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

May 18, 2020

**By Electronic Submission to www.regulations.gov**

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

Re: Supplemental Proposal to Limit Use of Scientific Evidence, Docket ID No. EPA-HQ-OA-2018-0259, 85 Fed. Reg. 15,396 (Mar.18, 2020).

Dear Administrator Wheeler:

The undersigned twenty-five State Attorneys General and County and City Attorneys ("Coalition") respectfully submit the following comments on the U.S. Environmental Protection Agency's ("EPA") March 18, 2020, supplemental notice of proposed rulemaking to limit the use of scientific evidence in agency decision-making, 85 Fed. Reg. 15,396 ("supplemental proposal" or "SNPR"). This anti-science proposal is particularly troubling coming in the midst of the worst public health crisis our nation has faced in over a century; now is not the time for EPA to deviate from well-founded agency practices for developing science-based regulations and information to protect human health and the environment. Accordingly, we urge you to withdraw this ill-advised proposal or to treat it, at most, as an Advance Notice of Proposed Rulemaking to be revisited after the current pandemic has abated and important stakeholders, including scientists and public health officials, have a meaningful opportunity to participate in any rulemaking process.

We strongly support transparency and the use of the best available science in agency decision-making, but the proposed rule would severely undermine those important policies. The proposed rule ostensibly addresses the lack of transparency in data underlying scientific studies that EPA uses in setting standards and making other science-based decisions. However, the restrictions that the proposed rule would impose on EPA's use of scientific information will only detract from the robustly transparent peer review process that EPA currently uses to evaluate the integrity of scientific studies and modeling. The proposed rule is thus a "solution" in search of a problem. Even "a 'regulation perfectly reasonable and appropriate in the face of a given problem

may be highly capricious if that problem does not exist.'" *Home Box Office, Inc. v. Fed. Commc'n Comm'n,* 567 F.2d 9, 35 (D.C. Cir. 1977), quoting *City of Chicago v. FPC*, 458 F.2d 731, 742 (D.C. Cir. 1971).

EPA's supplemental proposal fails to address many of the problematic issues identified in comments that a subset of our Coalition submitted regarding EPA's 2018 initial proposal,[1] and, in fact, compounds those problems by broadening the scope of the proposed rule so that it would now apply to *all* data and models and would be used in the development of "influential scientific information" as well as regulatory decision-making. This harmful and deeply flawed proposed rule will not improve the science relied upon by EPA but will instead unlawfully and arbitrarily exclude or give less weight to much of the science underpinning EPA action to protect human health and the environment. And far from "strengthening transparency," the supplemental proposal fails to identify objective standards to govern the vast discretion EPA proposes to give itself to ignore or demote relevant, peer-reviewed science, giving rise to the very arbitrariness that the federal Administrative Procedure Act ("APA") prohibits. Further, as EPA's own Science Advisory Board recently commented in response to the SNPR, "key considerations that could inform the Proposed Rule are not present in the proposal or presented without analysis and explanation of scope. In addition, certain key terms and implementation issues have not been adequately defined or described."[2]

In short, nothing in the supplemental proposal alters the conclusions from the 2018 Comments: the proposed rule violates controlling federal law, is arbitrary and capricious, contains clear errors in reasoning, and is contrary to best scientific practices. We encourage EPA to abandon this deeply flawed proposal and instead initiate a collaborative, inclusive process with experts in the field, such as the Science Advisory Board and the National Academies, as well as with the state and local governments that are on the front lines of public health and environmental protection, to address issues such as transparency and data quality. If, however, the agency persists in this destructive effort and finalizes the proposed rule, we stand ready to pursue legal remedies.

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[1] *See* Comments of Attorneys General of New York et al., (Aug. 16, 2018) ("2018 Comments"), available at www.regulations.gov, Docket ID No. EPA-HQ-OA-2018-0259. Those comments are incorporated herein by reference. The States of Michigan and Wisconsin did not participate in the 2018 Comments but are part of the Coalition submitting comments regarding the SNPR.

[2] Letter from Dr. Michael Honeycutt, Chair, Office of the Adm'r, Sci. Advisory Bd, U.S. Envtl. Prot. Agency to the Hon. Andrew Wheeler, Adm'r, U.S. Envtl. Prot. Agency, Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled Strengthening Transparency in Regulatory Science 2 (Apr. 24, 2020) [hereinafter SAB Report], https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf.

## EXECUTIVE SUMMARY

The scientific community has roundly criticized both the initial and supplemental proposals for good reason: EPA has invented an arbitrary standard for consideration of scientific studies and information—public availability of the underlying data and the public's ability to independently validate—that is unrelated to the robustness or merit of the scientific information and would exclude or demote much of the best science on which the agency should rely. As the leading scientists in the country have informed EPA,[3] the proposed rule's restrictions pose a threat to the credibility of regulatory science, and therefore undermine EPA's core mission to protect human health and the environment. Indeed, years ago, EPA successfully fought off an industry effort to impose the same strictures that the agency now seeks to impose on itself and made plain that requiring the agency to obtain and publicize the data underlying all studies on which it relies would mean that "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 v. U.S. Envtl. Prot. Agency*, 283 F.3d 355, 372 (D.C. Cir. 2002). And the D.C. Circuit agreed, finding that such a requirement "would be impractical and unnecessary." *Id*.

In addition to failing to heed expert advice from the scientific community, EPA has also disregarded the 2018 Comments. For example, despite the clear identification of the significant harms the proposed rule would inflict on states, counties, cities, and their residents, 2018 Comments at 18, EPA continues to falsely assert that the proposed rule "will not have substantial direct effects on the states." 85 Fed. Reg. at 15,404. Nothing could be further from the truth. 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 their own standards, based on rigorous, comprehensive science. Therefore, any change to EPA's process for developing its standards will necessarily affect state standards as well, and failure to consider the best available science will undermine the efficacy and protectiveness of those standards.

Beyond its failure to remedy the many problems identified in the 2018 Comments, many of which were also identified by other commenters, the SNPR creates a number of new problems, all of which make this proposed rule unworkable as a practical matter in addition to being contrary

[3] 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 the Hon. Andrew Wheeler, Acting Adm'r, U.S. Envtl. Prot. Agency (July 16, 2018) [hereinafter NAS Letter], http://www.nationalacademies.org/includes/EPA%20Proposed%20Rule%20Docket%20EPA-HQ-OA-2018-0259%20NASEM%20Comment.pdf.

to law. Among the SNPR's legal and technical infirmities, which we address in detail below, are the following:

- EPA fails to identify a valid legal basis for the proposed rule and fails to acknowledge that the proposal to restrict consideration of scientific information conflicts with EPA's specific obligation, expressed in EPA's core statutes, to use the best available science;

- EPA unlawfully attempts to characterize a substantive rule with national impact as a matter of internal agency "housekeeping";

- EPA's expansion of the initial proposal to cover all data and models and to apply to influential scientific information in addition to significant regulatory decisions increases the harmful impacts of the proposal by broadening the scope and number of agency decisions that will be subject to arbitrary exclusion or down-weighting of relevant, probative scientific evidence;

- The supplemental proposal violates the APA in multiple respects, including failing to allow sufficient time for comment, failing to provide sufficiently clear descriptions of key terms, and failing to adequately explain how implementation would occur;

- The proposal provides EPA with vast, unlawful discretion regarding consideration of scientific information without any objective criteria to guide that discretion in order to ensure that EPA's decisions are transparent and not arbitrary;

- EPA failed to consult with states in violation of Executive Order 13132, despite the severe impacts the proposed rule would have on states' ability to protect public health and the environment, and also failed to comply with several other Executive Orders; and

- The core principle of the proposed rule—that EPA will either exclude or give less weight to relevant, probative scientific studies, models, or other information that have been validated through peer review on the sole basis that the underlying data are not publicly available or are not able to be independently validated—is arbitrary, unlawful, and inconsistent with accepted scientific practice, because EPA would be evaluating studies not on their quality, but on a non-scientific metric.

For these reasons, and as set forth in more detail below, EPA should abandon this ill-advised and illegal proposal. Alternatively, EPA should reclassify the proposal as an Advance Notice of Proposed Rulemaking to allow the agency to gather additional information and clarify the many points of uncertainty in the proposed rule, such as what authority EPA has for the rule, whether the rule should apply to past studies, and other fundamental questions the agency poses in the SNPR. 85 Fed. Reg. at 15,403. Moreover, any effort to improve the use of science in EPA's regulatory and policy actions must start with meaningful consultation on these issues with the scientific community, including the National Academy of Sciences and EPA's Science Advisory Board. Further, EPA should work cooperatively with state and local governments, which bear

primary responsibility for implementing public health and environmental standards. Now, more than ever, it is critical that EPA employ the best available science to protect public health and the environment.

