaining the underlying data, review of the data to address confidentiality concerns, formatting the data for public access, providing computer codes and models used, and providing directions for accessibility of the data. And the CBO did not include in its cost estimate the additional costs related to the potential need for contractors due to EPA staffing issues to assist with this work. Similar costs can be expected with the proposal as drafted, undermining the proposal's assertion that it does not amount to an Executive Order 13771 regulatory action. *See* 83 Fed. Reg. at 18,772. Rather than acknowledging those costs, however, the only place where the proposed rule even mentions costs is in Section 30.8, which states that "EPA shall implement the provisions of this subpart in a manner that minimizes costs"—a misleading and fatally vague projection of the impacts of the proposed rule. 83 Fed. Reg. at 18,774.

Because EPA's existing processes, including peer review, already help ensure that studies used by EPA are scientifically sound, the proposed rule is not needed to add credibility or reliability to the development of EPA models and standards. Instead, it will burden EPA and the public with unnecessary delays and expense, and result in the unnecessary exclusion of important scientific evidence that is critical to the development of standards that are protective of human health and the environment.

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[18] An IRB is a committee that applies research ethics to review the methods proposed for research to make sure they are ethical. Membership generally consists of individuals with varying backgrounds and affiliations, knowledgeable not only about a specific research activity, but also applicable law, institutional regulations, and standards of professional conduct. *See, e.g.*, 45 C.F.R. § 46.107; 21 C.F.R. § 56.107.

[19] Cong. Budget Office, *Cost Estimate: H.R. 1430 Honest and Open New EPA Science Treatment (HONEST) Act of 2017* 3 (Mar. 29, 2017), *available at* https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf. The predecessor to the HONEST Act was the so-called Secret Science Reform Act, H.R. 1030, 114th Cong. (2015). The CBO estimated that costs associated with redacting confidential information to comply with the latter act would be even higher--around $250 million per year initially. *See Cost Estimate: H.R. 1030 Secret Science Reform Act of 2015* 1-3 (Mar. 11, 2015), *available at* https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf.

ED_002389_00029319-00017

VI. EPA Has Not Considered the Substantial Direct Effects the Proposed Rule Would Have on the States

States, as sovereign entities, have an interest in protecting the natural resources within their borders, and the health and well-being of their residents. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982). EPA states that the proposed rule "does not have federalism implications" and "will not have substantial direct effects on the states." 83 Fed. Reg. at 18,772-73. This is simply incorrect because states are often statutorily required to adopt EPA standards, sometimes lack resources to deviate from EPA standards, frequently are required to obtain EPA approval of state-set standards, and may feel the effects of EPA decisions far beyond the environmental sphere.

Most obviously, some states' environmental laws and regulations explicitly adopt the standards set by EPA or require an express justification for any deviation. For example, under state law, Pennsylvania's Department of Environmental Protection may not promulgate air quality control measures to implement a NAAQS if the control measures are more stringent than federal measures unless it demonstrates that the higher standard is necessary to attain or maintain a NAAQS, to satisfy related CAA requirements, to prevent assessment or imposition of CAA sanctions, or to comply with a final federal court decree. *See* 35 *Pa. Consol. Stat.* § 4004.2. Similarly, New Jersey's Department of Environmental Protection must justify any deviation from federal standards pursuant to Executive Order 27 (Whitman 1994). Changes to federal standards resulting from the application of an arbitrary subset of the available science will either change the standards applicable at the state level or require states to initiate proceedings to impose and justify the imposition of different standards based on rigorous, comprehensive science. Therefore, any change to EPA's process for developing its standards will necessarily impact state standards as well.

Even those states that are not statutorily required to apply federal standards may not have the institutional capacity to develop their own standards and therefore, for practical reasons, often rely on the standards set by EPA. For example, because of lack of institutional capacity, and in acknowledgement of EPA's expertise, Washington D.C. has traditionally relied on EPA to set air quality standards. Further, even more states rely on the publicly available models created by EPA in determining appropriate state standards. For all the reasons discussed in the technical comments that follow, the adoption of this proposed rule would very likely affect the protectiveness of the standards that EPA sets and limit the models that EPA makes available to the public. The regulatory programs of all states that rely on EPA standards or models, including all the signatories of this letter, would therefore be affected by the proposed rule, and states' ability to protect their environment and the health of their citizens would be undermined by its adoption.

Still more, under some programs, standards set by the states must be approved by EPA. *See, e.g.*, 40 C.F.R. §§ 131.20, 131.21 (Water Quality Standards). If the proposed rule were applied to EPA's review and approval of state standards (and it is unclear whether that would be so—another fatal flaw in the proposal), then the rule would also affect the states in this context—further altering the balance of cooperative federalism in the implementation of these programs. Needless to say, if the proposed rule applies to EPA's review and approval of state standards, the

ED_002389_00029319-00018

federalism implications could not be any clearer—and EPA's failure to grapple with them or even recognize that they exist is arbitrary and capricious. The proposal's lack of clarity on this issue impairs the states' ability to provide meaningful comment.

