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California Environmental Protection Agency

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May 18, 2020

Andrew Wheeler, Administrator
U.S. Environmental Protection Agency
William Jefferson Clinton Federal Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Docket ID No. EPA-HQ-OA-2018-0259

Dear Administrator Wheeler:

The California Environmental Protection Agency, Air Resources Board ("CARB"), Office of Environmental Health Hazard Assessment, Department of Toxic Substances Control, Department of Pesticide Regulation, and State Water Resources Control Board (collectively, "CalEPA") submit the following comments to the U.S. Environmental Protection Agency ("U.S. EPA") on the March 18, 2020, supplemental notice of proposed rulemaking ("SNPRM"), "Strengthening Transparency in Science."

Congress has charged U.S. EPA with administering and enforcing laws to protect human health and the environment. These laws consistently require U.S. EPA to use the best available science to assess the circumstances and levels of exposure to risks, the harms that could result, and the optimal techniques for reducing or eliminating those harms. But the proposal set forth in the SNPRM would unlawfully and imprudently deprive U.S. EPA experts and decision-makers of access to the best available science.

The proposal would require U.S. EPA to deemphasize or disregard altogether any studies for which the underlying data and models are not publicly available. U.S. EPA claims that the purpose of the rule is to improve the transparency and validity of the scientific information it uses. But the SNPRM does not clearly explain the reasons the proposal is allegedly needed or attempt to reconcile it with statutes expressly requiring the agency to use the best available science.

Regardless of what prompted U.S. EPA to consider it, the proposal would have significant adverse public health consequences. It would prevent U.S. EPA from considering important epidemiological studies. It would introduce a bias at U.S. EPA toward less sensitive studies. And it would skew future U.S. EPA actions in a manner that would disproportionately impact environmental justice communities.

Many commenters have warned U.S. EPA about the proposal and have asked the agency to withdraw it. When U.S. EPA published the NPRM in 2018,[1] leading voices in the scientific community condemned it as unnecessary, unworkable, and harmful to human health and the environment. U.S. EPA disregarded their concerns and proposed a broader and even more reckless SNPRM.

The SNPRM would: (1) require that U.S. EPA either reject or de-emphasize scientific studies based upon the public availability of their underlying data and models; (2) apply the proposed rule to *all* forms of science; (3) apply the proposed rule to *all* influential scientific information; (4) broaden the scope of mandatory internal peer

[1] "Strengthening Transparency in Regulatory Science," Notice of Proposed Rulemaking, 83 Fed. Reg. 18768 (April 30, 2018), Docket ID EPA-HQ-OA-2018-0259-0001.

review to include work that may already have received peer review or that is well-established; and (5) establish ambiguous and arbitrary grounds on which U.S. EPA's administrator may grant exemptions from the application of the rule.

As a result, the SNPRM would prevent U.S. EPA from considering the results of both foundational and groundbreaking studies, arbitrarily restricting U.S. EPA experts' ability to make informed scientific judgments and likely biasing agency decision-making. The SNPRM, if finalized, would violate U.S. EPA's legal obligations and compromise the agency's ability to protect public health and the environment. We urge U.S. EPA, as we did in our comment on the NPRM, to abandon the proposal.

I. The SNPRM is Unlawful.

The SNPRM is ill-founded and deeply problematic; it is also unlawful for at least four reasons. First, the SNPRM would violate U.S. EPA's statutory directives to use the use best available science. Second, the SNPRM has no legal basis. Third, the SNPRM is arbitrary and capricious. Finally, U.S. EPA has failed to comply with applicable procedural requirements in developing the SNPRM.

a. The SNPRM Conflicts with U.S. EPA's Governing Statutes.

U.S. EPA administers and enforces most of the country's foundational environmental laws, including the Clean Air Act, Clean Water Act, Safe Drinking Water Act, Resource Conservation and Recovery Act ("RCRA"), Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), Emergency Planning and Community Right-To-Know Act, Federal Insecticide, Fungicide, and Rodenticide Act, and Toxic Substances Control Act. These laws include statutes that expressly require U.S. EPA to consider the best available science. If adopted, the SNPRM would violate these statutes.

In the SNPRM, U.S. EPA proposes to consider only (or, in the alternative, more heavily weight) studies and models with publicly available data. However, restricting agency consideration of scientific studies and models would run afoul of U.S. EPA's obligations under many of its operating statutes to rely on the best available science. For example:

- The Clean Air Act requires, "Air quality criteria for an air pollutant shall accurately reflect the *latest scientific knowledge* useful in indicating the kind and extent of *all identifiable effects on public health or welfare* which may be expected from the presence of such pollutant in the ambient air, in varying quantities."[2]

- The Safe Drinking Water Act requires that findings which support a determination to regulate a contaminant "be based on *the best available public health information*" and that, in developing the National Primary Drinking Water Regulations, "to the degree that an Agency action is based on science, the Administrator shall use *the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices.*"[3]

- The Clean Water Act requires that water quality criteria "accurately reflect[] *the latest scientific knowledge.*"[4]

[2] 42 U.S.C. § 7408(a)(2) (emphasis added).
[3] 42 U.S.C. §§ 300g-1(b)(1)(B)(ii)(II), 300g-1(b)(3)(A)(i) (emphasis added).
[4] 33 U.S.C. § 1314(a)(1).

- The Toxic Substances Control Act requires the Administrator, in decisions based on science, to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed *in a manner consistent with the best available science*," and, in carrying out certain sections of the Act, to "take into consideration information relating to a chemical substance or mixture . . . that is *reasonably available* to [him or her]."[5]

- The Emergency Planning and Community Right-to-Know Act requires that a determination to add a chemical to the Toxics Release Inventory "be based on *generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, available to the Administrator.*"[6]

These statutes require U.S. EPA to make decisions based on many of the kinds of science that the SNPRM would prevent U.S. EPA from considering. The SNPRM, if finalized, would violate these statutes and would prevent U.S. EPA from discharging its duties under the related laws.[7]

b. U.S. EPA Lacks Authority to Issue the SNPRM.

The SNPRM does not address or even acknowledge the statutes that affirmatively require U.S. EPA to consider the best available science. It instead invokes additional statutes that it claims provide authority for the proposed rule. It argues that the rule may be authorized by the Federal Housekeeping Statute, by certain substantive statutes, or by a combination of the two. But the statutes the SNPRM cites do not address the use of science and certainly do not allow U.S. EPA to disregard its express statutory mandates to use best available science.

i. The Federal Housekeeping Statute Does Not Authorize the SNPRM.

In the NPRM, U.S EPA attempted to justify the proposed rule on the basis of several substantive statutes. Presumably out of recognition that these statutes do not support the proposal, the agency is now attempting to frame the proposal as a mere "housekeeping" measure. It invokes the Federal Housekeeping Statute, 5 U.S.C. section 301, which states in relevant part:

> The 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.

As a threshold matter, the Federal Housekeeping Statute does not apply to U.S. EPA for the reasons explained in the comment submitted on the SNPRM by California Attorney General Xavier Becerra and other attorneys general. Even if the Federal Housekeeping Statute applied to U.S. EPA, it would be cabined by

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[5] 15 U.S.C. § 2625(h), (k).
[6] 42 U.S.C. § 11023(d)(2).
[7] The SNPRM's proposed § 30.3, which provides, "[i]n the event the procedures outlined in this part conflict with statutes that EPA administers, or their implementing regulations, the statutes and regulations will control[,]" does not save the SNPRM from this legal violation. Even if U.S. EPA exempts actions under the statutes requiring "best available science," "latest scientific knowledge," or similar mandates, Congress has never instructed U.S. EPA to prioritize public data availability over all else, and has issued directives to the contrary under nearly every substantive law that U.S. EPA administers. Additionally, as discussed below, U.S. EPA has not indicated whether it considers provisions requiring "best available science," "latest scientific knowledge," or similar, to qualify as conflicting statutes or regulations that would control over the SNPRM.

substantive environmental statutes, which Congress enacted *after* the Federal Housekeeping Statute. Most significantly, by its terms, the Federal Housekeeping Statute only authorizes (other) agencies to adopt regulations for purely internal matters, such as record retention and employee conduct. It cannot redeem the SNPRM.

A. The SNPRM Is Not an Internal Rule.

U.S. EPA contends that the proposed regulation should qualify as a housekeeping measure because, allegedly, it "exclusively pertains to the internal practices of the EPA[,]" and would simply "establish an agency wide approach to handling studies[.]"[8] To date, U.S. EPA has cited the Federal Housekeeping Statute as authority for regulations covering such topics as subpoenaed employees, subpoenas *duces tecum*, the handling of confidential business information, agency practices under the Freedom of Information Act and the Privacy Act of 1974,[9] and agency-sponsored research involving human subjects.[10] Such regulations affect how U.S. EPA employees conduct internal procedural and administrative tasks.

The SNPRM, by contrast, would govern the science that U.S. EPA would be permitted to consider when implementing a range of substantive environmental laws. The SNPRM would directly limit the public's ability to provide effective comment on future agency proposals, as it would force U.S. EPA to summarily reject public comments referencing studies or models relying on non-publicly available data. As detailed throughout the remainder of this comment, the SNPRM would profoundly affect future U.S. EPA regulatory decisions and "influential scientific information"—which, per U.S. EPA's proposed definition, is information that would have a "clear and substantial impact on important public policies or private sector decisions."[11]

The amount of attention the proposal has attracted—from the scientific community, elected officials, the media, and nonprofit organizations—reflects the extent of its impacts.[12] In response to the NPRM, for example, U.S. EPA received nearly 600,000 comments and more than 9,000 unique substantive comments. Many of these were comments from scientific organizations, scientists, and public health officials explaining the dire impacts the NPRM would have on public health and the environment. A purely internal housekeeping measure would not have drawn such widespread stakeholder interest.

B. The Substantive Statutes Would Control Over the Federal Housekeeping Statute.

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[8] 85 Fed. Reg. at 15398.
[9] 5 U.S.C. §§ 552, 552a. *See*, *e.g.*, 40 C.F.R. §§ 2.100, 2.211, 2.404, 2.405, 16.6.
[10] *See* 40 C.F.R. Part 26.
[11] *See* proposed section 30.2.
[12] E.g., *E.P.A. to Limit Science Used to Write Public Health Rules*, N.Y. TIMES (Nov. 11, 2019); *E.P.A. Updates Plan to Limit Science Used in Environmental Regulations*, N.Y. TIMES (March 4, 2020); *The E.P.A. Says It Wants Research Transparency. Scientists See an Attack on Science*, N.Y. TIMES (March 26, 2018*); E.P.A. Announces a New Rule. One Likely Effect: Less Science*, N.Y. TIMES (April 24, 2018); *The EPA's Anti-Science 'Transparency' Rule Has a Long History*, Wired (Nov. 13, 2019); Ellie Kauffman and Gregory Wallace, *EPA ices plan to limit how many health-related studies can be considered in forming regulations*, CNN (October 17, 2018); Heidi Voigt, *EPA Wants New Rules to Rely Solely on Public Data*, WALL STREET JOURNAL (April 24, 2018) Eva Botkin-Kowacki, *Is transparency always a good thing? EPA weighs controversial new rule*, CHRISTIAN SCIENCE MONITOR (March 12, 2020); BRADY DENNIS, *EPA pushes ahead with effort to restrict the science it uses to craft regulations*, Washington Post (November 13, 2019); Steven Mufson; Chris Mooney, *EPA excluded its own top science officials when it rewrote rules on using scientific studies*, WASHINGTON POST (Oct. 3, 2018); Joel Achenbach, *Scientists decry new EPA proposal as a way of suppressing solid science*, WASHINGTON POST (May 8, 2018).