## LEGAL COMMENTS

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

As explained in the 2018 Comments, EPA lacks statutory authority to promulgate the proposed rule. Nothing in the supplemental proposal alters that conclusion. EPA's citation to the federal Housekeeping Statute, 5 U.S.C. § 301, either alone or in combination with other substantive statutes that EPA administers, does not in any way alleviate this problem. First, a rule that requires EPA to exclude or give less weight to scientific information based purely on the availability of underlying data for independent validation is inconsistent with EPA's legal duty under numerous statutes it implements to use the best available science. Second, EPA may not rely on a general grant of authority, i.e., housekeeping, to promulgate regulations or develop policies that are otherwise inconsistent with more specific statutory directives. Third, 5 U.S.C. § 301 does not apply to EPA. Fourth, even assuming EPA has some inherent housekeeping authority apart from 5 U.S.C. § 301, the proposed rule does not constitute a "housekeeping" measure given its massive substantive impact.

#### A. The proposed rule conflicts with fundamental statutory requirements to use the best available science and citation to "housekeeping" authority cannot cure that defect.

Whether EPA is arbitrarily barring consideration of scientific studies or information with nonpublic underlying data or data that are not able to be independently validated, or arbitrarily ascribing less weight to such studies or information, neither approach constitutes "housekeeping," and neither comports with statutory requirements that EPA use the best available science. To reiterate from the 2018 Comments, EPA's obligation with respect to the use of scientific information 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. 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," Safe Drinking Water Act of 1996, 42 U.S.C. § 300g-1(b)(3)(A)(i); the "best available science," Toxic Substances Control Act, 15 U.S.C. § 2625(h); "the latest scientific knowledge," Clean Water Act of 1977, 33 U.S.C. § 1314(a)(1), and Clean Air Act of 1970, 42 U.S.C. § 7408(a)(2); and "generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies," Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11023(d)(2). EPA has repeatedly emphasized the importance of this fundamental precept, including in its 2018-2022 strategic plan,

which states that one of the agency's priorities is to "identify, assess, conduct, and apply the best available science to address current and future environmental hazards."[4]

These statutory requirements apply to all aspects of EPA's decision-making, including its scientific evaluations, adoption of regulatory standards, and development of policies. They do not permit what EPA proposes here: to either exclude or give less weight to scientific studies or information based on criteria—availability of the underlying data and ability to independently validate underlying data—that are not determinative of whether the studies or information constitute the best available science. 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. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-44 (1984). Furthermore, neither 5 U.S.C. § 301 nor any other purported housekeeping authority allows EPA to negate these statutes' fundamental, substantive, and common sense commands. And even assuming EPA has some inherent housekeeping authority, it cannot rely on a general grant of rulemaking authority to promulgate regulations or develop policies that are otherwise inconsistent with more specific statutory directives. *Glob. Van Lines, Inc. v. Interstate Commerce Comm'n*, 714 F.2d 1290, 1293-97 (5th Cir. 1983).[5]

Finally, EPA acknowledges that the statutes it administers would control in the event of a conflict between the proposed rule and those statutes, *see* 85 Fed. Reg. at 15,398, but that caveat cannot save the proposed rule. First, the core principle of the proposed rule is facially invalid, i.e., there is *no* circumstance in which it would be acceptable for EPA to exclude or give less weight to relevant, probative scientific studies, models, or other information that have been validated through peer review, on the sole basis that the underlying data are not publicly available or are not able to be independently validated. EPA cannot save an invalid rule by including what amounts to a waiver procedure, because the "essence of waiver is the assumed validity of the general rule." *Alltel Corp. v. Fed. Commc'n Comm'n*, 838 F.2d 551, 561 (D.C. Cir. 1988). Second, the agency's essential duty in rulemaking is to exercise its subject matter expertise to enact rules that implement and further the purposes of the statutes Congress has assigned it to administer. *Chevron*, 467 U.S. at 842-44. This does not include proposing rules without first determining the source of legal authority but instead asking commenters to supply that information. Third, the agency must propose its rules with specificity and be clear as to the programs, regulations, and information to which they will apply. 5 U.S.C. § 553(b)(3); *Home Box Office, Inc., supra,* 567 F.2d at 35-36.

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[4] U.S. Envtl. Prot. Agency, Working Together: FY 2018-2022 EPA Strategic Plan, (2018) at page 42, https://www.epa.gov/sites/production/files/2019-09/documents/fy-2018-2022-epa-strategic-plan.pdf..

[5] EPA's citation to Clean Water Act, CERCLA, and RCRA provisions granting authority to promulgate rules to carry out the agency's responsibilities under those statutes, 85 Fed. Reg. at 15,397, is also unavailing. Restricting consideration of the best science is neither necessary nor consistent with those statutes' goals of protecting human health and the environment.

B. The Housekeeping Statute does not authorize the proposed rule both because it does not apply to EPA and because the proposed rule does not constitute "housekeeping."

It is troubling, and telling, that more than a year and a half after making its initial proposal EPA remains so uncertain of its legal authority for the proposed rule that it is seeking advice from the public. However, the agency's request for "comment on whether to use its housekeeping authority" is largely an academic exercise, both because of the unambiguous statutory provisions that require EPA to use the best available science and because the proposed rule is plainly not a matter of housekeeping. No citation to housekeeping authority, alone or in combination with other statutes, authorizes what EPA proposes here.

1. *The Housekeeping Statute does not apply to EPA.*

By its plain language, the federal Housekeeping Statute provides no authority to EPA. The statute states, in pertinent part, that "[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." 5 U.S.C. § 301. Moreover, as EPA concedes, a separate statute, 5 U.S.C. § 101, provides an exclusive list of the executive departments that are covered by the Housekeeping Statute and EPA is not included in that list.

EPA instead argues that it "gained" the housekeeping authority of 5 U.S.C. § 301 through the Reorganization Plan No. 3 of 1970. That Plan created EPA by transferring certain functions from the Department of Health, Education and Welfare ("HEW") to the newly established agency.[6] HEW was later divided into what are now the Departments of Education and Health and Human Services. What EPA fails to note, however, is that Congress then amended 5 U.S.C. § 101 to add the Departments of Education and Health and Human Services, granting those agencies the housekeeping authority of 5 U.S.C. § 301, but did *not* also add EPA. Congress subsequently amended 5 U.S.C. § 101 several times to add other federal entities to the list but, again, it never added EPA. It is thus clear that Congress knew how to give housekeeping authority to executive entities when it wanted to, and the absence of EPA from 5 U.S.C. § 101 reflects congressional intent to not confer the authority of 5 U.S.C. § 301 on EPA.

The inapplicability of the Housekeeping Statute here is further confirmed by a 2001 opinion by the U.S. Department of Justice Office of Legal Counsel ("OLC") that rejected a similar attempt by the Office of Government Ethics to arrogate to itself the housekeeping authority in 5 U.S.C. § 301. Opinion of the Office of Legal Counsel of the Department of Justice, 25 Op. O.L.C. 13 (2001). As OLC observed, Congress used both "executive department" and "agency" in title 5 (*see, e.g.*, sections 302, 305), "and we presume that that difference was intentional." *Id.* at 15.

[6] Under Reorganization Plan No. 3 certain functions of several other entities including, among others, the Departments of Interior and Agriculture, were also transferred to the newly created EPA.

"The fact that Congress, in conferring particular powers, distinguished between the heads of executive departments in section 301 and the heads of agencies in section 302 counsels against assuming that Congress meant to confer the authority in section 301 on the heads of all executive agencies." *Id.* at 15-16. EPA thus may not use 5 U.S.C. § 301 as authority for the proposed rule.

Nor can EPA rely on the 2008 OLC opinion addressing EPA's authority to establish a policy for its employees' use of government personal property and agency-issued cell phones. Opinion of the Office of Legal Counsel of the Department of Justice, 32 Op. O.L.C. 1 (2008). First, and far from supporting EPA's position, that opinion explicitly finds that "EPA is not an 'Executive department' within the meaning of section 301," and that any housekeeping authority would come from EPA's organic statute. *Id.* at 82. Second, unlike the proposed rule here, the EPA policy addressed by the 2008 opinion had no effect outside of EPA and was not inconsistent with specific statutory directives regarding the subject matter of the policy. Thus, like the Department of Labor regulations the Supreme Court found defective in *Chrysler Corp. v. Brown*, 441 U.S. 281, 310-12 (1979), the proposed rule finds no support in 5 USC § 301.[7]

2. *The proposed rule is not a matter of "housekeeping," but instead has broad, substantive effect.*

Even assuming EPA has some inherent authority apart from 5 U.S.C. § 301 to make rules that apply exclusively to internal EPA practices, the proposed rule is not authorized by any housekeeping authority because it would unquestionably have broad impacts outside of EPA. Indeed, the very fact that EPA is engaging in notice-and-comment rulemaking is an implicit admission that the proposed rule is not a matter of housekeeping since housekeeping rules are exempt from APA requirements. "The APA exempts from [5 U.S.C. § 553's] procedural requirements: (1) interpretative rules; (2) general statements of policy; and (3) rules of agency organization, procedure, or practice." *Mendoza v. Perez*, 754 F.3d 1002, 1020-21 (D.C. Cir. 2014). Conversely, rules to which the notice and comment requirements do apply are considered "substantive rules." *Id.*

More importantly, the nature of the proposal is not, on its face, a simple matter of housekeeping. Restricting the information that EPA staff can consider in setting standards and criteria to protect public health and the environment, or requiring staff to arbitrarily put a thumb on the scale when weighing information in setting such standards, will directly impact the decisions that EPA makes regarding standard setting. Those standards apply not to EPA but to the regulated community, and many have nationwide applicability. In addition, many states' environmental laws and regulations explicitly adopt EPA standards, or at the very least require an express justification for any deviation. *See* 2018 Comments at 18-19. Furthermore, some states lack resources to develop their own standards and federal standards therefore apply by default. *Id*. EPA's proposed rule would thus have far-ranging impacts outside the agency and would directly

[7] The other cases cited by EPA in the SNPR also provide no support because they do not address the question presented here.

affect the health of the nation's residents and natural resources. Indeed, EPA explicitly acknowledges that the supplemental proposal will have an impact on third parties by, for example: (1) requesting comment on how to cause researchers outside of EPA to change their practices to increase access to data, 85 Fed. Reg. at 15,403; and (2) conceding that the development of "influential scientific information" will have "a clear and substantial impact on important public policies or private sector decisions," *id.* at 15,398.