Finally, the proposed rule would also impact the states through the incorporation of EPA standards into the regulations or programs of other federal agencies that rely on EPA standards and/or modeling. Should EPA adopt a deficient standard due to the arbitrary exclusion of available scientific information, other federal agencies relying on EPA standards as a basis for action would be affected, as would be the states that interface with those federal programs. As such, the impacts of the proposed rule are likely to impact states in areas far beyond the environmental field.

Based on EPA's complete failure to consider or discuss the effects of its action on state programs, the proposal should be withdrawn so that EPA can adequately consult with state officials to analyze these important impacts. *See* Exec. Order 13132 § 6(a) (instructing agencies to "ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications"); *Chem. Mfrs. Ass'n v. U.S. Envtl. Prot. Agency*, 870 F.2d 177, 203 (5th Cir. 1989).

TECHNICAL COMMENTS

I. Consideration of Valid Scientific Studies Most Relevant for Regulatory Standards Would Be Severely Limited

For reasons discussed below, the proposed rule would severely limit EPA's ability to consider valid and important scientific studies and data, including many that are most relevant for use as the basis for regulatory standards.

a. The Proposed Rule Would Exclude the Use of Studies That Were Based on Confidential Data

The proposed rule fails to recognize or acknowledge the existence of many studies already designed and published with terms that make complete transparency difficult or impossible because of IRB requirements and other important confidentiality protections. The proposal thus could have the effect of excluding important peer-reviewed studies of health effects from use as sources to support EPA's past and future regulatory efforts simply because they do not meet excessively rigid transparency standards. This is particularly true for long-standing confidential epidemiological studies that EPA has relied upon in setting air quality and other health-based standards.

In general, and specifically in EPA's 2005 *Guidelines for Carcinogen Risk Assessment*, human (i.e., epidemiology) data are preferred to animal data as the basis for risk assessment toxicity factors (e.g., cancer potency factors or reference doses for non-carcinogenic effects) when they are of sufficient quality and are amenable to dose response modeling.[20] This is

[20] U.S. Envtl. Prot. Agency, *Guidelines for Carcinogen Risk Assessment* 2-3 (Mar. 2005),

ED_002389_00029319-00019

because animal data always carry inherent uncertainties in regard to their relevance to humans. *Id.* Epidemiology data collected over at least the last 40 years, however, have been generated under the auspices of IRBs working to protect the patient or participant information obtained by academic institutions, government entities, hospitals, and other organizations, and thus disclosure of that data would be difficult, if not impossible.

Generally accepted professional practice for the collection of human data requires IRB review and informed consent from the individuals from whom the data are collected. Although the proposal states that "concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government," 83 Fed. Reg. at 18,770, this will not be possible for many studies because IRBs dictate the specific terms of this informed consent, including that the conditions of collection and analysis of human data be specified *before* initiation of the study. These *a priori* conditions include the types of analyses that will be performed, how the data will be used, and whether and how the data can be shared. In general, *a priori* conditions preclude sharing raw data with entities not included in the original IRB approval and performing analyses not specified in the original IRB approval, even if portions of the data are redacted. Furthermore, clinical data collected from physicians, hospitals, clinics, etc., may also be subject to restrictions under HIPAA, over and above IRB restrictions.

These factors would all preclude EPA's or researchers' ability to provide raw, unpublished data for re-analysis as required under the proposed EPA rule. Thus, the provisions of the proposed rule would essentially prohibit the use of such epidemiology data in human health risk-based assessment despite their clear superiority over animal data for use in risk assessment. For older epidemiology data, such as data from studies on occupational exposures to workers in factories before the advent of strict IRB requirements, raw data are seldom if ever still available. Therefore, such data, including high quality data generated by major corporations in conjunction with academic institutions, would also not be available to EPA under the proposed rule. Thus, effectively, the proposed rule would restrict the epidemiology data available for use by EPA, even where the weight of the evidence clearly supports a finding of causality and risk.

Two examples of studies that could be impacted by EPA's proposed rule are the Harvard Six Cities Study and the American Cancer Society Cancer Prevention Study II.[21] These studies followed thousands of people over nearly two decades, and linked personal medical histories, occupational histories, and home locations to detailed air quality data to show that people exposed to more particulate matter are more likely to die prematurely. In order to collect all the

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available at https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[21] Douglas W. Dockery, C. Arden Pope, Xiping Xu, John D. Spengler, James H. Ware, Martha E. Fay, Benjamin G. Ferris, Jr., and Frank E. Speizer, *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 New Eng. J. Med. 1753, 1753-59 (1993), *available at* https://www.nejm.org/doi/10.1056/NEJM199312093292401; *Cancer Prevention Study II*, Am. Cancer Soc'y, https://www.cancer.org/research/we-conduct-cancer-research/epidemiology/cancer-prevention-study-2.html.