Even if the Federal Housekeeping Statute somehow applied (which it does not), it could not authorize the proposal set forth in SNRPM. The Federal Housekeeping Statute does not compel U.S. EPA to adopt the SNPRM or authorize it to issue regulations counter to the substantive statutes it administers. These statutes consistently require U.S. EPA to use the best available science; there is no reasonable way that the general Federal Housekeeping Statute could be read as impliedly repealing the more specific and later-enacted substantive statutes.[13]

ii. The Cited Substantive Statutes Do Not Support the SNPRM.

The NPRM cites to several substantive statutes that it claims authorize the proposed rule. These statutes do not authorize either the NPRM or the SNPRM, for the reasons that we and California Attorney General Becerra (jointly with other Attorneys General) discussed in comments on the NPRM. The SNPRM cites to three additional statutes—provisions of RCRA, CERCLA, and the Clean Water Act—that it contends provide the necessary authority.

Even if these additional citations *did* authorize the SNPRM (which they do not), they would do so only within their respective substantive ambits, not for all U.S. EPA actions.[14] The absence of such provisions in other statutes establishes that similar activities are not authorized in their scopes. Moreover, for each statute, the ostensibly "authorizing" language must be read in context of other mandates in those statute's schemes; they cannot be read to contradict direction to use the "best available science" or similar mandates, and therefore provide U.S. EPA no support. Aside from these limitations, the statutory provisions referenced as authority in the SNPRM are as unavailing as those cited in the NPRM.

A. RCRA Does Not Authorize the SNPRM.

The SNPRM cites to one additional RCRA statute – 42 U.S.C. section 6981 ("Section 6981"). Section 6981 consists of three subdivisions, the most relevant of which mandates that "[t]he Administrator shall establish a management program or system to insure the coordination of all such activities and to *facilitate* and *accelerate* the process of development of *sound* new technology (or other discoveries) from the research phase, through development, and into the demonstration phase."[15] The SNPRM—which would often screen out the best available science and which has alarmed leading scientific bodies—would not "facilitate" or "accelerate" the advancement of "sound" science, for the reasons discussed throughout this comment.

B. CERCLA Does Not Authorize the SNPRM.

The SNPRM cites to an additional CERCLA provision – 42 U.S.C. section 9615 – that consists of a single statement of delegation: "The President is authorized to delegate and assign any duties or powers imposed upon or assigned to him and to promulgate any regulations necessary to carry out the provisions of this subchapter." The SNPRM does not identify any "duties or powers imposed upon or assigned to" the president

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[13] In case of apparent conflict, statutes must be interpreted harmoniously when possible; to the extent that statutes cannot be harmonized, the later-in-time statute prevails. E.g., *Morton v. Mancari*, 417 U.S. 535, 551 (1974); *Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 155 (1976). The Federal Housekeeping Statute was enacted prior to the adoption or amendment of the cited provisions of the Clean Air Act (42 U.S.C. § 7408); the Safe Drinking Water Act (42 U.S.C. §§ 300g-1); the Clean Water Act (33 U.S.C. § 1314); the Toxic Substances Control Act (15 U.S.C. § 2625); and the Emergency Planning and Community Right-to-Know Act (42 U.S.C. § 11023).

[14] Even if the cited provisions of RCRA, CERCLA, and the Clean Water Act supported the SNPRM (which they do not), such statutes could not, for example, authorize the SNPRM with regard to air pollution data.

[15] Emphasis added.

under RCRA that would authorize U.S. EPA to depart from accepted practices in the scientific community and to exclude and/or deprioritize the best available scientific studies for arbitrary reasons.

C. The Clean Water Act Does Not Authorize the SNPRM.

The SNPRM cites to one additional Clean Water Act provision – 33 U.S.C. section 1361. The most arguably relevant subdivision simply states that "[t]he Administrator is authorized to prescribe such regulations as are necessary to carry out his functions under this chapter." It does not address the use of science, and the SNPRM fails to explain how the proposed regulation would be "necessary to carry out" the Clean Water Act, particularly when another section of the Act requires that water quality criteria "accurately reflect[] the *latest scientific knowledge.*"[16]

c. The SNPRM is Arbitrary and Capricious, in Violation of the Administrative Procedure Act.

Agency action violates the Administrative Procedure Act (APA), 5 U.S.C. section 706, if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[17] Agency action is arbitrary and capricious when the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise[,]"[18] or otherwise fails to "examine the relevant data and articulate a satisfactory explanation for its action 'including a rational connection between the facts found and the choice made.'"[19]

If finalized, the SNPRM would be arbitrary and capricious, and not in accordance with law. Congress has directed U.S. EPA to use the "best available science"[20] or the "latest scientific knowledge"[21] in a multitude of programs. Congress has never directed U.S. EPA to consider the public availability of underlying data and models as the sole or even predominant factor in evaluating the soundness of science.[22] Nevertheless, U.S. EPA is proposing to codify public availability as a threshold requirement for agency consideration or publication of or reference to a scientific study.[23] Codifying this requirement, when public availability is not a factor that

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[16] 33 U.S.C. § 1314(a)(1) (emphasis added).
[17] 5 U.S.C. § 706(2)(A).
[18] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983).
[19] *Ibid.* (citing *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).
[20] E.g., Safe Drinking Water Act, 42 U.S.C. § 300g-1; Toxic Substances Control Act, 15 U.S.C. §§ 2617(f), 2625(h), Clean Water Act, 33 U.S.C. § 1321(a)(27).
[21] E.g., Clean Air Act, 42 U.S.C. § 7408(a)(2).
[22] Moreover, recent legislation prescribes priorities and processes for data use in agency rulemakings, and requires federal agencies to make their own data publicly available (consistent with existing legal restrictions), yet does not authorize agencies to exclude or deprioritize non-federal data based on public non-availability. Foundations for Evidence-Based Policymaking Act of 2018, PL 115-435, January 14, 2019, 132 Stat 552. Title II of this Act is the "Open, Public, Electronic, and Necessary (OPEN) Government Data Act."
[23] U.S. EPA's preamble to the SNPRM claims: "Under this regulation EPA would continue to use standard processes for identifying, evaluating, and reviewing available data, models, and studies. When the Agency has potentially identified multiple key studies or models of similar quality that could drive its subsequent decisions, the Agency will investigate the availability of the underlying data." 85 Fed. Reg. at 15399. This portrayal of the SNPRM, as merely establishing public data availability as a tie-breaker among key studies or models of similar quality, is belied by the SNPRM's proposed regulatory text. Under the SNPRM's proposed section 30.5, "[w]hen promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will use only pivotal regulatory science and/or pivotal science that includes studies" that meet the proposed public availability requirements. As proposed, this inquiry into public availability

Congress intended U.S. EPA to prioritize, would itself be arbitrary and capricious in violation of the APA. U.S. EPA has also manifestly failed to consider important aspects of the ostensible problem, offered explanations for its proposed decision that run counter to the evidence, and failed to articulate any rational explanation for the proposal, as discussed below under, "The SNPRM Fails to State a Reasoned Basis for the Proposed Regulation."

Finalizing the SNPRM would render subsequent U.S. EPA actions arbitrary and capricious as well. The SNPRM would prohibit or restrict U.S. EPA's consideration of relevant and high-quality data, studies, and models that do not meet U.S. EPA's arbitrary and outcome-seeking proposed requirements for public availability. In excluding relevant science from expert consideration, based on a factor that Congress did not intend for the agency to prioritize, U.S. EPA would inevitably fail to consider important aspects of the problems under consideration, issue decisions counter to the evidence before the agency, and commit other basic APA violations with every affected action. Indeed, the D.C. Circuit Court of Appeals rejected the proposed approach decades ago, agreeing that, "[i]f EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much *plainly relevant scientific information* would become unavailable to EPA for use in setting standards to protect public health and the environment."[24] This instability would also create significant liabilities, and hence reliance risks, for States, regulated entities, and the public.

In addition to its substantive prohibition on arbitrary and capricious actions, the APA establishes general procedural requirements for agency rulemakings, including a requirement for agencies to consider the relevant information presented via public comment on proposed rulemakings.[25] By precluding agency experts from considering relevant studies and models raised in public comments on proposed agency actions, the SNPRM would also cause future U.S. EPA actions to violate the APA's procedural requirements.

d. The SNPRM Fails to Comply with Procedural Requirements.

Federal agencies must comply with certain procedural requirements when undertaking rulemakings. The SNPRM fails to comply with procedural requirements established by the APA and at least five executive orders. In addition to the illegality of violating procedural requirements, these failures further demonstrate the arbitrariness of the SNPRM.

i. The SNPRM Fails to Comply with APA Procedural Requirements.

The APA sets forth procedures that federal agencies must comply with when developing a new regulation. These procedures are meant to ensure that, "federal agencies are accountable to the public and their actions subject to review by the courts."[26] U.S. EPA failed to comply with them when developing the SNPRM. Specifically, the SNRPM fails to state a reasoned basis for the proposed regulation and fails to state a reasoned justification for the proposed change in agency policy.

A. The SNPRM Fails to State a Reasoned Basis for the Proposed Regulation.

takes place before consideration of quality, and excludes science that does not meet the public availability test regardless of whether other studies or models are "of similar quality," or exist at all.

[24] *American Trucking Ass'ns., Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002) (emphasis added) (quoting National Ambient Air Quality Standards for Particulate Matter: Final Rule, 62 Fed. Reg. 38,652, 38,689 (July 18, 1997)).

[25] 5 U.S.C. § 553(c).

[26] *Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992).

As part of its notice-and-comment rulemaking requirements, the APA requires an agency to provide notice of a proposed rulemaking,[27] and to "disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based."[28] As the D.C. Circuit Court of Appeals has noted, "a prerequisite to the ability to make meaningful comment is to know the basis upon which the rule is proposed."[29] Yet U.S. EPA has not provided a justification, let alone a detailed disclosure of its reasoning and data, for either the NPRM or the dramatic expansion proposed in the SNPRM. The proposals merely assume and assert that: transparency is the determinant of scientific quality; transparency is presently lacking; public data availability is the only guarantor or indicator of transparency; and there exist no less disruptive means of increasing transparency that U.S. EPA could consider.

We discussed U.S. EPA's failure to explain the basis of its NPRM in our 2018 comments. The SNPRM fails to rectify this issue: it does not provide a reasoned basis for either the NPRM or the drastic expansion proposed in the SNPRM. As in the NPRM, the SNPRM provides no references to U.S. EPA regulatory science or influential scientific information that subsequent review suggests were falsified or otherwise problematic, or instances in which public unavailability of data or models has resulted in irrational or arbitrary regulations or other harms.