We are also aware that EPA confirmed to Staff of the House Committee on Science, Space, and Technology that "the bulk of the responsibility for instituting new methods for access to data and models falls on outside parties. The researchers would be responsible for managing the logistics of making the data and models publicly available in a manner that complies with the rule, in consultation with EPA staff."[8] This concession flatly contradicts the SNPR's assertion that the proposed rule "pertains exclusively to internal practices at EPA." 85 Fed. Reg. at 15,398. Accordingly, EPA should set aside the pretense that the proposal is a matter of agency housekeeping and directly confront the conflict between the proposed rule and the substantive statutes that command EPA to use the best available science.

In sum, EPA has entirely failed to address the 2018 Comments regarding the lack of legal authority for the initial proposal. Whether EPA is arbitrarily barring consideration of scientific studies or information with nonpublic underlying data, or arbitrarily according such studies or information less weight, the proposed rule unquestionably has substantive impacts and conflicts with the statutory commands that EPA use the best available science; no citation to "housekeeping" authority can cure that fatal flaw.

## II. The Supplemental Proposal Violates the APA and Numerous Executive Orders.

### A. The comment period is too short to allow for meaningful public participation.

The APA requires agencies to "give interested persons an opportunity to participate in the rule making" through the submission of written comments or oral presentation. 5 U.S.C. § 553(c). The importance of this public comment process—the purposes of which include ensuring informed agency decision-making, encouraging public participation in the administrative process, and ensuring that agencies keep an open mind towards their rules—"cannot be overstated." *N.C. Growers' Ass'n v. United Farm Workers*, 702 F.3d 755, 763 (4th Cir. 2012). In order to achieve these purposes, "the opportunity to comment 'must be a meaningful opportunity.'" *Id.* (quoting *Prometheus Radio Project v. FCC*, 652 F.3d 431, 450 (3d Cir. 2011).

Although EPA provided a brief extension of the comment period after a subset of our Coalition, and many other stakeholders, requested an extension of the initial 30-day deadline, the

[8] Letter from Honorable Eddie Bernice Johnson to Democratic Members of the House Committee on Science, Space and Technology (May 6, 2020) [hereinafter Johnson Letter] https://science.house.gov/chairwoman-johnson-letter-to-science-committee-democratic-caucus-on-epa-transparency-rule

60-day comment period is still grossly inadequate given the significant changes made in the supplemental proposal and the profound effect the proposed rule would have on the regulatory process for all or nearly all of the statutes EPA implements and enforces. As noted in the request for an extension, a comment period of 120 days is necessary and in line with the comment period for the 2018 proposal. Moreover, to continue with this rulemaking at all—let alone on such a tight timeframe—is highly irresponsible in light of the demands the COVID-19 pandemic is currently placing on state and local governments, the public, and above all, many of the scientists, public health experts, and scientific institutions that are best placed to provide feedback on the broad impacts of this proposal. EPA's brief comment period deprives the public of a meaningful opportunity for comment and must be extended.

B. The supplemental proposal is arbitrary and too vague to allow for meaningful public participation.

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., supra,* 567 F.2d at 35-36. Further, an agency's regulations cannot be arbitrary, capricious, or contrary to the agency's statutory authority. 5 U.S.C. § 706. Courts will not hesitate to strike down final rules based on proposals lacking in specificity. *See, e.g. Horsehead Res. Dev. Co. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) ("general notice that a new standard will be adopted affords the parties scant opportunity for comment"). Here, however, in the words of EPA's own Science Advisory Board, "[g]iven the relatively skeletal nature of the Proposed Rule, it is not possible to define the implications of the rule with confidence." SAB Report, at 2. In particular, it is unclear which definitions are included in the proposed rule, EPA fails to define key features of the two "options" proposed for determining which data and models may be used, and the proposed rule's exemptions provision contains insufficient standards to guide the Administrator's discretion. The supplemental proposal thus runs afoul of the APA's substantive and procedural requirements due to its vagueness as well as its arbitrariness, thus depriving the public of a meaningful opportunity to comment. Accordingly, if EPA does not abandon the proposal altogether, it should reclassify the proposal as, at most, an Advance Notice of Proposed Rulemaking.

1. *The supplemental proposal's definitions section is contradictory and unclear.*

The supplemental proposal's contradictory and confusing discussion and presentation of the definitions section of the proposed rule violates the APA's requirement that a proposal must allow for meaningfully informed comment. Specifically, the narrative section of the supplemental proposal states that EPA is "modifying, deleting and proposing new regulatory text" in the definitions section, including "deleting the first paragraph of the 2018 proposed rulemaking regulatory text" and the definition of research data. 85 Fed. Reg. at 15,398. But in the proposed rule section, EPA states that it is "[r]evis[ing] § 30.2 by *adding* the [listed] definitions . . . to read as follows." *Id.* at 15,404 (emphasis added). Unlike other sections of the supplemental proposal

where EPA appears to have included the full revised provision, the proposed rule text for section 30.2 appears to include only the added definitions. It is thus unclear which, if any, portions of the original proposed rule text are being "modif[ied]" or "delet[ed]" as the narrative description indicates. EPA's unclear presentation of the changes it is making to this section of the supplemental proposal deprives the public of the opportunity to provide meaningful feedback on this portion of the rule.

The definitions are also problematic because the proposed rule repeatedly refers to "significant regulatory decisions," *id.* at 15,405-06, but the proposal fails to provide any definition of the terms "significant regulatory decisions" or "significant." Even more confusingly, "regulatory decisions" are defined in the original proposal as "final regulations determined to be 'significant regulatory actions' by the Office of Management and Budget." 83 Fed. Reg. 18,768, 18,773 (Apr. 30, 2018). Moreover, numerous other definitions in the proposed rule are also fatally flawed as described in our Technical Comments below.

The confusion throughout the definitions section infects the entire proposal, because understanding whether and how EPA has defined key terms is critical to understanding how the other substantive provisions of the rule would operate. The supplemental proposal, like the original proposal, is therefore unlawfully vague and arbitrary.

2. *Both EPA's revision and "alternate approach" to Section 30.5 fail to address concerns regarding the arbitrary exclusion or down-weighting of relevant scientific studies.*

In purported response to comments received on its April 2018 initial proposal, EPA's supplemental proposal includes both a revision of and an "alternate approach" to proposed section 30.5. 85 Fed. Reg. at 15,405-06. Each approach would, however, still limit the studies EPA can consider in promulgating significant regulatory decisions, and now, finalizing influential scientific information, and both fail to address concerns regarding the arbitrary exclusion or down-weighting of relevant scientific studies.

Under EPA's "Option 1" for a revised section 30.5, the agency would no longer simply exclude any study for which the underlying data is not publicly available as initially proposed in April 2018, but would now also consider studies with restricted data, so long as there is some method of tiered access sufficient for independent validation. *Id.* at 15,405. It is unclear whether studies with data and models generated before the effective date of this proposed rule would be subject to these criteria. *Compare id.* at 15,399, *with id.* at 15,403. Nonetheless, this revised provision is still fatally flawed in that it continues to unlawfully and arbitrarily exclude from consideration valid scientific studies where the underlying data is unavailable, regardless of whether the studies have been peer reviewed or would be considered part of the "best available science" the agency is commanded to consider.

In apparent recognition of the flaw in Option 1, EPA has alternatively proposed "Option 2," which would, "other things equal," require EPA to give greater consideration to studies for which the data is publicly available as well as to studies with restricted data, so long as there is

some method of restricted access sufficient for independent validation.[9] *Id.* at 15,405-06. Under Option 2, EPA could also consider studies for which the data is not available or where "access is limited"; however, such consideration would be at the agency's discretion and to a "lesser" degree. *Id.* at 15,405. Specifically, the proposed rule states that, "the Agency *may* still consider these studies, *depending on the other attributes of the studies*." *Id.* (emphasis added). Again, it is unclear whether this provision would apply to studies with data and models generated before the effective date of this proposed rule, *compare id.* at 15,399, *with id.* at 15,403, but it is arbitrary and unlawful regardless.