ED_002389_00029319-00020

information, researchers entered into confidentiality agreements with the study participants, agreeing that their private information would not be made public. These promises of confidentiality (wholly apart from the difficulty and cost of redacting personal information) would render the studies "non-transparent" under the proposed rule, enabling or requiring EPA to ignore them. This is so even though the studies have been thoroughly peer-reviewed and their results have been re-analyzed by the Health Effects Institute, which confirmed the robustness of the studies' findings with respect to air pollution and mortality.[22] Under the proposed rule, EPA could ignore these two foundational studies and other peer-reviewed studies built upon them in setting health-based air quality standards for particulate matter and other pollutants.[23] The effect could be devastating and deadly, as these standards save lives. EPA estimates that reductions in ambient particulate matter under the 1990 Clean Air Act Amendments will prevent 230,000 adult deaths by 2020.[24]

b. The Proposed Rule Would Also Exclude Studies That Cannot Be Reproduced

"Reproducibility," "replication," and "validation" of scientific studies are mentioned throughout the proposed rule, but these terms are not defined. *See, e.g.*, 83 Fed. Reg. at 18,773-74. These terms could be interpreted to mean that studies used as the basis for regulations must be replicated. It would clearly be impossible to replicate many key studies based on data on human or ecological effects resulting from unintentional adverse events and disasters. Some extreme examples are data on the effects of radiation from atomic bomb survivors, data on wildlife toxicity from the Exxon Valdez oil spill, and data on the human health impacts of the September 11, 2001 World Trade Center disaster.[25] Other important data may come from older studies of human volunteers that could not be replicated under current ethical standards.

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[22] Daniel Krewski, Richard T. Burnett, Mark S. Goldberg, Kristin Hoover, Jack Siemiatycki, Michael Jerrett, Michael Abrahamowicz, & Warren H. White, Health Effects Institute, *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality* (2000), *available at* https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air; Daniel Krewski, Richard T. Burnett, Mark S. Goldberg, Kristin Hoover, Jack Siemiatycki & Warren H. White, *Validation of the Harvard Six Cities Study of Particulate Air Pollution and Mortality*, 350 New Eng. J. Med. 198, 198-99 (2004), *available at* https://www.nejm.org/doi/full/10.1056/NEJM200401083500225.

[23] *See Changing What Science the EPA Will Consider—Part I*, Environmental Law at Harvard (2018), http://environment.law.harvard.edu/2018/04/changing-science-epa-will-consider/.

[24] *Benefits and Costs of the Clean Air Act 1990-2020, the Second Prospective Study*, U.S. Envtl. Prot. Agency (Jan. 4, 2017), https://www.epa.gov/clean-air-act-overview/benefits-and-costs-clean-air-act-1990-2020-second-prospective-study.

[25] Comm. to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation, Nat'l Research Council, *Health Risks From Exposure to Low Levels of Ionizing Radiation, Beir VII Phase 2* (2006), *available at* https://www.nap.edu/read/11340/chapter/1; Charles H. Peterson, Stanley D. Rice, Jeffrey W. Short, Daniel Esler, James L. Bodkin, Brenda E. Ballachey & David B. Irons, *Long-Term Ecosystem Response to the Exxon Valdez Oil Spill*, 302 Sci. 2082, 2082-

ED_002389_00029319-00021

Laboratory animal studies are controlled studies which use genetically similar test subjects maintained under identical conditions, with the only difference between the control and treated groups being exposure to the chemical being tested. Although such studies are expected to give the same results if they are reproduced, scientists do not routinely perform laboratory experiments that are identical to previously reported studies, but rather, use results from the scientific literature as the basis for design of different studies that will add to the body of knowledge on the topic being studied. In contrast to the controlled conditions of animal studies, there is more variability among humans than the strains of lab animals utilized. Additionally, the exact underlying conditions of human studies can rarely be exactly replicated (i.e., under the same circumstances of exposure and other factors) even when the same protocols are followed. Thus even a contradictory result in a "reproduced" epidemiological study would not necessarily invalidate an observation from an earlier study, provided that the first study followed valid methods and conducted appropriate statistical analyses.

In addition, although it would depend on the specifics of the study and the nature of the endpoint investigated, a single human study would not generally be considered definitive by itself. Rather, all such well-conducted studies contribute to the weight of evidence supporting a scientific conclusion. Reliance on the weight of the evidence, rather than on any one individual study, is a safeguard that helps to ensure validity of the overall conclusions. Therefore, even if such studies could be replicated, their replication is not necessary for making a conclusion based on the overall weight of the evidence.