Instead of providing a justification for profoundly expanding the scope of the NPRM in the SNPRM, U.S. EPA references only unspecified public comments and uncomplicated requests for clarification of the NPRM. For example, the NPRM preamble clearly explained the proposal's applicability only to dose-response data and models, but one provision of the proposed regulatory text was ambiguous on this point. U.S. EPA now cites this single ambiguity as its basis for the SNPRM's dramatic expansion of the proposal to all types of data and models.[30]

U.S. EPA also claims that the SNPRM is necessary to "ensure consistency with" a White House Office of Management and Budget (OMB) memorandum that is largely irrelevant, and that requires nothing resembling the SNPRM's provisions.[31] However, the only provisions of the memorandum that U.S. EPA specifically references merely suggest that agencies "prioritize" and "explore" methods that provide data access "consistent with statutory, regulatory, and policy requirements for protections of privacy and confidentiality, proprietary data, and confidential business information."[32] They do not serve as a basis for the SNPRM. Indeed, several provisions of the OMB memorandum actually contradict or otherwise undermine the SNPRM.[33] Even if the memorandum could legally provide a basis for the SNPRM (which it cannot), the SNPRM vastly

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[27] 5 U.S.C. 553(b).
[28] *Home Box Office, Inc. v. F.C.C.*, 567 F.2d 9, 35 (D.C. Cir. 1977).
[29] *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 393 (D.C. Cir. 1973).
[30] 85 Fed. Reg. at 15399.
[31] *Id*. at 15398 (citing Memorandum for the Heads of Exec. Dep'ts & Agencies from Russell T. Bought, Acting Dir., OMB, *Improving Implementation of the Information Quality Act*, M-19-15 (Apr. 24, 2019), https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf). The OMB memo requires only that federal agencies update certain existing guidance documents, largely concerning procedures for the public to request corrections of agency-issued information. M-19-15 at 2.
[32] 85 Fed. Reg. at 15402, citing OMB M-19-15, Implementation Updates 3.4, 3.5.
[33] OMB issued the memorandum as an update under the Information Quality Act (IQA), which applies to agency-disseminated information but not to regulatory decisions. Appropriations Act of 2001, Pub. L. No. 106-554, § 515, 114 Stat. 2763 (2000) (codified at 44 U.S.C. § 3516, note). As such, the memorandum can, at most, apply to agency-issued information, not regulatory decision-making as proposed under the SNPRM. Thus the memorandum cannot serve as a basis for the SNPRM. Pursuant to the OMB guidelines, U.S. EPA has its own guidelines to ensure that information disseminated by EPA is substantively "accurate, reliable, and unbiased." U.S. EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (2002), https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information, at 15.

exceeds anything the memo contemplates. Moreover, the SNPRM conflicts with the recommendations and requirements of OMB's IQA Guidelines, the federal government's primary directive to federal agencies regarding dissemination of "influential information."

Ultimately, U.S. EPA provides no reasoned basis for the SNPRM's drastic expansion of the NPRM. Instead, the agency summarily announces its intent to apply the NPRM's provisions to "the broader approach that EPA uses to evaluate the entire body of scientific literature"[34] and to all "types of data and models [that] drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions and influential scientific information."[35] This acknowledgement of an intent to expand the proposal's applicability, however, does not comprise the detailed disclosure of basis and data that the APA requires.[36]

B. U.S. EPA Fails to Provide Reasoned Justification for the Change in Agency Policy.

Under the APA, changes in agency policy positions are permissible only when the agency provides a reasoned justification for the change.[37] Further, "[t]he requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it is changing position."[38]

U.S. EPA fails to acknowledge that the SNPRM and NPRM comprise a profound change in agency policy position, let alone provide a justification. Instead, the agency struggles to situate the proposals within existing federal policies and guidance on public data availability and peer review. This includes referencing a variety of U.S. EPA and OMB guidance documents dating back to 2002 that, as discussed above, bear little relationship to the current proposals.[39] The SNPRM represents a wholesale departure from past and current U.S. EPA policy with powerful and far-reaching impacts for U.S. public health and the environment. U.S. EPA's failure to justify or even acknowledge its proposed policy change falls far short of the APA's requirements.[40]

ii. The SNPRM Fails to Comply with Executive Orders.

The SNPRM fails to comply with at least five executive orders (E.O.): (1) E.O. 12866 regarding economic impacts; (2) E.O. 13132 regarding federalism implications; (3) E.O. 13045 regarding environmental health and safety risk to children; (4) E.O. 12898 regarding environmental justice; and (5) E.O. 13563 regarding comment periods.

A. The SNPRM Fails to Comply with E.O 12866.

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[34] 85 Fed. Reg. at 15399.
[35] *Id*. at 15402.
[36] *See Home Box Office, Inc. v. F.C.C.*, 567 F.2d 9, 35 (D.C. Cir. 1977).
[37] *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-516 (2009).
[38] *Ibid*.
[39] 85 Fed. Reg. at 15403-04.
[40] *See* 85 Fed. Reg. at 15398. Though U.S. EPA desperately avows its authority under the Federal Housekeeping Statute, 5 U.S.C. § 301, for this ostensible "rule[] of agency organization, procedure or practice," as described in the APA, U.S. EPA does not invoke the APA's procedural exemptions for such rules. *See* 85 Fed. Reg. at 15397 ("As the Supreme Court further notes, section 301 authorizes "what the [Administrative Procedure Act] terms `rules of agency organization, procedure or practice' as opposed to substantive rules.") (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979)). The APA exempts "rules of agency organization, procedure, or practice" from the requirement to publish a notice of proposed rulemaking, 5 U.S.C. § 553(b)(A), which U.S. EPA has now done twice for this proposed action.

U.S. EPA determined the SNPRM to be a "significant regulatory action" and, as a result, was required to conduct a regulatory impacts analysis under E.O. 12866.[41] Yet U.S. EPA failed to conduct the required impacts analysis or provide any sort of explanation for not doing so. This failure underscores the arbitrariness and capriciousness of the proposed rule.

The purpose of regulatory impacts analyses—to help the public and the agency itself understand the costs and benefits of a significant rule—is thwarted when impacts are not critically assessed. Yet U.S. EPA did not estimate the increased resources necessary for the agency to implement the SNPRM, even though, as discussed elsewhere in this comment, complying with the rule would considerably burden agency resources. U.S. EPA did not attempt to quantify the purported benefits of providing tiered access to restricted data and models or the profound impacts to agency protection of public health and the environment.[42] Not only does this failure violate E.O. 12866, it precludes fully-informed public comment on this highly-consequential and far-reaching set of proposals.

B. The SNPRM Fails to Comply with E.O. 13132.

Although E.O. 13132 requires U.S. EPA to analyze the cooperative federalism implications of this rule and consult with states on its impacts, the agency declined to fulfill these requirements. U.S. EPA incorrectly states that the SNPRM "does not have federalism implications [and that it] will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government."[43] In fact, the SNPRM would disrupt the cooperative relationship between the federal government and California to implement federal environmental laws, including potentially undercutting state-level air quality standards under the Clean Air Act.

The Clean Air Act represents a hallmark example of cooperative federalism, as U.S. EPA and state air agencies partner to protect public health from harmful effects of air pollution. An essential aspect of this relationship includes basing federal and state-level implementation decisions on the best available science. This includes U.S. EPA setting of National Ambient Air Quality Standards (NAAQS) at a level requisite to protect the public health,[44] while states meet the standards through development and implementation of State Implementation Plans (SIP). The NAAQS must be based on air quality criteria developed using the "latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare," and updated at least every five years following a thorough review by an independent scientific review committee.[45] The Clean Air Act sets out specific actions for this committee to advise U.S. EPA on areas where

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[41] E.O. 12866, 58 Fed. Reg. 51735 (October 4, 1993) Section 6(a)(3)(B).
[42] Similarly, the SNPRM fails to meet the standards of OMB Circular A-4, the OMB guidance to federal agencies on analyses in regulatory decision-making that was heralded in President Trump's E.O. 13783, "Promoting Energy Independence and Economic Growth" (March 28, 2017). As E.O. 13783 noted, Circular A-4 "was issued after peer review and public comment and has been widely accepted for more than a decade as embodying the best practices for conducting regulatory cost-benefit analysis." 82 Fed. Reg. 16093 (March 31, 2017), § 5(c), citing Circular A-4, September 17, 2003. Circular A-4 requires agencies to quantify anticipated benefits and costs of proposed rulemakings as accurately as possible using the best available techniques, and to ensure that any scientific and technological information or processes used to support their regulatory actions are objective. 58 Fed. Reg. 51735 (October 4, 1993); Circular A-4, September 17, 2003. Not only did U.S. EPA fail to quantify the NPRM and SNPRM's costs and benefits, but the proposed rule would force future rulemakings out of compliance with these guidelines by precluding objective use of scientific information based solely on its public availability.
[43] 85 Fed. Reg. at 15404.
[44] 42 U.S.C. § 7409(a), (b)(1).
[45] *Id*. at §§ 7408(a)(2), 7409(d)(1), (d)(2)(A) and (B).

additional knowledge is required for reviewing NAAQS and the research efforts necessary to obtain that information, among related topics.[46]

California relies on the legitimacy of this scientific review process for purposes of commenting on the NAAQS-setting process and developing and implementing its SIPs.[47] The SNPRM does not address how the proposal would affect this scientific review process.[48]

If a finalized SNPRM prevents U.S. EPA and its Clean Air Act Advisory Committee from considering the best available science, it would severely restrict U.S. EPA's decision-making when establishing, reviewing, or revising air quality criteria and NAAQS. The resulting effect is likely to be confusion and disagreements between CARB (and its counterparts in other states) and U.S. EPA about what studies can and should be considered. This is likely to harm the cooperative relationship between U.S. EPA and state air agencies, in addition to hindering the ability of U.S. EPA and CARB to meet the obligations of the Clean Air Act, and, ultimately, harming public health through the setting of substandard NAAQS.

The same dynamic would likely play out under other environmental laws that depend upon cooperative federalism, such as the Clean Water Act. This would risk damaging the cooperative federalism framework devised by Congress for these laws. U.S. EPA's failure to consult with the states on the impact of this rule is also inconsistent with U.S. EPA's own primary goal set forth in its 2018-2022 Strategic Plan to create more effective partnerships with the states, among others, in carrying out shared responsibilities and communicating results to all Americans.[49] Given the potentially significant impacts, U.S. EPA's failure to analyze the cooperative federalism impacts of the SNPRM under E.O. 13132 further demonstrates the arbitrariness of U.S. EPA's rulemaking process.

C. The SNPRM Fails to Comply with E.O. 13045.

Executive Order 13045, section 5-501, provides that, for each "covered regulatory action" submitted to the Office of Information and Regulatory Affairs (OIRA), the issuing agency must provide: "(a) an evaluation of the environmental health or safety effects of the planned regulation on children; and (b) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency."[50] The E.O. defines a "covered regulatory action" as a rulemaking that could be economically significant or that "concern[s] an environmental health risk or safety risk that an agency has reason to believe

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[46] *Id*. at U.S.C. § 7409(2)(C).
[47] Separately but relatedly, California sets California Ambient Air Quality Standards (CAAQS) under state law to define maximum allowable levels of certain pollutants, which include the federal Clean Air Act criteria pollutants and additional pollutants. 42 U.S.C. § 7509. Though California continues to require meeting CAAQS, attainment of NAAQS has precedence due to federal preemption and federal penalties for failure to meet federal attainment deadlines. Further, CAAQS must be met by a showing of incremental progress compared to NAAQS, which must be met by deadlines subject to sanction under the federal law. *See* Cal. Health & Saf. Code § 40910. To the extent that NAAQS are negatively impacted by inadequate science, California could be impelled to consider changes to its own laws or procedures, consistent with the Clean Air Act, to ensure that the State can ensure effective air quality regulation and protection of the public health.
[48] The SNPRM provides, "[i]n the event the procedures outlined in this part conflict with statutes that EPA administers, or their implementing regulations, the statutes and regulations will control." 85 Fed. Reg. 53, 15405. However, the SNPRM does not indicate whether U.S. EPA considers U.S. EPA's process for setting and revising air quality criteria and NAAQS to conflict with the SNPRM.
[49] U.S. EPA, Working Together, FY 2018-2022 U.S. EPA Strategic Plan, February 2018 (Updated: September 2019), available at https://www.epa.gov/sites/production/files/2019-09/documents/fy-2018-2022-epa-strategic-plan.pdf.
[50] 62 Fed. Reg. 19885, 19887.

may disproportionately affect children."[51] It bases its requirements on the recognition that "children may suffer disproportionately from environmental health risks and safety risks."[52]

The proposed regulation could disproportionately affect children by preventing U.S. EPA from considering children's health studies, thereby increasing risks and negative health outcomes for American children. U.S. EPA recognizes the SNPRM as significant (and submitted it to OIRA, as discuss below), but failed to conduct the evaluation of health impacts to children required by E.O. 13045.