Option 2 is flawed not only because it weighs the value of scientific studies using a non-scientific and largely irrelevant criterion—the public availability of data for independent validation—but also because it identifies no criteria for when or how EPA would exercise the vast discretion the agency creates for itself. Quite the opposite, EPA has instead requested comment on "how much consideration should be given to studies where there is limited or no access to the underlying data and models." *Id.* at 15,403. Thus, Option 2 does nothing to ensure that important and valid scientific studies for which the data may be unavailable receive any consideration at all.

Notably, Option 2 appears to leave open the possibility that the agency's consideration of studies would not be based in any way on the public availability of the underlying data, since the proposed language indicates such weighting would only occur "other things equal." *Id*. at 15,405. But again, EPA's proposed rule suffers from vagueness and lack of criteria to put bounds on the agency's discretion. It is unclear what it would mean or what would be required for "other things [to be] equal," and without knowing this, it is impossible to comment on whether this caveat is sufficient to address concerns regarding the agency's consideration of scientific studies.

Lastly, the arbitrariness of both alternatives for section 30.5 raises troubling conflict of interest concerns regarding the types of studies that EPA would be able to consider. For example, as noted below and in the2018 Comments, toxicology studies for which the underlying data are or could likely be made available for independent validation are typically Good Laboratory Practice ("GLP") studies performed by industry. While EPA has requested comment on "how to ensure that, over time, more of the data and models underlying the science … are available to the public," as well as "how to provide sufficient incentives and support to researchers to increase access to the data," *id.* at 15,403, there is no indication of how this would be accomplished. Accordingly, either version of section 30.5 would strongly favor the agency's consideration of scientific studies conducted by or on behalf of the very industries and special interest groups that will ultimately be regulated by EPA's standards. These are the entities whose studies are more likely to have

[9] Option 2 introduces yet another ambiguity. It does not use the term "tiered access," but nonetheless discusses giving intermediate consideration to studies based upon data with "restricted access." *Id.* at 15,405. It is unclear whether there is a distinction between "tiered access" and "restricted access" and, if so, what that distinction is.

underlying data that is currently available for public validation or who can, going forward, afford to comply with the proposed rule's public availability requirements.

Accordingly, for the above reasons, EPA's unlawful revision and alternate approach to proposed section 30.5 are arbitrary and concerning.

3. *The revised exemption provision remains unduly vague and does not alter the proposal's arbitrary and capricious exclusion of relevant studies, data, and models.*

Like the 2018 initial proposal, the SNPR allows the Administrator to grant case-by-case exemptions based on his or her subjective determination that compliance with the rule is "impracticable." *Id.* at 15,406; 83 Fed. Reg. at 18,774. However, allowing the Administrator to make ad-hoc exemptions for specific studies or models does not cure the supplemental proposal's fatal defect of requiring EPA to consider factors other than those specified by Congress. *See Alltel Corp.*, 838 F.2d at 561 (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 supplemental proposal contains no standards requiring the exemptions to be based on the relevance, importance, or scientific validity of the study or model at issue, and public availability is not a criterion that is meaningful for scientific validity and relevance, the Administrator's ability to arbitrarily include certain studies at his or her discretion simply compounds the extent to which the SNPR would allow EPA to deviate from the requirements of the statutes it is charged with implementing.

The SNPR narrows the grounds for the exemption to cases where compliance is impractical because: (1) technological barriers make sharing the data or models infeasible; (2) development of the data or model was completed before the date of the rule; or (3) making the data and models publicly available is contrary to law. 85 Fed. Reg. at 15,406. However, the SNPR still offers no definition or standards to guide the Administrator's determination of what is "practicable" or "feasible" or what constitutes a "technological barrier," and the waiver process is still wholly discretionary. Without any standardized and objective criteria, the exemption process could, for example, allow the Administrator—a political appointee—to arbitrarily grant exemptions for confidential business information in studies submitted by chemical and pesticide manufacturers, but fail to give similar exemptions for confidential patient or medical information in academic toxicology or epidemiology studies. The National Academies 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. Further, the proposal does not require the Administrator to spell out the criteria applied in granting an exemption. And, given how severely the supplemental proposal 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 EPA's alleged goal of greater transparency. The revision thus fails to improve upon the initial proposal.

In addition, even the ostensibly neutral exemption factors will bias the rule towards the inclusion of industry studies and the exclusion of academic studies. Although EPA rightly recognizes that it may not be possible to make data and models publicly available for many older studies, focusing the exemption solely on models and data developed before the effective date of the rule ignores the fact that—as noted in the 2018 Comments (pp. 23-24)—academic researchers and others whose research is relevant to EPA's work may not conduct and report their studies in a way that satisfies the rule's requirements, and may not have the resources to change their protocols simply to comply with the rule's requirements. Moreover, academic researchers who are focused on publishing their studies in peer-reviewed journals and on obtaining grants and other funding sources for their research have little reason or incentive to even consider whether their studies would qualify for EPA's use under this rule. And members of the academic community may have conducted and published a particular study with grant money that is long gone, may have moved on to other projects or endeavors, and may have utilized research participants who can no longer be found. By contrast, industry-generated studies are almost always funded and conducted for the purpose of being submitted for consideration by EPA and the industry sector has a strong incentive, as well as sufficient resources, to provide whatever is required to address any modified or additional "data transparency" requirements imposed by EPA in this new rule. It is therefore unreasonable for EPA to expect that data generated and models used in academic research will be available in ways that comply with the proposed rule simply because they were developed after its effective date.

C. EPA arbitrarily and capriciously failed to conduct analyses and consultation required by relevant Executive Orders and OMB Memoranda.

In developing both the initial proposal and the SNPR, EPA failed to comply with various Executive Orders and thereby failed to assess significant issues implicated by the proposed rule, including federalism, cost-benefit, and environmental justice issues. Among the APA's bedrock requirements is that agency decision-making be based on a consideration of the relevant factors and data, and failure to perform such analysis is arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983). EPA's failure to conduct the analyses and consultation required by the multiple Executive Orders it has ignored is a textbook example of an arbitrary and capricious failure to consider "relevant factors." Accordingly, the SNPR should be withdrawn.

1. *The SNPR violates the principles set forth in Executive Order No. 13132, Federalism, 64 Fed. Reg. 43,255 (Aug. 4, 1999).*

Of paramount concern to our Coalition, the SNPR violates Executive Order 13132, which provides that agencies must have an accountable process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications. Federalism implications are defined as including regulations and actions that have substantial direct effects on states or local governments (individually or collectively). *Id.* at 1. Contrary to EPA's unsupported, cursory assertion, 85 Fed. Reg. at 15,404, the SNPR indisputably has

substantial federalism implications because, as explained herein, states and local communities are directly and significantly impacted by health and risk-based standards established by EPA.

The standards adopted by EPA under the SNPR's directive to exclude or demote relevant and valid scientific studies will have substantial direct effects on states and cities. As set forth in the 2018 Comments (Section IV, at 18) and stated above, states may be statutorily required to adopt EPA standards or to obtain EPA approval of state-set standards, and may lack the resources or institutional capacity to deviate from EPA standards. States, counties and cities are also significantly impacted through incorporation of EPA standards into the regulations or programs of other federal agencies that rely on EPA standards and/or modeling. This includes, *inter alia*, fuel economy standards set by the National Highway Transportation and Safety Administration, which have an impact on vehicle emissions of harmful air pollutants. Despite the substantial impact EPA's SNPR would have on states and local governments, EPA did not seek any input from states and local governments in developing the SNPR, in violation of Executive Order 13132. EPA must engage in the required consultation with state and local officials, as required by the Executive Order, before proceeding further.

*2. The SNPR does not comply with Executive Order No. 13771, Reducing Regulations and Controlling Regulatory Costs, 82 Fed. Reg. 9339 (Feb. 3, 2017).*

Pursuant to Executive Order 13771, agencies must assess and consider the costs of regulatory actions when making regulatory decisions. Section 3(d) of the Order requires the Director of the Office of Management and Budget (OMB) to identify to agencies, including EPA, a total amount of incremental costs (or "regulatory cap" as stated in section 2) for all Executive Order 13771 actions finalized during the fiscal year. The total incremental cost imposed by each agency cannot exceed the agency's allowance for that fiscal year, unless required by law or approved by the OMB Director. However, the SNPR fails to assess costs to EPA and to researchers. Instead, EPA claims the SNPR is not expected to be an Executive Order 13771 regulatory action because it relates to "agency organization, management or personnel." 85 Fed. Reg. at 15,404. Yet, as discussed in Section I of this comment, EPA's proposed action does not fall within this category.

In fact, the SNPR constitutes an Executive Order 13771 regulatory action, as it is a "significant regulatory action" as defined in Section 3(f) of Executive Order No. 12866, Regulatory Planning and Review, 58 Fed. Reg. 51735 (Oct. 4, 1993) namely, a regulatory action that is likely to result in a rule that may (1) have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, the environment, public health or safety, or State, local, or tribal governments or communities; or (2) raises novel legal or policy issues arising out of the principles set forth in Executive Order 12866. Indeed, EPA states the SNPR is a "significant regulatory action." 85 Fed. Reg. at 15,404.

a. Annual effect on the economy

First, the SNPR greatly expands the amount of studies and information that would be covered by the proposed rule, as it would now apply to research supporting "influential scientific information"—not just the science used in regulatory efforts.[10] In addition, rather than applying only to dose-response data and models, the SNPR now proposes to cover a wide array of scientific research, including "environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on environmental releases, exposure estimates, quantitative structure activity relationship data, and environmental studies." 85 Fed. Reg. at 15,400. The SNPR also proposes a complicated "tiered" access system under which sensitive data underlying scientific studies used by the agency would be accessible in a restricted manner. EPA is also requesting comment on whether the proposed rule's public availability requirements should apply only to data and models generated after the effective date of the rulemaking. *Id.* at 15,403. If not, this would further expand the studies and data covered by the proposed rule.