To the extent the proposal seeks to enable third parties to "re-run" an analysis using the same supporting data and the same models, this may not be possible where proprietary models, methods, designs, and/or data were used in the study. But, as EPA points out in its Information Quality Guidelines, in cases where the Agency relies on proprietary models that cannot be made publicly available, the model applications are subject to EPA's peer review policy and other validation checks. *Information Quality Guidelines* at 47. The Guidelines indicate that "[t]hese steps, along with transparency about the sources of data used, various assumptions employed, analytic methods applied, and statistical procedures employed should assure that analytic results are 'capable of being substantially reproduced.'" *Id.*

c. <u>The Proposed Rule Would Favor Industry Contract Laboratory Toxicology Studies, Which May Not Evaluate the Most Sensitive and Relevant Effects</u>

The proposed rule would also favor consideration of industry toxicology studies over equally valid peer reviewed studies from other institutions. It states that "where available and appropriate, EPA will use . . . standardized test methods, consistent data evaluation procedures, and good laboratory practices." 83 Fed. Reg. at 18,770. Under current EPA risk assessment approaches, all relevant scientific data are considered.[26] In contrast, this language indicates the

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2086 (2003); *available at* https://www.afsc.noaa.gov/Publications/misc_pdf/peterson.pdf; City of New York, Dept. of Health & Mental Hygiene, *World Trade Center Health Registry*, https://www1.nyc.gov/site/911health/about/wtc-health-registry.page.

[26] *See, e.g.*, Integrated Risk Info. System, Nat'l Ctr. for Envtl. Assessment, Office of Research &

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proposed rule is significantly more restrictive than current EPA guidance as far as the types of valid peer-reviewed scientific data that can be considered.

It is critical to note that the phrase "good laboratory practices" (GLP) referenced by EPA is not a value descriptor. Rather, it is a technical term referring to a specific category of study conduct and reporting that is intended for specific regulatory purposes. GLP/standardized test method studies are typically conducted by industrial or contract laboratories, and test for limited parameters in order to meet specific regulatory requirements, such as for registration of pesticides, drugs, and other products. These protocols often have not been updated to incorporate recent approaches in toxicology, and they may not look at the most sensitive and relevant toxicological effects of the product being studied. In contrast, other equally scientifically valid studies, typically conducted in research laboratories in academic, industrial, or government institutions, use specialized approaches to evaluate specific toxicological effects of the chemical under study, and may not follow the standardized protocols specified in regulatory requirements. The use of GLP protocols does not necessarily mean that the study is of higher quality, and there is no scientific reason that the data generated under the highly circumscribed regulatory requirements for product registration should receive greater weight than any other valid scientific data. Rather, all studies should be evaluated on their own merits.

d. The Proposed Rule Would Exclude Studies for Which Underlying Data Are Not and May Not Be Available

The proposed rule would preclude consideration of studies – old and new – for which data are not and may not be available. Many of the standards that are developed or updated by EPA are for chemicals that have an extensive, older body of scientific literature on their effects, but that are not currently being actively researched. Thus, the vast majority of studies considered for standard-setting are not new and were not conducted, designed, or published with the goal of ensuring data availability. Accordingly, their data are likely unavailable and, even if data were kept, the formats in which older data are stored may not be accessible from currently available computers, potentially invalidating the use of those studies as the basis for future regulatory standards. Processes for additional data availability are currently being developed and will likely increasingly be incorporated into research protocols in the future; however, it is unknown whether these forthcoming protocols will meet the transparency requirements of the proposed rule.

In addition, even going forward, many academic scientists whose research is relevant to EPA regulations may not conduct and report their studies in a way that satisfies the requirements of the proposed rule. The proposed rule's provisions would require significant additional resources and could impose unreasonable and impractical requirements beyond those included in current protocols. Academic researchers, who often study sensitive and relevant health effects that are not evaluated in industry-sponsored GLP studies, typically focus on publishing their studies in peer-reviewed journals and obtaining research funding; they may not be concerned about or even consider whether their studies would qualify for use in establishing EPA

Dev., U.S. Envtl. Prot. Agency, *Toxicological Review of Benzo[a]pyrene*, xxxiii-xxxvi (2017), *available at* https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0136tr.pdf.

regulations, and/or may not have the resources to reshape their approach to maintaining data. Additionally, many researchers, particularly in other nations but also in the United States, may not even be aware of EPA requirements for a study's use in regulations. For those researchers who do attempt to comply with the proposed rule's requirements, the extent and nature of the data that must be maintained and made publicly available is vague and unclear, making compliance virtually impossible.