D. The SNPRM Fails to Comply with E.O. 12898.

E.O. 12898 requires a federal agency to consider the environmental justice "effects of its programs, policies, and activities . . . to the greatest extent practicable and permitted by law."[53] The SNPRM incorrectly asserts that the proposed regulation is not subject to E.O. 12898 "because it does not establish an environmental health or safety standard."[54] Yet E.O. 12898 does not apply only to "standard[s]," but rather to all "programs, policies, and activities." To the extent that U.S. EPA has any doubt about whether the SNPRM could have environmental justice impacts, E.O. 12898 directs agencies to consider such justice impacts "to the greatest extent practicable." And as discussed below, the SNPRM would have such impacts.

II. The SNPRM Is Unnecessary.

Our comments on the NPRM noted that U.S. EPA failed to explain a need for the proposed rule—and that there is, in fact, no need for it. In the intervening two years, U.S. EPA had ample opportunity to develop an explanation for its proposal to upend established scientific practices and deprive itself of access to the best available science. But U.S. EPA failed to provide such an explanation in the SNPRM. The proposal remains an expensive and reckless solution in search of an unidentified problem.

a. The SNPRM Is Based on a Faulty Premise Regarding the Determinants of Research Quality.

Access to data and models may be restricted because they incorporate personal health information, confidential business information, or proprietary intellectual property. But the scientific community has accepted practices for assessing the validity of the research based on such data and models. U.S. EPA does not even articulate, let alone provide, any basis for alleging, that the scientific community's established practices are faulty or inadequate. Nonetheless, it would replace these practices with a single threshold requirement: public availability of the underlying data.

The fact that the proposed rule is at odds with U.S. EPA's and the scientific community's established practices—as underscored by the many unique, substantive comments submitted in opposition to the rule by

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[51] *Id*. at 19885.
[52] *Ibid*. More recent studies support this reasoning and show that children can be at a higher level of health risk due to air pollution exposures. *See e.g.,* Ghosh, R., et al. *Near-roadway air pollution and coronary heart disease: burden of disease and potential impact of greenhouse gas reduction strategy in Southern California*, ENVIRONMENTAL HEALTH PERSPECTIVES, 2016. 124(2):193- 200. 1 Kim JJ, Smorodinsky S, Lipsett M, Singer BC, Hodgson AT, Ostro B. *Traffic-related air pollution near busy roads: the East Bay Children's Respiratory Health Study*, AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE, 2004.
[53] Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 Fed. Reg. 7629 (Feb. 11, 1994), section 1-101 (emphasis added).
[54] 85 Fed. Reg. at 15404.

scientists, scientific organizations, and scientific journals—suggests that U.S. EPA intends for the SNPRM to advance political priorities rather than the quality of science the agency uses.[55]

b. U.S. EPA Already Has Safeguards for the Use of Best Available Science.

Congressional directives already require U.S EPA to consider whether scientific information is reasonable, clear, and complete and whether it has been peer reviewed.[56] Existing mechanisms complement these directives. Such mechanisms include: the Science Advisory Board, established by Congress in 1978 to advise on scientific matters[57]; existing independent peer review of much of the scientific research relied on for regulatory action and publication; legal requirements that prohibit U.S. EPA's adoption of regulations that are arbitrary, capricious, or unsupported by substantial evidence[58]; and procedures to request reconsideration of agency decisions and correction of agency information.[59]

The process for setting NAAQS illustrates the scientific review procedures that are already in place for U.S. EPA's regulatory actions.[60] In the NAAQS process, research results that are given the most weight are from the peer-reviewed literature. After U.S. EPA staff and their contractors review the literature and subject it to further internal review, they develop a staff report. The Clean Air Scientific Advisory Committee (CASAC) of the Science Advisory Board, which consists of internationally recognized experts in their scientific disciplines, reviews the U.S. EPA staff report. CASAC provides advice to the Administrator regarding the adequacy of current standards and recommendations for revisions, if necessary for the protection of public health. The reports also receive public comment, including from independent and industry scientists, and the CASAC review includes consideration of those public comments. U.S. EPA NAAQS documents typically receive multiple rounds of expert scientific review before they are finalized.

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[55] Any approach that U.S. EPA takes toward its use of science should be driven by scientific considerations. But the SNPRM was not. Many of leading members of the scientific community have expressed alarm at the NPRM and the SNPRM. The NPRM and the SNPRM appear to be the works of a purely political exercise. The political motivation underlying the SNPRM and NPRM is confirmed by the highly unusual substantive edits made by the White House Office of Management and Budget, Office of Information and Regulatory Affairs (OIRA), as discussed elsewhere in this comment made substantive and highly unusual edits to the proposal. A detailed discussion of these edits is beyond the scope of this comment, but they appear to confirm the political motivation underlying the SNPRM and NPRM. *See* EO 12866 Documentation; Changes Made During Review—FR Document (RIN 2080-AA14; SNPRM), Docket ID No. EPA-HQ-OA-2018-0259-9321. The redline version also fails to note which changes were made by OIRA, in conflict with the text of the EO 12866 documentation. *See* Documentation of EO 12866 Review, Strengthening Transparency in Regulatory Science; Supplemental Proposed Rule (RIN 2080-AA14), Docket ID No. EPA-HQ-OA-2018-0259-9321. While U.S. EPA's EO 12866 documentation form indicates, "Changes made at the suggestion or recommendation of OIRA, if any, are clearly identified through attribution to OIRA[,]" the post-OIRA review version contains no such identification.

[56] *See*, e.g., the Toxic Substances Control Act at 15 U.S.C. § 2625, subds. (h) and (i), requiring U.S. EPA to consider several factors to evaluate science relating to toxic chemicals and requiring that decisions be based on "the weight of the scientific evidence," the Safe Drinking Water Act at 42 U.S.C. § 300g-1(b)(3)(A)(i), requiring U.S. EPA to rely on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices," and the Clean Air Act at 42 U.S.C. § 7408(a)(2), requiring U.S. EPA to use "latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare."

[57] 42 U.S.C. § 4365.

[58] E.g., 5 U.S.C. § 706.

[59] U.S. EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (2002), https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information, at 30; *see* https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration.

[60] *See* 42 U.S.C. § 7409(d).

The Information Quality Act (IQA), also known as the Data Quality Act, provides a backstop for non-regulatory science. The IQA requires OMB to issue guidelines "for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies."[61] The OMB guidelines require agencies to both issue their own information quality guidelines and to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the [agency] guidelines[.]"[62] OMB issued its guidelines in 2002,[63] and U.S. EPA issued its own guidance document later the same year.[64] U.S. EPA's guidelines ensure that information disseminated by EPA is substantively "accurate, reliable, and unbiased."[65] Moreover, they provide a process for the public to request correction of information "disseminated by the Agency that does not comply with EPA or OMB Information Quality Guidelines."[66] The guidelines also explain U.S. EPA's "Integrated Error Correction Process", "a process by which members of the public can notify EPA of a potential data error in information EPA distributes or disseminates."[67]

The SNPRM does not identify any regulations or "influential scientific information" that may have been inaccurate or falsified because data, studies, or models were not publicly available, or suggest that such regulations or information exist. Neither is there any suggestion that U.S. EPA has relied on flawed scientific methods as the basis for regulatory action or promulgation of influential scientific information, or that public unavailability of data or research methods has resulted in irrational or arbitrary regulations or information. All the same, the SNPRM would limit the scientific studies that U.S. EPA could consider, solely on the basis of the public availability of their underlying data and models.

III. The SNPRM Poses a Systematic Threat to Human Health and the Environment.

The mission of U.S. EPA is to protect human health and the environment.[68] Having the ability to timely consider, rely on, and disseminate the best available science is critical to this mission. Yet U.S. EPA is considering a proposed rule that could skew the scientific record before it. Moreover, the proposal could establish incentives that skew scientific research in general. Such consequences would pose dangers to human health and the environment.

a. The SNPRM Would Apply to a Broad Range of Data and Models.

The NPRM applied only to "dose response" data and models.[69] The SNPRM broadens the scope to apply to other types of data and models, including environmental fate studies, bioaccumulation data, water solubility

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[61] Appropriations Act of 2001, Pub. L. No. 106-554, § 515, 114 Stat. 2763 (2000) (codified at 44 U.S.C. § 3516, note).
[62] Pub. L. No. 106-554, § 515(b)(2).
[63] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 FR 8452 (Feb. 22, 2002), available at https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensurinng-and-maximizing-the-quality-obectivity-utility-and-integrity-of-information.
[64] U.S. EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency, 67 FR 63657 (Oct. 15, 2002), available at https://www.federalregister.gov/documents/2002/10/15/02-26176/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.
[65] *Id*. at 15.
[66] *Id*. at 30.
[67] *Id*. at 12. For examples of when this process has been used, *see* https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration.
[68] E.g., FY 2018-2022 Strategic Plan, p. 2, https://www.epa.gov/sites/production/files/2019-09/documents/fy-2018-2022-epa-strategic-plan.pdf.
[69] The NPRM defined "dose response data and models" to mean "the data and models used to

studies, environmental fate models, quantitative structure activity relationship data, and other environmental studies.[70] This profound expansion in scope severely limits the studies U.S. EPA would be allowed to consider, impeding U.S. EPA's ability to rely on important scientific research and make well-informed and scientifically sound decisions.

The SNPRM cursorily attempts to explain the expansion in scope by arguing that that "[t]ransparency of EPA's science should not be limited to dose-response data and dose-response models, because other types of data and models will also drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions and influential scientific information."[71] But the expansion in scope merely amplifies the amount of harm the proposed rule would have and increases the number of fields in which it would likely deprive U.S. EPA of access to the best available science.

b. The SNPRM Would Compromise U.S. EPA's Ability to Protect Human Health and Environment.

By significantly reducing the amount and types of high-quality research U.S. EPA can rely on, the proposal would compromise the agency's ability to protect public health and the environment. Peer review has long been the arbiter of good science. The SNPRM would allow public availability of data to supersede the evaluation of scientific quality by independent expert peer reviewers, to the detriment of public health in both routine regulatory actions and crises that rely on the federal government's use of science. It would reduce the consideration given to many important, high-quality studies (or preclude that consideration entirely) and could even distort the practices used to conduct certain studies in the first place.

For example, if a team of researchers investigated and published in a top medical journal, following a rigorous peer-review process, urgent information about the health effects of lead, the SNPRM could preclude or delay U.S. EPA consideration of this information. If the study relied on extensive exposure analyses with county-level data on household wipe samples and vital signs in populations of concern, the SNPRM would prohibit or undermine U.S. EPA consideration of the study until the time-consuming process of redacting personally identifiable information from the raw data was complete, if even possible. Further, another team of scientists could publish an inferior study without county-level or demographic data, albeit with underlying data made available, that does not help state and local officials identify hot-spots based on county results or populations of concern. Depending on the proposed alternative, the SNPRM would either favor the inferior study or prohibit U.S. EPA experts from considering the superior study. Such an outcome would fall short of the agency's statutory duties and would adversely affect public health.

i. The SNPRM Would Exclude or Limit Consideration of Epidemiological Studies.