Second, all of these proposed changes will add significant regulatory costs. Making the data underlying the studies used to generate all "influential scientific information" and "significant regulatory decisions" publicly available or ensuring that such data is publicly available in the future will require significant resources. Further, the additional tiered access system EPA now proposes is complicated and unclear and merely adds to the burden of evaluation and decision-making that EPA must conduct in order to determine what data and studies to use when developing standards and health-based criteria. Establishing tiered access to protect personally identifiable information and other confidentiality protections involves creating multiple versions of a single dataset with varying levels of specificity and protection. *See* Memorandum from Office of Mgmt. & Budget, Exec. Office of the President, OMB M-19-15, Improving Implementation of the Information Quality Act (Apr. 24, 2019), at 9. As agencies add more tiers, they must build in sufficient controls to monitor who is accessing the data and allow only for authorized access. *Id.* The SNPR does not specify how confidential health information covered by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule can be protected outside of HIPAA-covered entities but, again, designing and implementing such protections would be expensive and time consuming. And, although setting up and maintaining tiered access levels involves significant additional time and cost, the SNPR is silent on the "logistics, processes, and funding for such data sharing."[11] Given the expanded scope of the SNPR, which now covers not just pivotal regulatory

[10] The costs of the initial proposal are discussed on pages 16-17 of the 2018 Comments.

[11] *See* J. Samet and T. Burke, Deregulation and the Assault on Science and the Environment, *Annual Review of Public Health* 41:347, 355 (2020), https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-040119-094056.

science but also pivotal science supporting influential scientific information, the costs of the proposal may well exceed the $100 million annual threshold for Executive Order 12866.[12]

b. Adverse material impact on public health, safety, and the environment

In addition to its economic impacts, the SNPR will have a material adverse effect on public health and safety and the environment, as well as State, local and tribal communities. The SNPR would eliminate or de-emphasize consideration of relevant, peer-reviewed scientific studies where the underlying data cannot all be made public or cannot be made available via the proposed complicated tiered access system. In addition, it gives complete discretion to the EPA Administrator to decide what studies with non-public data are subject to the rule. This would likely eliminate from consideration any research studies that, for valid reasons, do not have underlying data that can be made publicly available, including public health studies that form the basis of many critical nationwide protections.

Additionally, given that the requirements set forth in the SNPR might also be applied to historical studies considered by the agency in any actions it takes going forward, many groundbreaking studies conducted in accordance with accepted scientific research principles could be either excluded from consideration or accorded less weight under EPA's tiered hierarchy for consideration. As but one example of such studies, Harvard University's seminal, peer-reviewed "Six Cities Study," completed in 1993, forms the basis of nationwide health-based air quality standards. EPA used data from this well-respected study to strengthen ambient air quality standards for fine particulate matter, improving the health and welfare of citizens throughout the county, particularly those in urban areas. The results of this study were validated by the Health Effects Institute,[13] which reanalyzed the study and confirmed the robustness of the study's findings

[12] *See*, 2018 Comments at 17. 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 estimated that costs to EPA associated with redacting confidential information to comply with this act would be at least $100 million per year. Cong. Budget Office, *Cost Estimate, Honest and Open New EPA Science Treatment (HONEST) Act of 2017, H.R. 1430* (as passed by the U.S. House of Representatives, Mar. 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.

[13] "HEI [the Health Effects Institute] is a nonprofit corporation chartered in 1980 as an independent research organization to provide high-quality, impartial, and relevant science on the health effects of air pollution. HEI typically receives balanced funding from the U.S. Environmental Protection Agency and the worldwide motor vehicle industry. Other public and private organizations periodically support special projects or certain research programs." Health Effects Inst., About HEI: What is the Health Effects Institute?, https://www.healtheffects.org/about (last visited May 18, 2020).

with respect to air pollution and mortality.[14] It would be extremely challenging for the researchers who originally conducted this Harvard study to meet the "open data" criteria the SNPR now proposes for inclusion in EPA's decision-making, even under the proposed tiered system. This study and others may be unable to make their data public because researchers who conduct health-based studies on humans cannot legally share participants' medical data without their permission. Similarly, environmental research also may rely on confidential business information or data collected on private land that owners may not want made public.

In sum, the SNPR would arbitrarily diminish the value of any study that does not make its data public, and would thus limit the number of studies EPA can consider, ultimately weakening the pool of research from which EPA draws it conclusions. By expanding the research that is subject to the rule, requiring public access, and giving the Administrator complete discretion to decide what data and models are subject to the rule, the SNPR will result in important and relevant studies being ignored or under-weighted, to the detriment of the thorough scientific inquiry that is necessary to ensure that scientific and technological information used to support the agency's regulatory actions are robust and objective. *See* 2018 Comments at 19-23. In short, the proposed rule will limit the scientific research that can be used to protect public health and the environment, which in turn will have a material adverse effect on State, local, and tribal communities. It is therefore a "significant regulatory action," subject to the mandates of Executive Order 13771.

*3. The SNPR violates the principles of Executive Order No. 12866, Regulatory Planning and Review, 58 Fed. Reg. 51,735 (Oct. 4, 1993).*

Because the SNPR is a "significant regulatory action" as described above, it is also subject to Executive Order 12866. That order provides as its overarching regulatory philosophy that federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. *Id.* at 1. The proposed rule violates this principle because crafting a rule that establishes a complicated tiered review system for the sake of "transparency" alone and that is inconsistent with standard scientific practice is entirely unnecessary and indeed unlawful, as explained throughout these comments. Access to raw data and model computer code

[14] Daniel Krewski, et al., Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality. Health Effects Institute (2000), https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air.

Daniel Krewski, Ph.D., M.H.A., Univ. of Ottawa, et al., Validation of the Harvard Six Cities Study of Particulate Air Pollution and Mortality, New England Journal of Medicine 350 (2), 198–199 (2004), https://doi.org/10.1056/NEJM200401083500225.

is not the decisive criterion for evaluating studies and other scientific research that underlie the rulemaking process and inform agency decisions. Rather, the integrity of scientific studies and modeling is evaluated through the peer review process. Peer reviewers who are experts in the field of study being researched evaluate the methods, validity, and quality of the research performed and ensure that the data and conclusions are sound and are in accordance with accepted scientific and research principles. This independent and transparent peer review process—which uses consensus in the scientific community to come to a judgment—is robust, and is guided by the principles set forth in Memorandum from Office of Mgmt. & Budget, Exec. Office of the President, OMB M-05-03, Final Information Quality Bulletin for Peer Review (Dec. 16, 2004). Given the existing peer review process, there is no need to limit or exclude evidence from consideration in decision-making because the raw data or models are not publicly available. In short, the original proposal and the SNPR together constitute a rulemaking in search of a problem, in violation of Executive Order 12866.

In addition, because the SNPR likely meets the $100 million threshold of economic significance and is otherwise considered "significant" as set forth above, Executive Order 12866 requires an assessment of potential benefits and costs. *See id.* Section 6(a)(3)(B), (C). Further, the requirements for the analysis of benefits and costs increase in complexity and detail for *economically* significant rules, i.e., those that have an annual effect on the economy of $100 million or more. For these rules, Executive Order 12866 requires that in addition to assessing potential costs and benefits, federal agencies must include the underlying analysis informing that assessment, quantify alternative approaches, and provide the underlying analysis of that alternatives assessment. *Id.* Section 6(a)(3)(C). OMB's Circular A-4, which provides guidance to federal agencies on the development of regulatory analysis of economically significant rules as required by EO 12866, states that analysts should generally analyze at least three options: (i) the preferred option, (ii) a more stringent option, and (iii) a less stringent one. OMB Circular A-4, Regulatory Analysis (Sept. 17, 2003), at 10, https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/. Agencies also must provide a prominent standardized accounting statement, with one or more tables summarizing costs and benefits, both qualitative and quantitative, at both 3% and 7% discount rates. *See* Circular A-4 at 5, Question 8. In this case, EPA failed to undertake the economic analysis required by Executive Order 12866, which is another reason why EPA must withdraw the proposed rule and, at minimum, conduct a full cost-benefit analysis.

*4. The SNPR violates the principles of OMB Memorandum M-05-03, Final Information Quality Bulletin for Peer Review.*

The SNPR also violates the principles set forth in OMB Memorandum M-05-03, titled "Final Information Quality Bulletin for Peer Review." This memorandum establishes government-wide guidance "aimed at enhancing the practice of peer review of government science documents." *Id.* at 1. The memorandum notes that peer review "is one of the important procedures used to ensure that the quality of published information meets the standards of the scientific and technical community." *Id.* at 3. It sets forth various peer review requirements, including individual versus panel review, timing of peer review, scope of the review, and selection of reviewers, as well

as additional, "more rigorous" requirements that apply to peer review of "highly influential scientific assessments." *Id.* at 23.