II. The Proposed Rule is Wrongly Premised on Unsupported Assumptions Regarding Scientific Studies

a. The Proposed Rule Assumes Erroneously and Without Explanation that Only Studies for Which the Underlying Data Are Publicly Available Are Valid

A fundamental premise of the proposed rule is that only studies for which the underlying data are publicly available are valid for decision-making. This premise is inconsistent with generally accepted practices for conducting and evaluating scientific research. Furthermore, the rationale for the premise is not provided: EPA presents no evidence for the conclusion that its current criteria for selecting studies result in scientifically invalid conclusions or overly stringent regulations. Indeed, the D.C. Circuit has already rejected EPA's proposed approach of excluding studies relying on non-public data as "impractical and unnecessary" when raised by a trade association as part of a challenge to an air quality standard. *Am. Trucking*, 283 F.3d at 372.

b. The Proposed Rule Incorrectly Assumes that the Studies and Data Upon Which EPA Relies Are of Questionable Validity

The proposed rule also assumes that the studies and data used in EPA's decision-making are of questionable validity. However, this assumption is unsupported. It is not the case that the studies and data EPA uses to establish regulations are selected simply because they report effects at the lowest levels. Rather, EPA performs an extensive hazard identification process prior to selecting key studies and specific health endpoints. This process evaluates the relevant human epidemiology, animal toxicology, and mode of action studies to ensure that the studies and endpoints ultimately chosen are supported by the overall body of scientific literature. Recently, a rigorous systematic review process has been developed and implemented by EPA's Integrated Risk Information System program to ensure even greater thoroughness and objectivity in hazard identification.[27] Thus, EPA already ensures that the studies and data upon which it relies are valid.

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[27] Integrated Risk Info. System, Nat'l Ctr. for Envtl. Assessment, Office of Research & Dev., U.S. Envtl. Prot. Agency, *National Academy of Sciences Committee to Review Advances Made to the IRIS Process: A Workshop* (Feb. 1-2, 2018), *available at* https://www.epa.gov/sites/production/files/2018-02/documents/nas020118final.pdf.

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III. The Proposed Rule's Data Availability Requirements Are Unnecessary and Unclear

a. EPA's Proposed Data Availability Requirements Are Not Necessary to Improve or Ensure the Scientific Basis of Regulations

Studies and associated data do not have to be publicly available or reproducible to ensure that they are scientifically valid. This point has already been made in statements of concern about the proposed rule by authoritative scientists, including the editors of the most prestigious scientific journals (Science, Nature, PLOS, PNAS, Cell) and the members of a Work Group of the SAB itself. *See Joint Statement* and SAB Work Group Memo. As stated by the journal editors, "scientists, including peer reviewers, 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 . . . . [I]t does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them . . . . Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes." *Joint Statement*.

In fact, there are longstanding methodologies for evaluating the strength of epidemiology findings that are commonly used to draw conclusions about causality.[28] The SAB Work Group notes that "the proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods," using as an example the Health Effects Institute's well-known re-analysis of the Harvard Six Cities and American Cancer Society air quality studies, which successfully replicated those studies' findings. SAB Work Group Memo at 4.

b. EPA's Proposed Data Availability Requirements Are Not Clearly Defined and Do Not Ensure Validity of Data

The extent and nature of the data that would be required to be made publicly available is not clearly defined in the proposed rule. The proposed rule states that information is considered "publicly available in a manner sufficient for independent validation" when it includes the "information necessary for the public to understand, assess, and replicate findings. This may include, for example: (a) Data (where necessary, data would be made available subject to access and use restrictions)[;] (b) Associated protocols necessary to understand, assess, and extend conclusions; (c) Computer codes and models involved in the creation and analysis of such information; (d) Recorded factual materials; and (e) Detailed descriptions of how to access and use such information." 83 Fed. Reg. at 18,774.

This could be interpreted to require maintenance of data down to the most basic level, verging on the absurd, and could impose unreasonable and impractical requirements that go well beyond those already included in current protocols. For example, it could require maintenance of records that are not routinely archived by academic research labs, such as printouts of data from all calibration curves and analyses from instruments that measure clinical parameters in

[28] *See, e.g.*, Sir Austin Bradford Hill, *The Environment and Disease: Association or Causation?* 58(5) Proc. Royal Soc'y Med. 295, 295-300 (1965) ("The Hill Criteria for Causality").

ED_002389_00029319-00025

blood or other similar endpoints in animal and human studies, or photos of each individual organ as it is evaluated for gross pathology in toxicology studies. Even if such data are maintained for a period after a study is completed, it is not feasible for such records to be maintained indefinitely by research laboratories, which would then make the study that the data supports unavailable for use in future regulations.

For toxicology studies, such data availability requirements would result in favoring studies performed under GLP protocols, which typically retain more raw data than research studies. But, as discussed in more detail above, GLP studies may not evaluate the most sensitive and relevant toxicological effects of the chemical being studied and are not inherently of higher quality than studies conducted under other protocols.