The SNPRM would dramatically impede U.S. EPA's ability to consider epidemiological studies because of the type of data collected. These studies often collect names, addresses, health conditions, blood testing results, urine sample results, employment history, drug use, and other personally-identifying and personal health information. Epidemiological studies rely on this confidential information—with geographical location, and birth and death dates to determine the effects of specific hazards—to link health and lifestyle information.

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characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions typically underlie pivotal regulatory science that drives the size of benefit cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated." 83 Fed. Reg. at 18773.

[70] 85 Fed. Reg at 15400.

[71] 85 Fed. Reg. at 15399-00.

To protect participants' identities, researchers can utilize rigorous procedures to mask personal information. However, the SNPRM would require publishing data so thoroughly redacted as to be effectively useless for validation or would likely exclude long-term cohort epidemiological studies that have been integral to setting standards that protect public health and the environment, but for which raw data cannot legally or ethically be published.[72]

Examples of the types of studies and models that the SNPRM would force U.S. EPA to reject or discount include:

- *Studies related to fecal indicator bacteria concentrations and water-content recreation at ocean and freshwater beaches.* These studies of people swimming, wading, surfing, and contacting water at beaches include individual participant enrollment in the studies and follow-up to gather private medical data to estimate dose-related responses. Such studies informed the development of U.S. EPA's Clean Water Act section 304(a) criteria, including U.S. EPA's 2012 Recreation Water Quality Criteria, which is a foundational document for the California State Water Resource Control Board's recently adopted bacterial water quality objectives.[73]
- *Recent U.S. EPA lifetime health advisories for Perfluorooctanoic Acid (PFOA)[74] and Perfluorooctane Sulfonate (PFOS).[75]* These advisories were based on studies of laboratory animals[76] and were also informed by epidemiological studies of human populations that have been exposed to poly- and perfluoroalkyl substances.[77] These studies indicate that exposure to PFOA and PFOS over certain levels may result in adverse health effects, including but not limited to thyroid disease,[78] liver disease, testicular cancer, kidney cancer,[79] and developmental effects to fetuses during pregnancy[80] or to breastfed infants.[81]

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[72] Privacy laws like the Health Insurance Portability and Accountability Act of 1996 protect the privacy of such information.
[73] State Water Resources Control Board. Staff Report Including Substitute Environmental Documentation for Part 3 of the Water Quality Control Plan for Inland Surface Waters, Enclosed Bay, and Estuaries of California – Bacteria Provisions and a Water Quality Standards Variance Policy and Amendment to the Water Quality Control Plan for Ocean Waters of California – Bacteria Provisions and a Water Quality Standards Variance Policy. (2018). http://www.waterboards.ca.gov/board_decisions/adopted_orders/resolutions/2018/final_staff_report_bacteria_provisions.pdf.
[74] U.S. EPA. 2016. "Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)." Office of Water (4304T). Health and Ecological Criteria Division, Washington, DC 20460. EPA Document Number: 822-R-16-005. https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final_508.pdf.
[75] U.S. EPA. 2016. "Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS)." Office of Water (4304T). Health and Ecological Criteria Division, Washington, DC 20460. EPA Document Number: 822-R-16-004. May. https://www.epa.gov/sites/production/files/2016-05/documents/pfos_health_advisory_final_508.pdf.
[76] C8 Science Panel - Health Study. Mid-Ohio Valley Communities. http://www.c8sciencepanel.org/index.html.
[77] ATSDR. 2017. "An Overview of Perfluoroalkyl and Polyfluoroalkyl Substances and Interim Guidance for Clinicians Responding to Patient Exposure Concerns." Interim Guidance. Revised on 6/7/2017. https://www.atsdr.cdc.gov/pfas/docs/ATSDR_PFAS_ClinicalGuidance_12202019.pdf.
[78] Lopez-Espinosa, Maria-Jose, Mondal, Armstrong, Bloom & Fletcher (2012). *Thyroid Function and Perfloroalkyl Acids in Children Living Near a Chemical Plant*, ENVIRONMENTAL HEALTH PERSPECTIVES Volume 120 (Number 7).
[79] Vieira, Veronica M., Hoffman, Shin, Weinberg, Webster & Fletcher (2013). *Perfluorooctanoic Acid Exposure and Cancer Outcomes in a Contaminated Community: A Geographic Analysis*, ENVIRONMENTAL HEALTH PERSPECTIVES Volume 121 (Number 3).
[80] Stein, Cheryl R., Savitz, Dougan (2009). *Serum Levels of Perfluorooctanoic Acid and Perfluorooctane Sulfonate and Pregnancy Outcome*, AMERICAN JOURNAL OF EPIDEMIOLOGY Volume 170 (No.7).
[81] ATSDR 2015. ToxGuide® for Perfluoroalkyls. U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. Atlanta, GA. Accessed May 2017. https://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=237.

- *Studies that document adverse health impacts associated with air pollutants as part of setting NAAQS*, particularly given the iterative nature of NAAQS administrative record reviews. Epidemiological studies reveal the links between pollutant exposure and adverse health effects. The Harvard Six Cities study[82] of over 8,000 people and American Cancer Society study of 500,000,[83] in particular, have demonstrated the association between particulate matter (less than 2.5 microns) exposures and premature mortality. A more recent study of 61 million Medicare recipients found adverse health effects associated with particulate exposure below the current standard.[84] These studies rely on confidential information about each person in the cohort.

We cannot overstate the importance of these studies to public health. For example, had the proposed rule been in place 25 years ago, when the Harvard Six Cities and American Cancer Society studies were first published, air pollution today would be much worse. These two studies laid the foundation for the 1997 particulate matter (PM) NAAQS that set the first national standard for PM of 2.5 microns or less (PM 2.5). They also were used in all subsequent updates to the federal PM 2.5 standard as well as development of the national PM 10 standard. In addition, these studies were integral to the development of more than two dozen different rules adopted by U.S. EPA to implement the NAAQS since 1997. Key rules developed using these studies to evaluate particle pollution impacts on mortality and illnesses include the Control of Emissions from Non-road Diesel Engines and the Mercury and Air Toxics Standards.[85]

ii. The SNPRM May Discourage People from Participating in Future Studies.

[82] Johanna Lepeule, Francine Laden, Douglas Dockery, and Joel Schwartz. *Chronic Exposure to Fine Particles and Mortality: An Extended Follow-up of the Harvard Six Cities Study from 1974 to 2009*. ENVIRONMENTAL HEALTH PERSPECTIVES 2012. 120(7): 965-970.

[83] C. Arden Pope, III, PhD, Richard T. Burnett, PhD, Michael J. Thun, MD, Eugenia E. Calle, PhD, Daniel Krewski, PhD, Kazuhiko Ito, PhD, and George D. Thurston, ScD. Lung Cancer, *Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution*. JAMA. 2002 Mar 6; 287(9): 1132–1141.

[84] Qian Di, M.S., Yan Wang, M.S., Antonella Zanobetti, Ph.D., Yun Wang, Ph.D., Petros Koutrakis, Ph.D., Christine Choirat, Ph.D., Francesca Dominici, Ph.D., and Joel D. Schwartz, Ph.D. *Air Pollution and Mortality in the Medicare Population*, NEW ENGLAND JOURNAL OF MEDICINE. 2017. 376 (26): 2513-2522.

[85] U.S. EPA has cited to the Harvard Six and/or American Cancer Society studies in support of, among other actions, regulatory impact analyses for Reclassification of Major Sources as Area Sources under Section 112 of the Clean Air Act; Mercury Cell Chlor Alkali Plants NESHAP; ICI Boilers and Process Heaters NESHAP; Brick and Structural Clay Products NESHAP; Portland Cement Manufacturing NESHAP; Non-road Diesel Engines; Oil and Natural Gas Review, NESHAP, and NSPS; Petroleum Refineries NSPS; Manganese Ferroalloys RTR; Existing Stationary Spark Ignition (SI) RICE NESHAP; Existing Stationary Compression Ignition (CI) Engines NESHAP; Existing Reciprocating Internal Combustion Engines NESHAP Analysis of Potential Costs and Benefits for the "National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units – Subcategory of Certain Existing Electric Utility Steam Generating Units Firing Eastern Bituminous Coal Refuse for Emissions of Acid Gas Hazardous Air Pollutants; Repeal of the Clean Power Plan, and the Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units; Memo: Compliance Cost, HAP Benefits, and Ancillary Co-Pollutant Benefits for "National Emission Standards for Hazardous Air Pollutants: Coal-and Oil-Fired Electric Utility Steam Generating Units—Reconsideration of Supplemental Finding and Residual Risk and Technology Review"; Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units; Revisions to Emission Guideline Implementing Regulations; Revisions to New Source Review Program; Review of the Clean Power Plan; GHGs from Existing Electric Utility Generating Units, Federal Plan Requirements; NSPS for GHGs from New Electric Utility Generating Units; Carbon Pollution Guidelines for Existing Power Plants and Emission Standards for Modified and Reconstructed Power Plants; Mercury and Air Toxics Standards; Utility MACT and NSPS, Toxics Rule; Municipal Solid Waste Landfills NSPS; Commercial and Industrial Solid Waste Incineration Units NSPS and Emissions Guideline; Sewage Sludge Incineration Units, NSPS and Emissions Guideline, Cost and Benefit Changes Since Proposal; Residential Wood Heaters NSPS Revision.

Participation in epidemiological studies is often contingent on keeping subject data confidential. Consequently, studies that have already been completed may contain data that was collected contingent on confidentiality. Researchers cannot now make that data publicly available, in response to the SNPRM, without violating state and/or federal laws (e.g., California Information Practices Act,[86] the Health Insurance Portability and Accountability Act[87]) or locating research participants and requesting their consent to the release (an expensive and time-consuming process that may frequently result in participants declining to give their consent).

To the extent that researchers require the public availability of data for future studies, this could have a chilling effect on people's willingness to participate. The possibility of identification, with the specter of denial of future employment or benefits based on disclosure of medical information, may make some population groups less likely to participate in future studies. In the water context, for example, farmers, ranchers, and dairy farmers are often willing to participate in management practice effectiveness studies (e.g., composting practices, water use practices, riparian protection practices) only if their personal information remains anonymous or is presented in a compiled fashion at a regional or statewide scale. Discouraging individuals or particular groups of people from participating in future studies would introduce bias into the studies, again to the detriment of the public interest in protecting health and the environment. In addition, this chilling effect has important implications for environmental justice, as it may become more difficult to conduct studies in communities of concern.

iii. The SNPRM Would Introduce a Bias Toward Less Sensitive Studies.

The SNPRM also would introduce a bias towards less sensitive studies. Higher-quality study designs typically collect detailed demographic information and information on risk factors and medical conditions so that susceptible subpopulations can be identified. The more detailed the study, the more difficult it would be to remove personally identifiable information and eliminate the risk of re-identification.

Under the SNPRM, studies that omit personal information would be given greater weight, since this information can be released without linking to an individual. Personal information is used to strengthen a study by providing a way to account for impacts due to characteristics other than the exposure effects, such as effects due to age, gender, smoking status, and preexisting medical conditions. It also allows an investigator to stratify the analysis by income and race/ethnicity to see whether any subgroups may be more susceptible to exposure to pollution.