Contrary to this OMB memorandum, the SNPR would prevent or limit EPA's reliance on peer-reviewed research unless the underlying data can be made available for public review. For studies with restricted data that would require a tiered access system to achieve public availability, EPA does not state how such systems will work in practice other than to note that it is conducting a pilot study using the Research Data Center's "secure data enclave" to host EPA datasets in a restricted use environment. 85 Fed. Reg. at 15,402. EPA notes that development of standard data repositories "is still ongoing," and that EPA itself "does not intend to make all data and models underlying pivotal regulatory science and pivotal science publicly available." *Id*. In relation to the latter statement, EPA notes that it may not own, have access to, or have the authority to provide access to some data and models. *Id*. It is not clear if EPA will make data and models publicly available via some tiered access system where it does have access to data and models, or if EPA intends that scientists and other researchers must themselves establish and maintain a tiered access system that ensures privacy protections for sensitive data. Despite all these uncertainties regarding the mechanisms for public access, the SNPR claims, with no support, that studies where the data is publicly available—through a complex tiered access system or otherwise—are superior to studies where the data is not publicly available, regardless of the rigor of the underlying science and the thoroughness of the peer review process.

Disregarding or giving less weight to studies simply because the underlying data is not publicly available undermines OMB principles of peer review. Rather than excluding evidence from consideration absent the raw data's availability and pursuing adoption of a tiered access system that has yet to be developed or shown to be workable, EPA should continue to adhere to existing, time-tested, and well-established peer review requirements and guidelines to ensure that a consistent method is used to evaluate the quality of any data utilized by the agency for finalizing influential scientific information and significant regulatory decisions.

*5. The SNPR implicates Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Communities, 59 Fed. Reg. 7629 (Feb. 16, 1994).*

Executive Order 12898, among other things, directs federal agencies to identify and address the disproportionately high and adverse human health or environmental effects of their actions on minority and low-income populations with the goal of achieving environmental protection for all communities. *See* U.S. Envtl. Prot. Agency, Summary of Executive Order 12898 – Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, https://www.epa.gov/laws-regulations/summary-executive-order-12898-federal-actions-address-environmental-justice (last visited May 18, 2020). While EPA states that the SNPR is not subject to Executive Order 12898 because it does not establish an environmental health or safety standard, 85 Fed. Reg. at 15,404, Executive Order 12898 is not so limited in its application. Rather, it broadly applies to all agency "programs, policies, and activities," Exec. Order 12898 at 1, and, in any event, the SNPR would affect countless environmental health and

safety standards. In addition, to the extent EPA looks to existing environmental statutes as its authority for the proposed rule, those statutes generally require EPA to consider protection of human health and the environment in taking any regulatory action, which includes potential environmental justice concerns. *See, e.g.*, Resource Conservation and Recovery Act, 42 U.S.C. § 6981(a).

EPA must—but has altogether failed to—contend with the fact that the SNPR would have significant and impermissible environmental justice implications. Specifically, by limiting the scientific studies and data that EPA may consider in both crafting environmental regulations and finalizing "influential scientific information," the SNPR and the original proposal are agency actions that could have disproportionately high and adverse human health or environmental effects on environmental justice communities. Scientific evidence plays a crucial role in addressing the various sources of environmental pollution and reducing the public health burden attributable to environmental factors. The role of such evidence is particularly important to environmental justice communities, which are disproportionately affected by environmental risk.[15] Particularly relevant at this time is a recent Harvard study showing that long-term exposure to fine particulate matter is associated with higher mortality rates for persons infected with COVID-19. https://projects.iq.harvard.edu/covid-pm/home. Environmental justice communities tend to have more commercial and industrial land uses which generate higher levels of pollution, including those that generate fine particulate matter. *See supra*, note 13, at 17. To address this disparity, EPA should be able to consider without limitation studies documenting this link or informing regulations addressing fine particulate matter.

The SNPR would shift EPA's regulatory decision-making away from relying on the best peer-reviewed science in favor of a system that only allows consideration of studies where the underlying data is publicly available through a tiered access system or otherwise, or gives less weight to studies relying on data that cannot be made public. As discussed herein, this is particularly likely to impact epidemiological studies, where participants may be reluctant to make their confidential personal data publicly available. A case in point is EPA's latest action downplaying epidemiology studies, part of its recent proposal to retain the current National Ambient Air Quality Standard for PM2.5 of 12 ug/$m^3$, notwithstanding substantial evidence from such studies that PM2.5 poses significant risks even below 10 ug/$m^3$.[16] Further, a recent study by

[15] *See* Marie Lynn Miranda, *et al*., Making the Environmental Justice Grade: The Relative Burden of Air Pollution Exposure in the United States, *Int. J. Envtl. Res. & Public Health* 8 (June 2011) at 1755–1771, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3137995/.

[16] *See* Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft (Sept. 2019), at 3-94 to 3-99, 3-107 to 3-110, https://www.epa.gov/sites/production/files/2019-09/documents/draft_policy_assessment_for_pm_naaqs_09-05-2019.pdf, last visited 5/14/20; *Review of the National Ambient Air Quality Standards for Particulate Matter*, 85 Fed. Reg. 24,094 (Apr. 30, 2020) (proposed rule).

EPA scientists found that facilities emitting dangerous particulate air pollution—like soot—disproportionately impact low-income communities and communities of color.[17] If EPA can now ignore or give less weight to epidemiological or other studies where the underlying data is not publicly available, this could lead to even more disparities in the burdens that air pollution and other toxics impose on environmental justice communities.

In sum, EPA has violated numerous Executive Orders and memoranda in failing to assess the impacts of its proposal on our economy, states and cities, and most vulnerable communities.

## TECHNICAL COMMENTS

### I. The Supplemental Proposal Conflicts with Long-Established and Accepted Scientific Practices, Lacks Sufficient Specificity to Allow for Transparent Implementation, and Imposes Unnecessary, Time-Consuming and Costly Levels of Review.

The overarching premise of the proposed rule is that, for important scientific decisions, EPA should consider only studies with publicly available data that can be independently validated or should give greater weight to such studies. This quest to ensure that "data underlying [EPA's] actions are publicly available in a manner sufficient for independent validation," 85 Fed. Reg. at 15,399, will inappropriately eliminate the use of findings published in high quality, peer-reviewed journals, including critically important epidemiological studies. This approach is not only inconsistent with EPA's legal obligations to use the best available science as explained above, but it is also contrary to long-standing, accepted scientific practices.

Notably, EPA never explains, in either the initial proposal or the SNPR, how its new approach will improve the agency's scientific decision-making. On the contrary, as the leading independent scientists and science organizations have almost universally commented, it will make it worse. As stated in a 2019 joint statement of the editors of leading scientific journals, "[w]e urge the EPA to continue to adopt an approach that ensures the data used in decision-making are the best available, which will at times require consideration of peer-reviewed scientific data, not all of which may be open to all members of the public. The most relevant science, vetted through peer review, should inform public policy. Anything less will harm decision-making that claims to protect our health."[18]

The scientific bases of EPA risk and policy assessments are already peer reviewed by panels such as the EPA Science Advisory Board panels, Clean Air Science Advisory Committees, FIFRA Science Advisory Panels, and the TSCA Science Advisory Committee to ensure that the

[17] Ihab Mikati, B.S., et al., Disparities in Distribution of Particulate Matter Emission Sources by Race and Poverty Status, *American Journal of Public Health* 108, no. 4 (2018) at 480-485, https://doi.org/10.2105/AJPH.2017.304297.

[18] H. Holden Thorp, et al., Joint Statement on EPA proposed Rule and Public Availability of Data, *Science* (December 6, 2019), https://science.sciencemag.org/content/366/6470/eaba3197.

evaluation of studies is performed using appropriate scientific criteria. These reviewers have ample tools to evaluate the merit and robustness of scientific studies and information, including assessing: the quality of a study's design; the reasonableness of any assumptions; whether sample sizes are sufficient; whether the evidence is strong enough to support a conclusion; and how the study compares with other studies in the same subject matter area. EPA does not explain why these existing review criteria are insufficient or how its new, arbitrary requirements will add "transparency" or improve EPA's decision-making.

The supplemental proposal both fails to address many of the technical problems identified in the 2018 Comments on the initial proposal and creates several new problems. For example, the clarifications, modifications, and additions to the proposed rule, 85 Fed. Reg. at 15,396, raise significant additional concerns regarding the intent, applicability, and implementation of the rule, as discussed above. The expansion of the scope of studies that would now be excluded or given less weight is particularly problematic not only because the manner in which EPA proposes to evaluate data and studies for consideration defies basic scientific principles, but also because there is a complete lack of transparency regarding how the agency will apply the rule.