IV. Provisions of the Proposed Rule Related to Modeling Conflict with Scientific Guidelines

The proposed rule would flout long-accepted scientific modeling methods and require undue justification and explanation of assumptions and uncertainty.

a. The Proposed Rule Encourages Deviation from Linear Dose Response Modeling, the Generally Accepted Choice for Modeling in Carcinogen Risk Assessment

The proposed rule would favor less protective threshold modeling, contrary to EPA's own guidance and generally accepted toxicology practice. It states that "EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis" and that "EPA shall give explicit consideration to high quality studies that explore . . . various threshold models across the dose or exposure range." 83 Fed. Reg. at 18,774. These requirements are inconsistent with EPA guidance, specifically the 2005 *Guidelines for Carcinogen Risk Assessment*. These guidelines state that EPA's default dose response modeling approach for carcinogenic substances is linear extrapolation from the point-of-departure (essentially the lower limit of the range of the experimental data) to the origin (zero exposure, zero risk). This default no-threshold approach assumes that any dose of a carcinogen results in some level of risk, making it the most protective of human health. Threshold models, by contrast, assume that there is some dose of a carcinogen at which there is no cancer risk, an assumption that is less health protective and that has not been conclusively established in most cases. It is unclear what EPA means by "explicit consideration," or what EPA would consider to be "high quality studies," but insofar as those terms are intended to mean that EPA will give preference to studies utilizing threshold models, such a preference would be inconsistent with EPA's 2005 *Guidelines for Carcinogen Risk Assessment* as well as generally accepted practice in the field of toxicology.

In most cancer risk assessments, dose response data within the low risk range, which is the range of interest for regulatory purposes, are lacking. Thus, low-dose extrapolation is used to estimate risks in the lower dose range where data are unavailable. For estimation of risks below the range of the data, there are an infinite number of possible threshold and non-threshold assumptions regarding the shape of the dose response curve that can be envisioned, with no substantive basis for assuming the general superiority of one assumption over another. To

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deviate from the default assumption that any dose of a carcinogen results in some risk in the absence of chemical-specific data that demonstrate a threshold mode-of-action of carcinogenicity[29] would be mere speculation and would assume, with no scientific support, that Americans can be safely exposed to those substances. To "evaluate the appropriateness" of the linear, non-threshold approach for low-dose extrapolation by also considering non-linear and threshold models would provide no cognizable benefit in modeling accuracy or clarity, but instead could result in the manipulation of results, delay, and obfuscation.

In the limited circumstances where the data support threshold modeling, EPA's 2005 *Guidelines for Carcinogen Risk Assessment* already provide for departure from the default linear extrapolation in risk assessment and instead allow for the use of threshold modeling. *Id.* at A-8. In fact, EPA has used a threshold approach for carcinogen risk assessment when there is clear, chemical-specific, empirical evidence of a threshold mode of action.[30] This careful, well-founded approach is generally considered both scientifically supportable and protective of public health, as opposed to the proposed rule's requirement for justification of the default linear approach on a case-by-case basis and "explicit consideration [of] high quality studies that explore various threshold models across the dose or exposure range." 83 Fed. Reg. at 18,774. Without a well-founded and substantiated scientific basis, EPA should not entertain such a fundamental departure from accepted, public-health protective risk assessment practices.

b. <u>The Proposed Rule Would Unreasonably Require Consideration of Nonparametric Models</u>

The proposed rule would require that "when available, EPA shall give explicit consideration to high quality studies that explore . . . [a] broad class of parametric dose response or concentration response models" *and* "nonparametric models that incorporate fewer assumptions." 83 Fed. Reg. at 18,774. Parametric models are those in which the number and nature of the parameters (i.e., assumptions) are fixed in advance, while nonparametric models are those in which the assumptions are determined from the data. For approximately 20 years, EPA has employed parametric modeling in risk assessment by providing and using benchmark dose response modeling software. Although the proposal implies that this is not the case, this software already allows investigation of the most appropriate parametric model(s) for risk assessment and currently provides "a broad class of parametric dose response, concentration-response models." *Id.*

There is no obvious benefit to adding an additional layer of analysis—nonparametric modeling—on top of this longstanding approach. Nonparametric models are useful only when the quantity and quality of the data are sufficient to infer a clear and plausible estimate of the overall pattern. But when there are few data and/or data are of poor quality, as is often the case

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[29] Mode of action is defined by EPA as the "sequence of key events and processes, starting with interaction of an agent with a cell, proceeding through operational and anatomical changes, and resulting in cancer formation." *Guidelines for Carcinogen Risk Assessment* at 1-10 n.2.

[30] *See, e.g.*, U.S. Envtl. Prot. Agency, *Toxicological Review of Chloroform* (2001), *available at* https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0025tr.pdf.

ED_002389_00029319-00027

in situations to which the proposed rule would apply, nonparametric models can produce a wide variation of results with few, if any, constraints on plausibility. In such cases, the use of nonparametric models is not scientifically supportable, and moving forward, little would be gained from considering them in terms of accuracy and clarity of the predictions, while the potential for delay and obfuscation would again multiply. The proposed rule's requirement that nonparametric models be explicitly considered, without regard to the applicability of a particular model, is therefore misguided and scientifically unsound.

c. The Proposed Rule Would Unreasonably Require Justification of All Default Assumptions

The proposed rule would require EPA to "evaluate the appropriateness of using default assumptions" and "clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions." 83 Fed. Reg. at 18,774. This would effectively foreclose the important use of default assumptions, requiring a detailed justification for each of the many assumptions included in any given model—an inefficient, time-intensive, and unnecessary task.