Studies with individual personal information often are subject to agreements with the study subjects that limit who can view their personal information, making it impossible for this information to be released, even if it can be grouped in such a way as to not identify individuals. The studies that do not contain detailed personal level data are not as strong, since potential confounders cannot be corrected for, thereby limiting the ability of U.S. EPA to discover, and base its decisions on, the most accurate determination of the true causes and consequences of a health impacts. Indeed, the SNPRM could encourage greater reliance on studies on laboratory animals. Releasing raw data for animals is simpler, as there is no need to redact or otherwise protect personally identifiable information. Yet the results of animal studies alone do not always predict with accuracy the results in humans, particularly when taking into account the diversity of the human population and the potential susceptibility of certain humans to particular conditions. The greater the divergence between the findings of animal and human studies, the greater the harm of overly relying on animals studies would be. This

[86] California Civil Code §§ 1798-1798.78.
[87] Pub.L. 104–191.

is also contrary to Administrator Wheeler's September 10, 2019 memorandum directing the U.S. EPA to move away from animal testing.[88]

iv. The SNPRM Would Likely Exclude State-Funded Research.

The proposed rule is likely to preclude U.S. EPA from considering high-quality CARB-funded research that provides critical findings on air pollution exposures and health impacts. A significant number of the studies that CARB supports are epidemiological/cohort studies that the SNPRM is likely to preclude from U.S. EPA consideration. These likely include:

- *The 10-year Children's Health Study (CHS)*: Initiated in 1993, this was the first major study to assess the impacts of long-term air pollution exposure on the respiratory health of California's children.[89] Following 5,500 students in 12 southern California communities from fourth grade through high school, this study revealed the extent to which ozone, nitrogen dioxide, acid vapors consisting of nitric acid and hydrogen chloride, and particulate matter affect children's lung development. The results of this study are evidence for classifying children as sensitive receptors to air pollution and have influenced research since and shaped California legislation addressing children's microenvironments.[90]
- *The Los Angeles Family and Neighborhood Survey (LAFANS)*: This was a study of families in different neighborhoods in Los Angeles County.[91] The researchers found that children more highly exposed to traffic pollution were 30-40 percent more likely to report wheeze symptoms.[92]

[88] Memorandum from Andrew R. Wheeler, administrator, to Associate Deputy Administrator, et al., re Directive to Prioritize Efforts to Reduce Animal Testing (September 10, 2019) (https://www.epa.gov/research/administrator-memo-prioritizing-efforts-reduce-animal-testing-september-10-2019).

[89] Peters, J.M., et al. (1999) *A study of twelve Southern California communities with differing levels and types of air pollution. II. Effects on pulmonary function*, AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE. 159: 768-775; Avol, E.L., et al. (2001) *Respiratory effects of relocating to areas of differing air pollution levels*, AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE, 164: 2067-2072; Gauderman, W.J., et al. (2002) *Association between air pollution and lung function growth in Southern California children: Results from a second cohort,* AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE, 166(1): 74-84; McConnell, R., et al. (2002) *Asthma in exercising children exposed to ozone: A cohort study*, LANCET, 359: 386–391; Gauderman, W.J., et al. (2004) *The effect of air pollution on lung development from 10 to 18 years of age*, NEW ENGLAND JOURNAL OF MEDICINE 351(11): 1057-1067; Gauderman, W. J., et al. (2005) *Childhood asthma and exposure to traffic and nitrogen dioxide*, EPIDEMIOLOGY 16:737-743; McConnell, R., et al. (2006) *Traffic, susceptibility, and childhood asthma*, ENVIRONMENTAL HEALTH PERSPECTIVES 114:766-772; Gauderman, W. J., et al. (2007) *Effect of exposure to traffic on lung development from 10 to 18 years of age: a cohort study*, LANCET 369:571-577; Gauderman, W.J., et al. (2015) *Association of improved air quality with lung development in children*, NEW ENGLAND JOURNAL OF MEDICINE 372(10):905-913; Berhane, K. et al. (2016) *Association of changes in air quality with bronchitic symptoms in children in California, 1993-2012*, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 315(14):1491-1501.

[90] CARB 2018. Proposed Triennial Strategic Research Plan Fiscal Years 2018-2021, https://ww2.arb.ca.gov/sites/default/files/2018-04/FY2018-21_Triennial_Research_Plan-2018-04-24.pdf, pp. 6, 15.

[91] Ritz, B et al. (2009) "Traffic-Related Air Pollution and Asthma in Economically Disadvantaged and High Traffic Density Neighborhoods in Los Angeles County, California" Final Report ARB Contract No. 04-323 Prepared for the California Air Resources Board and California Environmental Protection Agency Sacramento, CA.

[92] CARB 2018. Proposed Triennial Strategic Research Plan Fiscal Years 2018-2021, https://ww2.arb.ca.gov/sites/default/files/2018-04/FY2018-21_Triennial_Research_Plan-2018-04-24.pdf, p. 15.

- *The East Bay Kids Study[93] and the California Health Interview Survey (CHIS)*:[94] These studies sought to determine impacts of pollution levels and greater sensitivity in low income neighborhoods on asthma, including in the CHIS study, on whether the asthma burden disparity is due to exposure to higher levels of air pollutants, greater vulnerability, or both. Findings from these studies have helped to inform policy decisions on motor vehicle emissions control and enforcement, and asthma prevention, control, and education in low socioeconomic status populations.[95]
- *Wildfire Impact*: Studies currently in progress are examining the impacts of wildfire smoke on lost work days and on respiratory symptoms.

IV. The SNPRM Would Have Environmental Justice Impacts.

In California, millions of residents suffer disproportionate health impacts caused by multiple and confounding vulnerabilities, stressors, and health burdens, including pollution burdens. For example, people living in disadvantaged communities are at increased risk of adverse health outcomes from environmental pollution exposure due to housing conditions, inadequate access to health food options, economic stress and lack of access to health care as documented in multiple state and national studies. Residents of disadvantaged communities are also more likely to live near major freeways and industrial facilities such as refineries, railyards, rendering plants, metal platers, ports, and agricultural operations that contribute to increased exposure to harmful pollution.[96]

The SNPRM would preclude U.S.EPA from researching and fully considering the health and economic impacts to disadvantaged communities. This would include both the impacts of increased exposure to pollution from nearby sources and the increased rates of illness and death from heightened vulnerability to the effects of pollution. Studies related to environmental justice are often conducted at the community level.[97] It would not be possible to organize the participants into larger and less identifiable groups and be able to fulfill the purpose of the studies, which is to identify the health impacts at the community level. Grouping in this way is costly, time consuming, and would result in a data set that would not have the same analytical power as the original study.[98] Grouping would also reduce the locational sensitivity of the data and make more local and community-based studies unusable.

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[93] Kim, J., et al. (2008) "Residential Traffic and Children's Respiratory Health." Environmental Health Perspectives 116.9 (2008): 1274-1279.
[94] Meng, Y-Y., et al. (2012) "Is Disparity in Asthma among Californians due to Higher Pollution Exposures, Greater Vulnerability, or Both?" Final Report ARB Contract No: 07-309 Prepared for the California Air Resources Board and the California Environmental Protection Agency.
[95] CARB 2018. Proposed Triennial Strategic Research Plan Fiscal Years 2018-2021, https://ww2.arb.ca.gov/sites/default/files/2018-04/FY2018-21_Triennial_Research_Plan-2018-04-24.pdf, p. 22.
[96] *See* e.g., Meng Y-Y, Wilhelm M, Rull RP, English P, Nathan S, Ritz B. *Are frequent asthma symptoms among low-income individuals related to heavy traffic near homes, vulnerabilities, or both?*, 18:343-350 ANNALS OF EPIDEMIOLOGY. 2008. Gunier, R.B., et al., Traffic density in California: socioeconomic and ethnic differences among potentially exposed children. JOURNAL OF EXPOSURE SCIENCE AND ENVIRONMENTAL EPIDEMIOLOGY, 2003. 13(3): pp. 240-246. A. Carlson, *The Clean Air Act's Blind Spot: Microclimates and Hotspot Pollution*, 65 UCLA L. REV. 1036, 1056 (2018).
[97] Stacey E. Alexeeff, Ananya Roy, Jun Shan, Xi Liu, Kyle Messier, Joshua S. Apte, Christopher Portier, Stephen Sidney & Stephen K. Van Den Eeden. *High-resolution mapping of traffic related air pollution with Google street view cars and incidence of cardiovascular events within neighborhoods in Oakland, CA*, ENVIRONMENTAL HEALTH volume 17, Article number: 38 (2018).
[98] *Environmental Justice: The Economics of Race, Place, and Pollution*, Spencer Banzhaf, Lala Ma, Christopher Timmins, JOURNAL OF ECONOMIC PERSPECTIVES, Vol. 33, No. 1, winter 2019, Pages 192-193 ("the relationship estimated from aggregated data is only equal to the relationship at the micro level if there are no group-level effects correlated with pollution") ("evidence of racial, ethnic, and income inequities becomes stronger when using smaller units of analysis").

Community level studies by CalEPA agencies—including those required under state law[99] and important for environmental justice considerations—would not be considered by U.S. EPA under the SNPRM, if finalized. The proposal would, for example, exclude multiple studies of the effects on children of prenatal pesticide exposure.[100] The inability to consider environmental justice research would also undercut implementation of Executive Order (E.O.) 12898 on environmental justice, as discussed further above. Therefore, the proposed ruling would likely lead to further worsening of health in disadvantaged communities.

V. The SNPRM Would Create Administrative Burdens.

The SNPRM would require U.S. EPA to complete unnecessary new procedural steps that would divert its resources, restrict its flexibility, and slow its actions. Notably, the SNPRM would require U.S. EPA to conduct redundant peer reviews and reevaluate sound default assumptions, but does not acknowledge a need for any resources to account for these new burdens.

a. The SNPRM Would Require U.S. EPA to Conduct Redundant and Resource-Intensive Peer Reviews.

The NPRM would have required U.S. EPA to "conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions*," but would have allowed the administrator to exempt science from this requirement on an ad hoc basis if "[i]t is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX." [101] The SNPRM proposes to broaden the peer review requirement so that it also applies to "all pivotal science underlying influential scientific information."[102] It also removes the NPRM's case-by-case exemption regarding peer review "because [U.S.] EPA does not believe that peer review of pivotal regulatory science or pivotal science would be infeasible."[103] As a result, U.S. EPA would effectively have to conduct independent review for all regulatory or influential science, regardless of the peer review process to which that science has already been subjected.

The SNPRM's proposed requirement for U.S. EPA to provide independent peer review on all pivotal regulatory science and on all pivotal science underlying influential scientific information comprises a comprehensive and highly burdensome new task for the agency. U.S. EPA would have to coordinate the peer review (or perhaps conduct the peer review itself), pay for it, wait for it to be completed, and ensure that it complied with the mandate under the SNPRM to "articulate the strengths and weaknesses of U.S. EPA's justification for the assumptions applied and the implications of those assumptions for the results."[104] The SNPRM fails to acknowledge this burden or explain where U.S. EPA would find the resources and staff to perform these tasks.

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[99] E.g., California Assembly Bill No. 617 (Chapter 136, Statutes of 2017).
[100] Rauh et al. 2011. *Seven-year Neurodevelopmental Scores and Prenatal Exposure to Chlorpyrifos, a Common Agricultural Pesticide*, ENVIRON. HEALTH PERSPECT. 119:1196-1201; Rauh et al. 2006. *Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children*, PEDIATRICS 118:e1845–e1859; Rauh et al. 2012 *Brain Anomalies in Children Exposed Prenatally to a Common Organophosphate Pesticide*, PROC. NATL ACAD. SCI. May 15; 109(20):7871-6; Bouchard et al. 2011. *Prenatal Exposure to Organophosphate Pesticides and IQ in 7-Year-Old Children,* ENVIRON. HEALTH PERSPECT. 119:1189-1195; Marks et al. 2010. *Organophosphate Pesticide Exposure and Attention in Young Mexican-American Children: The CHAMACOS Study*, ENVIRON. HEALTH PERSPECT. 118:1768-1774.
[101] 83 Fed. Reg. at 18774 (emphasis in original).
[102] 85 Fed. Reg. at 15406.
[103] *Id*. at 15403.
[104] Proposed section. 30.7.