Of particular concern is the SNPR's new definition of "reanalyze" as "to analyze exactly the same data to see if the same result emerges from the analysis by using the same or different programs and statistical methodologies that were originally used to analyze the data." *Id*. at 15,405. This new definition could ultimately result in scientific decisions being made based on reanalysis of data with different models and assumptions than those used by the original researcher(s), thereby altering the scientific conclusions presented in the originally published and peer-reviewed scientific study. Additionally, EPA does not explain how the reanalysis framework will work in practice, including whether EPA will delay its regulatory process in order for EPA or other entities or members of the public to reanalyze the data in some unknown and possibly lengthy time frame. Any such delays in promulgating stronger protections will be to the detriment of public health and safety. Indeed, as pointed out by the director of the Center for Science and Democracy at the Union of Concerned Scientists, such delays are not ethical for public health studies, where the impacts on individuals can be severe.[19].

Further, although the SNPR requires that data be available in a manner that allows reanalysis, it does not require that EPA perform a reanalysis of the data of every study that is used as the basis for decision-making, and no criteria for determining when a reanalysis would be performed are provided. Therefore, EPA could selectively decide whether to rely on a reanalysis based on how the results of the reanalysis compare with the original analysis performed by the researcher and EPA's preferred outcome. It is also not clear whether the sitting Administrator—a

[19] *See* Andrew Rosenberg, The EPA's Science Restrictions Go from Bad to Worse, Scientific American (Nov. 13, 2019), https://blogs.scientificamerican.com/observations/the-epas-science-restrictions-go-from-bad-to-worse/.

political appointee—could require independent validation of studies that he or she finds objectionable. All of this is contrary to the proposed rule's stated goal of increasing transparency.

Additional comments regarding some of the more concerning technical aspects of the SNPR are set forth below.

A. EPA's expansion of the scope of the proposal will greatly increase the number and types of studies that would be arbitrarily given less weight or excluded from consideration.

While the initial proposal applied only to studies that provide the dose-response data for human health risk assessment, the supplemental proposal expands the types of studies to which the proposed rule would apply and now includes "data and models underlying pivotal regulatory science and pivotal science used to support significant regulatory decisions and influential scientific information." 85 Fed. Reg. at 15,400-01. The expanded scope would thus include the data from many other types of studies such as environmental fate and transport, bioaccumulation, and ecological toxicity studies and will severely curtail EPA's ability to consider studies that provide the most relevant data in many types of regulatory and non-regulatory scientific decision-making. For example, while risk assessment evaluations performed under EPA's Integrated Risk Information System (IRIS) are not regulatory in nature, the toxicity factors provided by IRIS are used as the basis for many regulatory standards developed by EPA and numerous states, as well as federal and state guidance values and cleanup decisions. In fact, some states' regulations require that IRIS toxicity factors be used as the basis for human health standards for environmental contaminants. The SNPR would significantly limit IRIS's consideration of and reliance on many key studies that are crucial for the assessment of human health effects and development of toxicity factors for environmental contaminants.

EPA also fails to provide a rationale to support expanding the data restrictions to non-regulatory decisions; the SNPR points to no evidence that the criteria EPA is currently using or has used in the past when selecting studies to support decision-making have resulted in scientifically invalid conclusions or overly stringent regulations. And, as noted above, the D.C. Circuit has already rejected the approach of excluding studies relying on non-public data as "impractical and unnecessary" when proposed by a trade association as part of a challenge to an air quality standard. *Am. Trucking*, 283 F.3d at 372.

B. The SNPR's definitions open the door to unscientific and arbitrary practices in the implementation of the rule.

As noted above, EPA has proposed revisions to previously unclear definitions, but it has not improved the clarity of these terms and has proposed definitions for new key terms that are equally confusing and subject to multiple interpretations. The interpretation of these key terms could significantly influence how the rule is implemented and open the door to a range of arbitrary and unscientific practices.

*1. "Reanalyze"*

The SNPR proposes to use the term "reanalyze" instead of "replicate" and defines "reanalyze" as "to analyze the same data to see if the same result emerges from the analysis by using the same *or different* programs and statistical methodologies than were originally used to analyze the data." 85 Fed. Reg. at 15,405 (emphasis added). EPA also states that "[i]n addition to identifying potential analytical errors in the original work, reanalyzing the data would allow assessment of the robustness of the original analysis and conclusions by, for instance, showing the variability that can occur when a previously omitted variable is added to the statistical model, different functional form assumptions are made … or different assumptions are made when estimating standard errors and drawing statistical inferences." *Id.* at 15,400. But the selection of the specific approach, models, and input parameters used by researchers to analyze their data is a basic part of the research process that is peer-reviewed prior to publication of the study. EPA's reanalysis would generally not be subject to the same rigorous peer review as the initial study. Therefore, the SNPR's general endorsement of reanalysis as part of the EPA's process for developing regulations and influential scientific information would open the door for the opponents of regulation to introduce ill-considered or "red-herring" arguments that would do nothing to advance the science or understanding. The new policy would be as likely to baselessly undermine valid analysis and conclusions as it would be to "identif[y] potential analytical errors." *Id*.

The basis for the SNPR's proposal to allow for reanalysis using different variables, assumptions and approaches is unclear and unfounded, and it will likely lead to differing, but not better, results that EPA would then rely upon as the basis for regulatory decision-making. This approach is contrary to accepted scientific practice and would do nothing to increase transparency.

*2. "Independent validation"*

The SNPR defines "independent validation" as the "reanalysis of study data by subject matter experts who have not contributed to the development of the original study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced." *Id.* at 15,405. The SNPR goes on to say that information is considered "available in a manner sufficient for independent validation" when it includes the information necessary to understand, assess, and reanalyze the findings; for example: data, protocols, computer codes and models, recorded factual materials, and information on how to access and use this information. *Id.* The SNPR's requirement that underlying data be available in a manner sufficient for independent validation is technically unworkable. The potential problems with this approach include that the actual feasibility of making data and models available in a manner sufficient for independent validation is unclear, as studies may be formatted in a manner that makes the data difficult to share, the lab that has generated the data may not be willing or able to collate and release the data, data from studies generated in other countries may be difficult to obtain, and some important conclusions are drawn from meta-analysis of numerous other studies. These issues would preclude potentially relevant studies from being considered, or would give them less weight without a valid scientific reason for such a restriction.

*3. "Capable of being substantially reproduced"*

The SNPR defines this term as meaning that "independent analysis of the original or supporting data using identical methods would generate similar analytic results subject to an acceptable degree of imprecision or error." *Id.* The use of the word "substantially in the term itself and the words "similar" and "acceptable degree" in the definition reflect that this new term is highly subjective. The proposed rule does not include any criteria for what would constitute "substantial" or "similar" or "acceptable." Further, the supplemental proposal does not indicate where in the regulatory process those determinations would be made, who would make them, and whether those determinations would be explained in the public notice process.

*4. "Publicly available"*

The SNPR defines "publicly available" as "lawfully available to the general public from federal, state, or local government records; the internet; widely distributed media; or disclosures to the general public that are required to be made by federal, state or local law." *Id.* As this definition suggests, it appears that some data and documents that interested parties or commenters might want to obtain could only be obtained through Freedom of Information Act requests. Further, both versions of section 30.5 imply that EPA may make previously private data "publically available." *Id.* at 15,405. Accordingly, although the data may technically be "available," it is likely to be difficult and costly to obtain and often may not be received by the requestor until after the comment period ends, if at all. If this is the case, it is unlikely that interested parties would be able to obtain the information in a manner timely enough to allow for their own review and comment within any timeframe designated by EPA. These limitations on the *actual* ability for requestors to obtain data and documents upon which EPA relies increase the likelihood that when EPA adopts regulations or standards, it will consider studies or data that are not in any practical manner available to the public, while at the same time failing or refusing to consider peer-reviewed studies that have been published in the open literature but which have private underlying data.[20]

Additionally, the SNPR acknowledges that, in some cases, the data and models used in a reanalysis would not be available to the public (e.g., instances where EPA does not own the data and models, lacks access to part or all of the data and models, or does not have the authority to provide access to part or all of the data and models). *Id.* at 15,405-06. Therefore, EPA could use a reanalysis, its own or that of another party, which differs from the analysis provided in the original publication of the study, and the data and models underlying this reanalysis would not be available to the public. Again, this conflicts with EPA's stated goal of increasing transparency.

[20] Were EPA to adopt this misguided proposal, it should at least make its process for excluding studies transparent. Any final rule should require that in any future rulemaking or standard setting, EPA will clearly identify each study that it rejected based on the present rule and fully explain that the basis for the rejection.

*5. "Pivotal regulatory science," "pivotal science," and "influential scientific information"*

In the initial proposal, EPA defined "pivotal regulatory science" as "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions," and stated that such science includes "studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated." 83 Fed. Reg. at 18,770. The SNPR indicates that EPA is retaining this definition of pivotal regulatory science and is adding a definition of "pivotal science." 85 Fed. Reg. at 15,398. The SNPR proposes to define "pivotal science" as "the specific scientific studies or analyses that underlie influential scientific information," *id.* at 15,405, and states that OMB has defined "influential scientific information" as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions," *id.* at 15,398.