Default assumptions are selected from a range of possible values based on both scientific considerations (e.g., whether they are supportable based on available data) and policy considerations (e.g., whether the upper or lower percentile, rather than the mean or median value, should be used to protect most of the population). In cases of significant variability and/or uncertainty in the available data, there are essentially an infinite number of alternative assumptions that can be chosen. The use of default assumptions thus provides a straightforward way to manage the complexity presented by variability and uncertainty.

And, while default assumptions do need to be justified when initially selected, EPA uses a well characterized set of default assumptions in risk assessment and updates them when indicated by newer scientific information.[31] Accordingly, the rationales and limitations underlying these assumptions are well documented, including (as would be required by the proposed rule) discussion of variability, as well as sensitivity analyses that evaluate the impact on the model results of changing the default value to a range of non-default alternative values. Default values have been selected as both scientifically valid and protective of human health; if alternative values are selected, they are likely to be less health-protective than existing defaults. There is thus little benefit to be gained at this point by reinventing the wheel each time a default assumption is employed. To forego these well-established default assumptions and require

[31] *See, e.g.*, Memorandum from Dana Stalcup, Acting Director, Assessment and Remediation Division, Office of Superfund Remediation and Technology Innovation to Superfund National Policy Managers, Regions 1-10, *Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors* (Feb. 6, 2014), *available at* https://www.epa.gov/sites/production/files/2015-11/documents/oswer_directive_9200.1-120_exposurefactors_corrected2.pdf; Office of Water, U.S. Envtl. Prot. Agency, *Human Health Ambient Water Quality Criteria: 2015 Update* (2015), *available at* https://www.epa.gov/sites/production/files/2015-10/documents/human-health-2015-update-factsheet.pdf.

ED_002389_00029319-00028

justification of each assumption chosen from a long list of potentially less health-protective assumptions would only give rise to prolonged debate, obfuscation, and manipulation of model outcomes, not improvement of the scientific basis of the risk assessment. The delay this would cause, for no supportable reason, can only lead to the conclusion that it is EPA's intent to inhibit, rather than improve, regulation.

d. The Proposed Rule Would Require a Description of, But Fails to Define, Uncertainty

The proposed rule would also require that EPA "describe and document any assumptions and methods used . . . and uncertainty." 83 Fed. Reg. at 18,774. However, uncertainty is not defined in the proposed rule, and it is unclear what type of uncertainty is implied. Uncertainty could mean discussion of the magnitude of the statistically based range of model predictions. There could also be uncertainties unrelated to the model, such as qualitative uncertainty about the human relevance of the animal toxicity endpoint used as the basis for the risk assessment. EPA's failure to define the type of uncertainty at issue makes the proposed rule impermissibly vague and deprives the public of a meaningful opportunity to comment on its impacts.

V. The Proposed Rule Would Undermine Protection of Human Health and the Environment, in Contradiction to EPA's Mission

Overall, the requirements of the proposed rule discussed above would lead EPA to adopt less protective standards across many regulatory programs, which is contrary to EPA's mission to protect human health and the environment. The proposed rule would allow for the use of less protective dose response models and assumptions in human health risk assessment. It would also preclude consideration of scientifically valid human and animal studies reporting sensitive and relevant toxic effects based on unjustified requirements for public availability of data, and instead favor consideration of studies that do not assess the most sensitive and relevant health effects endpoints.

For example, EPA is required to review its air quality standards (NAAQS) for criteria pollutants every five years and, if necessary, revise them to protect public health and the environment. *See* 42 U.S.C. § 7409(d). The NAAQS review process builds on the administrative record from prior rulemakings, including historic studies that are part of that record. Under the proposed rule, EPA may refuse to consider these studies and others because they rely on data pertaining to the personal medical histories of participants that cannot, by the studies' terms or by law, be divulged. Restricting the use of such studies would significantly undermine current and future NAAQS reviews.

And, indeed, the proposed rule appears to be especially aimed at such a restriction. EPA's April 30, 2018 rule proposal follows an April 12, 2018 memorandum issued by President Trump to former EPA Administrator Pruitt directing him to "examine the current NAAQS review process and develop criteria to ensure transparency in the evaluation, assessment, and characterization of scientific evidence in such reviews."[32] But, as explained above, it would be

[32] Memorandum from Donald J. Trump, President of the United States, to the Administrator of the U.S. Envtl. Prot. Agency, *Presidential Memorandum for the Administrator of the*

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illegal for EPA, in setting standards, to ignore peer-reviewed, relevant science on the grounds that confidential, private patient data underlying a study have not been made public.