Notably, California statute requires "external scientific peer review of the scientific basis for any rule proposed for adoption by any board, department, or office within" CalEPA.[105] In California statute, however, "scientific basis" means "those foundations of a rule that are premised upon, or derived from, empirical data or other scientific findings, conclusions, or assumptions establishing a regulatory level, standard, or other requirement for the protection of public health or the environment"[106] By contrast, the SNPRM would require U.S. EPA to independently peer review, not the foundations of a science-based rulemaking, but the actual studies, data, and models underlying both every rule *and* every piece of "influential scientific information."

b. The SNPRM Would Require U.S. EPA to Needlessly Reevaluate Default Assumptions.

The SNPRM would also vastly increase the burden on U.S. EPA experts by expanding the NPRM's proposed requirement that U.S. EPA staff explain the scientific basis for critical assumptions. The SNPRM's proposed regulatory text states:

> EPA shall describe and document any assumptions and methods used and shall describe variability and uncertainty. EPA shall evaluate the appropriateness of using default assumptions on a case-by-case basis. EPA shall clearly explain the scientific basis for critical assumptions used in the analysis that drove the analytical results and subsequent decisions and shall present analyses showing the sensitivity of the modeled results to alternative assumptions.[107]

Requiring justification for all default assumptions ignores the establishment of defaults through prior public processes and external public peer reviews. For example, requiring justification for the use of default assumptions for every toxicity health factor derivation ignores the detailed development process of those default assumptions. Those default assumptions were developed in several U.S. EPA documents (including the 2005 Guidelines for Carcinogen Risk Assessment[108]), which received public comment and extensive external peer-review. Requiring EPA to rejustify those default assumptions every time they are used, as the SNPRM seems to require, would serve no purpose other than to add unnecessary delay to risk assessments, regulatory action, and publication of influential scientific information.

> As the D.C. Circuit Court of Appeals has explained:
> [W]hat [U.S. EPA] and other decision-makers often must do to make a science-based judgment: it sought out and reviewed existing scientific evidence to determine whether a particular finding was warranted. It makes no difference that much of the scientific evidence in large part consisted of "syntheses" of individual studies and research. Even individual studies and research papers often synthesize past work in an area and then build upon it. This is how science works. EPA is not required to re-prove the existence of the atom every time it approaches a scientific question.[109]

As with the new proposed peer review requirement, U.S. EPA fails to justify this proposed requirement, acknowledge the burden that it would place on the agency and its staff, or indicate how U.S. EPA would fulfill this new requirement.

VI. The SNPRM Fails to Address Problems Regarding Restricted Access.

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[105] Cal. Health & Saf. Code § 57004(b).
[106] *Id*. at § 57004(a)(2).
[107] Proposed section 30.6.
[108] No. EPA/630/P-03/001 F, available at https://www.epa.gov/sites/production/files/2013-09/documents/cancer guidelines final 3-25-05.pdf.
[109] *Coal. for Responsible Regulation, Inc. v. E.P.A.*, 684 F.3d 102, 119–20 (D.C. Cir. 2012), cert. denied in relevant part, *Util. Air Regulatory Grp. v. E.P.A.*, 571 U.S. 951 (2013), aff'd in part, rev'd in part sub nom. *Util. Air Reg. Group v. E.P.A.*, 573 U.S. 302 (2014).

In U.S. EPA's sole acknowledgement of States' and other stakeholders' comments opposing the NPRM's proposal on restricted data, the SNPRM preamble notes the "large number of comments stating that the approach in the 2018 proposed rulemaking would likely preclude the use of valid data and models from consideration as pivotal regulatory science[.]"[110]

Consequently, the SNPRM presents two alternatives. Under one, the SNPRM would "'merely' require agency experts to deprioritize" studies that rely upon restricted data.[111] Under the other, the SNPRM would not reject or discount science if access to underlying personally identifiable information, private health information, proprietary data, or confidential business information is provided, in a "tiered" fashion, only to data users with special authorization.[112] Both alternatives fail to make the SNPRM any more logical, legal, or workable.

There is simply no appropriate and non-arbitrary method for U.S. EPA to deprioritize studies or models relying on non-public data. Considering only science that provides such tiered access to private data is also arbitrary. A requirement to provide multiple tiers of access would disproportionately burden academic, public, and even smaller corporate researchers. At the same time, it would raise many of the same issues as requiring open access, discussed above. Rather than making U.S. EPA's proposals consistent with data privacy law, the SNPRM's proposed tiering provision underscores the arbitrariness, unworkability, and unlawfulness of the proposal.

VII. The SNPRM Would Privilege Industry-Funded Science.

Academia, the government, and private industry each sponsor a range of scientific undertakings. Although the SNPRM does not expressly privilege industry studies, it would, as a practical matter, have that effect. It is structured so as to create new challenges that would not apply to private industry-developed science or that private industry could overcome more readily than the academy or the government.

a. Industry Could Fund the Creation of Tiered Access Systems.

The SNPRM proposes that U.S. EPA only consider studies with restricted data and models "if there is tiered access to these data and models in a manner sufficient for independent validation."[113] The SNPRM describes "tiered access" in the following way:

> Under a tiered approach to accessing data and models that include CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects, access is more restricted for more sensitive data and models. Thus, the amount of information available or analysis is dictated by the tier. The greatest amount of information is made available at the most restricted access tier . . . . Restricted access for researchers through secure data enclaves for PII or through non-disclosure agreements for CBI may result in access to sufficient information about the data and models to allow for independent validation.[114]

[110] 85 Fed. Reg. at 15401-02.
[111] Proposed section 30.5, option 2.
[112] Proposed section 30.5.
[113] 85 Fed. Reg. at 15405.
[114] *Id*. at 15402.

U.S. EPA, in the SNPRM, disclaims any responsibility for obtaining, redacting, or publishing these data,[115] and the SNPRM has no provisions for compensating researchers for this activity. But as would be expected, developing and maintaining a tiered access system could prove onerous and expensive. Large industrial actors would be able to absorb the costs more readily than other researchers could. As a result, industry-funded science would be more likely to satisfy the requirements of the SNPRM and qualify for U.S. EPA consideration than other science would.

b. Criteria that Advantage Industry-Funded Science Could Skew the Scientific Record Away from Established Scientific Conclusions.

The SNPRM could potentially screen out "high-quality studies" developed by a mixture of academic, governmental, and private researchers over several decades and skew the scientific record in favor of newer industry-funded studies. Existing studies would be less likely to comply with the SNPRM, and unless the administrator applies an ad hoc and discretionary exemption, would be discounted relative to newer studies created after the adoption of the SNPRM. Academic and government researchers generally prefer, and only receive funding, to focus on expanding scientific knowledge and do not have the resources to revisit established scientific conclusions. Industry-funded groups, however, may have an incentive to invest in additional research to disprove those scientific conclusions. Such a dynamic has played out in studies of tobacco smoke: academic researchers are no longer interested in replicating numerous studies showing health effects, while researchers sponsored by the tobacco industry continue to publish analyses that reach different conclusions. Ignoring decades of research developed by a mix of academic, governmental, and private researchers in favor of new information backed by primarily private industry, which is the potential effect of the SNRPM's new and arbitrary criteria for assessing the relative value of scientific studies and information, would unscientifically skew the weight of the evidence toward industry research and interests.

c. The SNPRM Would Result in Inequitable Treatment of Intellectual Property Rights.

For scientists at academic and research institutions, intellectual property protections for innovative analytical tools, models, and computer code are important to the research process. Section 30.5(c) of the proposed rule, however, would require the publication of the details of such original models and code. It only allows for restricted access to the information if it contains "confidential business information, proprietary information or personally identifiable information." The intellectual property rights of academic or governmental researchers do not clearly fall into any of these categories. Moreover, intellectual property is absent from the list of potential exemptions to the data publication requirements in proposed section 30.9, which applies only to exemptions necessary to comply with laws governing privacy, confidentiality, confidential business information, and national and homeland security.[116]

This lack of protection for intellectual property would thwart innovation and/or prevent the consideration of newer tools and models in EPA's regulatory decision-making. Additionally, industry research might still be protected as confidential business information, while academic or public interest research would not be entitled to rely on intellectual property protections. The absence of publication exceptions or exemptions for protected intellectual property makes it far more likely that industry research, rather than academic or public interest research, would form the basis of regulatory decision-making. This could build an industry preference into EPA's regulatory process and disseminated information.

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[115] *Ibid*. ("EPA is also clarifying that the Agency does not intend to make all data and models underlying pivotal regulatory science and pivotal science publicly available . . . . Rather, EPA is describing how it will handle studies based on whether the underlying data and models are publicly available.").
[116] The tiering requirement of proposed section 30.5 also refers to "proprietary data," which is not defined.

d. The SNPRM Would Interfere with the Use of Proprietary Models.

Models are critical to help humans assess and analyze large quantities of data, but they are nearly always proprietary. Most scientists and agencies purchase access to and use these models for data. Restricting models to those that are publicly available, or that meet the vaguely described exceptions in proposed section 30.5, would severely limit the science that U.S. EPA may consider or reference.

VIII. The COVID-19 Pandemic Demonstrates the Need for Best Available Science.

U.S. EPA released the SNPRM during the most disruptive global pandemic in more than a century. The coronavirus disease 2019 (COVID-19) has already infected more than a million Americans and has killed more than the Vietnam War. It has so disrupted U.S. EPA activities that the agency's inspector general has announced plans "to examine the impact of the coronavirus pandemic on the EPA's programs and operations, regulatory and enforcement missions, and mandated activities, as well as to review measures that the EPA has taken to address the coronavirus pandemic."[117] Indeed, COVID-19 has apparently exacted such a toll on U.S. EPA that the agency felt compelled to relax its enforcement of bedrock environmental laws.[118]

To date, many of responses to the pandemic have fallen under the jurisdiction of other agencies. Nonetheless, U.S. EPA has a role to play here. At the same time that the agency has grappled with the impacts of COVID-19 on its internal operations,[119] it has had to channel resources toward addressing the broader public crisis. It has, for example, expedited its review of surface disinfectants under its Emerging Viral Pathogens program[120] and blocked the importation of an unregistered product that was being marketed as a disinfectant for coronavirus.[121] And on April 21, 2020, it requested that the Science Advisory Board provide a "rapid review" of certain research questions raised by COVID-19.[122]

Going forward, the role for U.S. EPA could grow, as connections between the impacts of the virus and environmental settings begin to emerge. A recent report from the Harvard T.H. Chan School of Public Health studied data from 3,000 counties and found that the presence of particulate matter in the atmosphere could increase the severity of COVID-19 cases. Specifically, it concluded:

> A small increase in long-term exposure to PM2.5 leads to a large increase in COVID-19 death rate, with the magnitude of increase 20 times that observed for PM2.5 and all-cause mortality.