Further, as discussed in the 2018 Comments, the 2018 proposal was unclear on whether EPA's requirement that data and models be available for independent validation would apply to the evaluation of scientific literature throughout the entire EPA evaluation process or only for pivotal studies. The current SNPR states that it would "continue to use *standard processes* for identifying, evaluating, and reviewing available data, models, and studies." (emphasis added) *Id.* at 15,399. The requirement that studies have data and models available for independent validation would only apply to studies that "could drive [EPA's] subsequent decisions." *Id.*

This distinction does not appear to be logical or defensible. Using human health risk assessment as an example, components of the scientific evaluation other than the quantitative basis of the toxicity factor (e.g., whether the chemical is classified as a carcinogen or a non-carcinogen or which adverse toxicological effects are well established and relevant to humans) are just as important. It is not logical that EPA would exclude studies from consideration in the quantitative part of its scientific evaluation but would consider these same studies in other equally important components of the scientific evaluation. EPA should consider all best available science in *all* components of the scientific evaluation.

Additionally, the SNPR's statement that the requirement that data and models be available for independent validation would only apply to studies that "could drive [EPA's] subsequent decisions," 85 Fed. Reg. at 15,399, is inconsistent with information EPA provided to staff of the House Committee on Science, Space, and Technology that for scientific evaluations designated as influential scientific decisions "*every study considered by the Agency* in writing a rule, regulation, risk assessment, and more would be subject to these data transparency requirements." Johnson Letter at 3 (emphasis added).

C. The revisions to proposed section 30.5 do not cure the technical problems with the initial proposal and are not scientifically defensible.

EPA's initial proposed section 30.5 precluded consideration of non-publicly available dose-response data and models, with the provision that the Administrator could exempt this requirement on a case-by-case basis. 83 Fed. Reg. at 18,773-74. The SNPR now seeks comment on two alternatives for section 30.5, but neither is any more valid than the highly flawed initial proposal. Option 1 would allow agency consideration of studies only where data and models are available for independent validation. 85 Fed. Reg. at 15,405. This includes tiered access to data and models that have confidential business information, proprietary data, or personally identifiable information that cannot be sufficiently de-identified to protect the data subjects. *Id.* But, EPA may not consider studies for which it does not have access to the underlying data sufficient for independent validation.

Option 2, the alternative approach, would allow the Agency to consider studies where access to the underlying data and models is not available, but would require that, "*other things equal*, [the agency] give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation." *Id*. In developing significant regulatory decisions or influential scientific information, EPA "will identify those studies that are given greater consideration and provide a short description of why greater consideration was given." *Id.* However, the SNPR does not provide any information or guidance regarding how "other things equal" is defined. In fact, we are unaware of any scientifically defensible criteria for determining whether studies are "equal" for consideration in scientific decision-making. As noted above, the clause "other things equal" infuses the decision-making with subjective considerations that cannot be evaluated. Option 2 also fails to identify objective criteria for selection of studies to be considered or for determining the weight to be given to studies with or without publicly available data and models.

The issue of protecting confidentiality of data has been well recognized. A 2002 National Academy of Sciences report states that, "[i]n an experiment to discover whether confidentiality could be preserved while opening the data for public review, the study investigators attempted to disguise the identity of the study participants. They deleted as many features as possible from the questionnaires, such as the name, the state file number, the mother's maiden name, and the name of the person providing the information. However, the investigators needed to retain a minimum set of features if other scientists were to be able to replicate the basic findings of the study… and found that even this minimum set of features could allow for identification of research participants."[21] This process demonstrates that, even after going through an arduous, time consuming process, the removal of personal identifying information would be difficult to

[21] National Research Council, *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of a Workshop*, National Academies Press (2002), https://www.nap.edu/read/10302/chapter/1.

achieve. Therefore, many valid, peer reviewed epidemiological studies would be excluded from consideration, or arbitrarily given less weight, because the data would not be publicly available.

Further, the tiered process to gain access to confidential business information, proprietary information, or personally identifiable information may lead to cybersecurity concerns. The National Academy of Sciences states that the identification of personal information is also a cybersecurity concern. "In addition to cybersecurity concerns, computer scientists and cryptographers have demonstrated that statistical analyses of data sets that generate highly precise results—such as geographic specificity or other characteristics that identify respondents—may result in privacy breaches. This presents a new challenge that federal statistical agencies are just beginning to address." NAS Letter at 4 (internal citation omitted). Accordingly, cybersecurity issues need to be addressed to protect the identity of all participants in a study. This presents yet another reason that data are not made publicly available, which the SNPR does not address.

As stated in the 2018 Comments, EPA 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 has discussed, redacting confidential data from large studies "'isn't just blocking out a line' . . . . It's a huge job that can occupy entire offices for thousands of hours," at commensurately high cost.[22] In a 2018 article discussing this same issue with respect to the HONEST Act, the Union of Concerned Scientists also said that:

> EPA career staff argue that the HONEST act would incur additional costs and time to implement, would limit research that gets conducted, and would deter industry and academics from working with the agency. In their comments to the CBO, [EPA] staff said that, "In addition to spending dollars and staff time on requesting and getting data from study authors, creating [information technology] infrastructure and a data management system to manage, store, and archive large volumes of data, and making the data available in a format that is useful and accessible to the public, EPA would also have to spend dollars and staff time combing through these extensive datasets to find and redact Personally Identifiable Information and Confidential Business Information."[23]

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

[23] Union of Concerned Scientists, Administrator Pruitt Ignores EPA Staff Analysis of HONEST Act Costs (May 20, 2018), https://www.ucsusa.org/resources/attacks-on-science/administrator-pruitt-ignores-epa-staff-analysis-honest-act-costs.

The article also noted that an EPA "staff-level analysis found that complying with Congress's proposed 'HONEST Act' would cost the agency more than $250 million per year." *Id.* Despite all of these prior comments identifying this cost issue, the supplemental proposal is devoid of any discussion of what the costs will be and how they would be paid.

Finally, according to the SNPR, EPA would prioritize or exclusively utilize studies where the data are publicly available, even if those studies do not look at the most sensitive or relevant effects. The use of Good Laboratory Practice (GLP) protocols or other protocols where data are publicly available does not necessarily mean that the study is of higher quality or that it has evaluated the effects that are most relevant for decision-making, 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.

D. Applying the public availability requirement to all studies, regardless of when generated, will lead to exclusion of relevant, probative scientific information that has played an important role in past EPA decision-making.

The SNPR's public availability requirements would potentially apply to all data, models, and studies evaluated at the time the "pivotal" science is being developed, regardless of when the data and models were generated. Applying the public availability requirement to all studies, regardless of when they were generated would severely restrict the body of scientific literature that could be considered as the basis for a "pivotal" science decision. According to this requirement, studies based on data that is not available or obtainable—which is the case for most older studies, many of which are crucial to the scientific issues considered by EPA—would no longer be used by EPA in its decision-making processes unless the Administrator used his or her discretion to grant an exemption under section 30.9. For example, EPA is required to review its National Ambient 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 SNPR, EPA could 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 other rulemakings and would flout EPA's duty to use the best available science when protecting public health and the environment**.**

## CONCLUSION

While EPA should seek to base its scientific decision on the highest-quality science, the proposed rule, as the comments above demonstrate, would only decrease the efficacy and

transparency of these decisions—and thus would lead to a decrease in protections afforded to public health, safety, and the environment. The supplemental proposal not only fails to address the fundamental flaws in the initial proposal but also exacerbates its infirmities by significantly expanding the proposal's scope. We urge EPA to abandon this damaging and unsound proposal and instead convene a process with the Science Advisory Board, the National Academies, and other experts in the field to develop a lawful and scientifically valid approach. We also urge EPA to consult with state and local governments in any such efforts, as principles of cooperative federalism dictate but which EPA has ignored in this process to date. However, we will not hesitate to seek judicial intervention should EPA adopt a final rule that arbitrarily restricts the use of the best available science in agency decision-making.

Sincerely,

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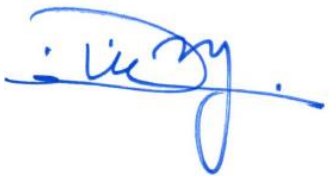

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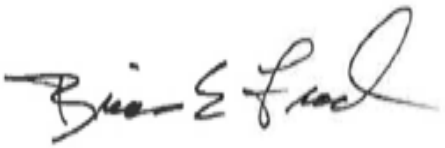

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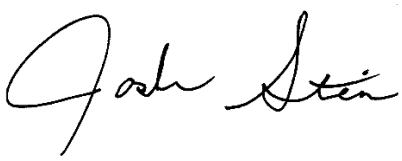

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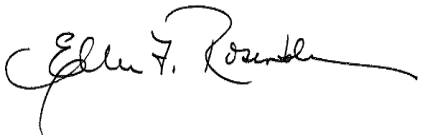

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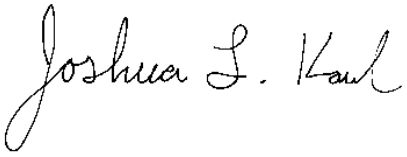

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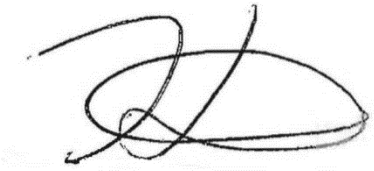

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