Relatedly, EPA's proposal may also restrict the health and welfare benefits tied to the NAAQS that support other rulemakings. For example, in calculating the costs and benefits of rules to reduce air emissions, in some cases the majority of the benefit estimates are attributable to reductions in one or more criteria pollutants that are not the primary objective of the rule. These reductions are referred to as co-benefits, and the health impacts and monetized benefits are based on studies used in the air quality standards-setting process for criteria pollutants. For example, in promulgating the Mercury and Air Toxics Standard rule governing air emission standards for hazardous air pollutants (including mercury) from power plants, EPA states "[i]t is important to note that the monetized benefits include many but not all health effects associated with $PM_{2.5}$ exposure." 77 Fed. Reg. 9304, 9431 (Feb. 16, 2012); *see also id.* at 9305. Thus, restricting the use of studies that underlie emission standards for criteria pollutants could significantly impact the cost-benefit analyses for various other health-related rules by failing to account for all the benefits, making it far more likely that the costs will be predicted to exceed the benefits and that the regulatory standards will, accordingly, be lowered.

Further, in developing regulations EPA uses other types of models in addition to dose response models. These include toxicokinetic models that predict a chemical's absorption, distribution, metabolism, and excretion, as well as fate and transport models that predict a chemical's movement in the environment and distribution to environmental media. The proposed rule's provisions that could decrease protectiveness of dose response analysis (e.g., requiring justification of default assumptions and precluding consideration of relevant studies due to data disclosure requirements) could similarly result in decreased protectiveness of these other types of models. In regulations based on dose response analysis combined with toxicokinetic and/or fate and transport analyses, the overall decrease in protectiveness would be magnified.

The proposed rule also does not differentiate between standards set to protect human health, and standards and models used to protect the environment, such as the CWA's aquatic life criteria and standards used in ecological risk assessments under CERCLA.[33] Many of the same serious concerns raised in these comments are equally applicable to such standards and models, including: EPA's lack of consultation with the SAB, the National Academy of Sciences, and the broader scientific community; the requirement that EPA conduct its own review of all pivotal regulatory science; and the proposed rule's potential to impose unreasonable data maintenance requirements. Also, the use of GLP protocols is inappropriate for studies involving ecosystems and associated biota. Consequently, the problems concerning EPA's ability to rely

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Environmental Protection Agency (Apr. 12, 2018), https://www.whitehouse.gov/presidential-actions/presidential-memorandum-administrator-environmental-protection-agency/.

[33] *National Recommended Water Quality Criteria*, U.S. Envtl. Prot. Agency (Apr. 2, 2018), https://www.epa.gov/wqc/national-recommended-water-quality-criteria; *Superfund Risk Assessment: Ecological Risk Topics*, U.S. Envtl. Prot. Agency (Feb. 16, 2018), https://www.epa.gov/ris/superfund-ris-assessment-ecological-risk-topics.

ED_002389_00029319-00030

on the best available scientific studies would also limit EPA's ability to protect ecosystems and wildlife in a scientifically robust manner.

CONCLUSION

As the comments above demonstrate, the proposed rule is antithetical to EPA's mission to protect human health and the environment. The proposed rule is riddled with substantive and procedural infirmities and would achieve the opposite of its purported purpose. EPA's failure to consult with its own internal science experts when developing the proposal is, at best, gross malfeasance and, at worst, a conscious effort to subvert the Agency's statutorily mandated practice of using the best available science. We urge EPA to jettison this tainted vestige of the prior leadership and restore public confidence in the Agency's commitment to its core mission, and we stand ready to pursue legal remedies should EPA persist in this misguided effort.

Sincerely,

BARBARA D. UNDERWOOD
Attorney General of New York

GURBIR S. GREWAL
Attorney General of New Jersey

XAVIER BECERRA
Attorney General of California

GEORGE JEPSEN
Attorney General of Connecticut

MATTHEW P. DENN
Attorney General of Delaware

LISA MADIGAN
Attorney General of Illinois

THOMAS J. MILLER
Attorney General of Iowa

JANET T. MILLS
Attorney General of Maine

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BRIAN E. FROSH
Attorney General of Maryland

MAURA HEALEY
Attorney General of Massachusetts

LORI SWANSON
Attorney General of Minnesota

JOSHUA H. STEIN
Attorney General of North Carolina

ELLEN ROSENBLUM
Attorney General of Oregon

JOSH SHAPIRO
Attorney General of the Commonwealth
of Pennsylvania

PATRICK MCDONNELL
Secretary of the Pennsylvania Department
of Environmental Protection

BOB FERGUSON
Attorney General of Washington State

KARL A. RACINE
Attorney General of the
District of Columbia

DANIEL T. SATTERBERG
King County (WA) Prosecuting Attorney

EDWARD N. SISKEL
Corporation Counsel
City of Chicago

MICHAEL N. FEUER
Los Angeles City Attorney

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ZACHARY W. CARTER
Corporation Counsel
City of New York

/s/
MARCEL S. PRATT
City Solicitor
City of Philadelphia

BARBARA J. PARKER
City Attorney
City of Oakland

DENNIS J. HERRERA
City Attorney
City of San Francisco

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