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[117] Memorandum re Notification: Research for Future Audits and Evaluations Regarding Effects of Coronavirus Pandemic (SARS-CoV-2 Virus and COVID-19 Disease) on EPA Programs and Operations Project No. OA&E-FY20-0212, dated May 7, 2020, from Charles J. Sheehan, Deputy Inspector General to Doug Benevento, Associate Deputy Administrator.
[118] Memorandum re COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program, dated March 26, from Susan Parker Bodine to All Governmental and Private Sector Partners.
[119] Rachel Frazin, *EPA faces possible coronavirus outbreaks at multiple offices*, THE HILL (March 18, 2019), available at https://thehill.com/policy/energy-environment/488324-epa-employee-in-montana-tests-presumed-positive-for-coronavirus; Corbin Hiar, *EPA HQ staffer tests positive for coronavirus*, E&E NEWS (Wednesday, March 25, 2020), available at https://www.eenews.net/greenwire/2020/03/25/stories/1062699367.
[120] U.S. EPA, Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens Not on EPA-Registered Disinfectant Labels (August 19, 2016), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf.
[121] https://www.epa.gov/newsreleases/us-epa-acts-protect-public-unregistered-virus-shut-out-product-imported-honolulu-and.
[122] U.S. EPA, Science Advisory Board Review: Identifying Research Needs to Address the Environmental and Human Health Impacts of COVID-19 (April 21, 2020) (Agency Charge), available at https://yosemite.epa.gov/sab/sabproduct.nsf/WebBOARD/2996BA363B41C2598525854C0048EA69/$File/PDF+for+COVID-19+Meeting+Materials+and+Charge_04-21-20.pdf.

> The study results underscore the importance of continuing to enforce existing air pollution regulations to protect human health both during and after the COVID-19 crisis.[123]

Other studies will likely follow; indeed, U.S. EPA has already directed the Science Advisory Board to investigate "[e]nvironmental [f]actors affecting transmission and severity of COVID-19."[124] More specifically, U.S. EPA has requested that the Science Advisory Board examine the following questions:

- Can particulate matter in the atmosphere serve as a vehicle for the transmission of SARS-CoV-2?
- Does exposure to air pollutants, including wildland fire smoke or other air pollutants (e.g. ozone, particulate matter, diesel exhaust, pollen) increase the susceptibility to respiratory viruses like SARS-CoV-2? Or exacerbate existing COVID-19 infection?
- Does ambient or indoor temperature or humidity affect the transmission of SARS-CoV-2 and severity of the COVID-19 illness?[125]

To the extent that current or future studies on these issues rely upon restricted data or models, the SNPRM would prevent U.S. EPA from considering them. As a result, it would interfere with U.S. EPA's long-term efforts to address this virus or potential future ones.

IX. The SNPRM is Unworkable.

Apart from its myriad other flaws, the SNPRM is unworkable. It relies on vague and ambiguous definitions and is structured in a manner that would impose unwieldy and at times illogical burdens on U.S. EPA. For these reasons, among the many others set forth in this comment, we urge U.S. EPA to withdraw the SNPRM.

a. The SNPRM Would Apply to Science Regardless of When It Was Performed.

The SNPRM proposes that the rule "would apply to data and models evaluated at the time a significant regulatory action or influential scientific information is developed, regardless of when the data and models were generated."[126] That is, for any regulation that U.S. EPA has not yet finalized, it would apply the SNPRM even if this means ignoring the best available science simply because that science was prepared prior to the adoption of the SNPRM, and thus could not have complied with its historically unprecedented and widely criticized requirements.

In seeming recognition of the arbitrariness of this approach, the SNPRM requests comment on whether the proposed regulation "should apply only to data and models that are generated (i.e., when the development of the data set or model has been completed or updated) after the effective date of this rulemaking."[127] The SNPRM threatens the scientific foundation of U.S. EPA's work for the reasons articulated throughout this comment. Retroactive application is even more problematic than prospective-only application, but either approach would abrogate U.S. EPA's duties to protect public health and the environment.

b. The SNPRM Runs Contrary to Established Scientific Practices.

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[123] Xiao Wu, et al., Exposure to Air Pollution and COVID-19 mortality in the United States: A Nationwide Cross-Sectional Study, available at https://www.medrxiv.org/content/10.1101/2020.04.05.20054502v2.
[124] Agency Charge, p. 1.
[125] *Id*. at p. 9.
[126] 85 Fed. Reg. at 15403.
[127] *Ibid*.

The SNPRM requests comment on "how to ensure that, over time, more of the data and models underlying the science that informs significant regulatory decisions and influential scientific information" comply with the proposed regulation "in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification."[128] Similarly, the SNPRM requests comment on "how to provide sufficient incentives and support to researchers to increase access to data that may be used as pivotal regulatory science or pivotal science." With these requests, U.S. EPA apparently recognizes that the SNPRM runs contrary to established practices and that it creates significant challenges regarding the legal and ethical obligations researchers must follow.

c. The SNPRM's Provision on Conflicts Is Vague and Unworkable.

The NPRM and SNPRM conflict with many of the statutes that U.S. EPA administers, which include requirements to use, for example, the "best available science,"[129] the "best available public health information",[130] the "latest scientific knowledge",[131] or "generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies",[132] among others. U.S. EPA tacitly acknowledges these conflicts in the SNPRM by adding proposed section 30.3, providing, "In the event the procedures outlined in this part conflict with statutes that EPA administers, or their implementing regulations, the statutes and regulations will control."[133] Yet neither this proposed provision nor the SNPRM preamble identify statutory or regulatory provisions with which U.S. EPA believes a conflict could emerge. Moreover, the proposed regulatory text does not provide any parameters for determining whether there is a conflict. Rather than improving the legality and workability of the SNPRM, this provision is impermissibly vague, in violation of the APA, and likely to mire the agency in additional litigation.

d. The SNPRM Provides for Arbitrary Ad Hoc Exemptions.

The NPRM included an exemption provision that seemed intended to mitigate the proposed regulation, but simply underscored the impracticality and arbitrariness of the whole venture. The exemption would have given the U.S. EPA administrator the authority to waive the requirements of the rule on an ad hoc basis if the administrator determined, in his or her subjective judgment, that compliance was "impracticable." It specified that the administrator—who may not be a trained scientist or have scientific judgment—could find impracticability only if the science could not be "feasibl[y]" made public or subject to independent peer review.[134] The SNPRM made the exemption provision, like so many other aspects of the proposal, much worse.

The version of the SNPRM that U.S. EPA submitted to OIRA would have somewhat cabined the administrator's discretion by providing factors that the administrator must consider in determining whether to grant an exemption, including "soundness, applicability and utility, clarity and completeness, uncertainty and variability, evaluation and review, and the age of the study."[135] OIRA stripped out the requirement to weigh

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[128] *Ibid*.
[129] Safe Drinking Water Act, 42 U.S.C. § 300g-1; Toxic Substances Control Act, 15 U.S.C. §§ 2617(f), 2625(h)); Clean Water Act, 33 U.S.C. § 1321(a)(27).
[130] Safe Drinking Water Act, 42 U.S.C. § 300g-1.
[131] Clean Air Act, 42 U.S.C. § 7408(a)(2)); Clean Water Act, 33 U.S.C. § 1314(a)(1).
[132] Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11023(d)(2).
[133] Proposed section 30.3.
[134] 83 Fed. Reg. at 18774.
[135] *See* EO 12866 Documentation; Draft Submitted to OMB—FR Document (RIN 2080-AA14; SNPRM), Docket ID No. EPA-HQ-OA-2018-0259-9321.

such factors,[136] giving the administrator unbounded discretion in applying the exemption provision. This opens the door to the use of political considerations—rather than scientific merit—in determining which scientific studies inform U.S. EPA actions and which do not. Such an arrangement would materially increase the risk of U.S. EPA actions not being based on the best available science. The SNPRM's proposed regulatory text adds "technological barriers" as one of three grounds for the administrator to apply an exemption,[137] in addition to privacy/CBI considerations and the age of the science.[138] Like much of the SNPRM, the "technological barriers" provision is vague and leaves the administrator with far too much discretion for vetting science based on distinctly non-scientific factors.

e. The SNPRM Relies Upon Vague and Arbitrary Definitions.

Many commenters faulted the NPRM for its use of vague and ambiguous terms. In response, U.S. EPA has added definitions for certain terms to the SNPRM. But the new definitions do not resolve the issues of vagueness and ambiguity and in many instances compound them. Two definitions stand out as particularly problematic: "data" and "influential scientific information."

i. The Definition of "Data" Is Vague and Ambiguous.

The SNPRM centers on the availability of "data" and "models." It defines data to mean "the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party." However, this definition fails to acknowledge or allow for the removal of other types of errors that are commonly removed from datasets, including outliers or incomplete data. Unscrubbed "raw" data can inappropriately skew results and cause significant issues in modeling and analysis for third parties who were not familiar with the data collection process. Well-established scientific approaches already exist for removing outlier or incomplete data. Scrubbed data should not be invalidated under the proposed definition merely because it is accurate and unable to be misused for skewed results.

ii. The Definition of "Influential Scientific Information" Is Vague and Ambiguous.

The NPRM would have applied the proposed regulation to "significant regulatory decisions." The SNPRM has expanded it to also apply to "influential scientific information"—a sweeping category that is defined to mean "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." The definition offers no parameters for determining whether scientific information could have "a clear and substantial impact" or which hypothetical "public policies or private sector decisions" should be considered "important." The breadth of the definition would empower the administrator to make subjective, *ad hoc*—and potentially inconsistent or politically motivated—determinations about whether theoretical "policies" and "decisions" would be "important" and thus would justify the application of the SNPRM.

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[136] *See* EO 12866 Documentation; Changes Made During Review—FR Document (RIN 2080-AA14; SNPRM), Docket ID No. EPA-HQ-OA-2018-0259-9321.

[137] The preamble to the SNPRM states: "EPA is clarifying that the exemption may be given if compliance is impracticable because technological barriers render sharing of the data or models infeasible." 85 Fed. Reg. at 15403. This statement and similar ones in the preamble could be read to suggest that U.S. EPA intends for the exemption provision to apply only when "technological barriers render sharing of the data or models infeasible."

[138] Unlike the NPRM, the SNPRM would not allow an exemption on the ground that it was "not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX."

f. The SNPRM May Be Inconsistent with U.S. EPA's Practices in Other Current Rulemakings.

U.S. EPA is in the process of adopting, and has recently adopted, multiple rules that will have a significant negative impact on air quality and human health, and it supports these rulemakings with information that may not meet the proposed standards for public availability. For example, in the Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule Part One: One National Program, U.S. EPA notes that some information relied upon in the rulemaking "is not publicly available, *e.g.,* confidential business information (CBI).[139] U.S. EPA has similarly relied upon information not publicly available in the "Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021-2026 Passenger Cars and Light Trucks."[140] U.S. EPA does not explain the extent to which the SNPRM would prevent the agency from relying upon non-public information in other concurrent or near-term rulemakings. It is an open question, then, whether U.S. EPA would need to amend its open rulemakings to eliminate the non-public information that it is proposing to limit itself from considering if the SNPRM is finalized – or whether U.S. EPA would simply find reasons to exempt its preferred studies from the SNPRM's requirements under its arbitrary exemption provision.

CONCLUSION

The SNPRM, if adopted, would severely undermine foundational regulatory science by excluding the best available science produced by long-established scientific practices, to the detriment of public health and the environment. It would ignore statutory directives regarding the use of best available science and would delay regulatory action. It would interfere with the agency's ability to respond to environmental and public health emergencies, all for no discernable reason. The SNPRM, like the NPRM, is unnecessary to ensure that EPA relies on high quality science for regulatory action. It is instead a dangerous and transparent attempt by U.S. EPA to limit consideration of important and valid science that might impel action to protect human health and the environment. U.S. EPA should abandon the proposed rules.

Sincerely,

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[139] 84 Fed. Reg. 51,310 (Sept. 27, 2019).
[140] 85 Fed. Reg. 24,174 (Apr. 30, 2020).

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