May 18, 2020

RE: Comments of Clean Air Task Force on the Supplemental Notice of Proposed Rulemaking on "Strengthening Transparency in Regulatory Science" (SNPRM). 85 Fed. Reg. 15,396 (Mar. 18, 2020); Docket ID No. EPA-HQ-OA-2018-0259.

Clean Air Task Force (CATF) respectfully submits these comments on the U.S. Environmental Protection Agency's (EPA or Agency) Supplemental Notice of Proposed Rulemaking on "Strengthening Transparency in Regulatory Science" (SNPRM).[1] CATF's lawyers, scientists, policy analysts, and advocates seek to help safeguard against the worst impacts of air pollution and climate change through research, analysis, and advocacy.

EPA's use of the best available science, especially the well-established body of research linking air pollution and risk of serious harms to public health, is critically important to the Agency's ability to meet its statutory obligations. If finalized, this supplemental proposal, like the proposed rule which it expands, would actively impede truly science-based decision-making. It is without legal justification, arbitrary, capricious, and an abuse of the Agency's discretion.

Introduction

The SNPRM contains many of the same flaws as the 2018 proposed rule[2] (2018 Proposal), namely a lack of statutory authority, never mind sufficient justification, and clarity. As we discussed in previous comments on the 2018 Proposal,[3] EPA's effort is both unnecessary and ultra vires. The SNPRM fails to remedy these critical defects, and indeed extends them. It is arbitrary and capricious, beyond EPA's authority to promulgate, and has had significant process issues. While EPA in the SNPRM acknowledged issues with the 2018 Proposal, it has failed to rectify its most critical problems, and indeed has expanded them.

The SNPRM proposes two approaches, a modified version of the approach in the 2018 Proposal, which includes a new "tiered access" option, and a new alternative approach that would weigh studies differently based on data availability.[4] The SNPRM also proposes to expand the scope of the rule's applicability to include Influential Scientific Information.[5] There is no more legal justification for these new approaches than there was for the 2018 Proposal, and the new approaches and expanded applicability in the rule lack significant analysis, explanation, and justification. These approaches present new challenges, including increasing the cost of implementation and impeding

[1] 85 Fed. Reg. 15,396 (Mar. 18, 2020).

[2] EPA, Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768 (Apr. 30, 2018).

[3] *See* Comments of Clean Air Task Force on the Proposed Rule Strengthening Transparency in Regulatory Science (August 16, 2018) (EPA-HQ-OA-2018-0259-6916), incorporated here by reference [hereinafter "CATF Comments"].

[4] 85 Fed. Reg. at 15,399.

[5] *Id.* at 15,398

the Agency's use of its own Influential Scientific Information. Also, despite EPA's claim of providing clarification of the 2018 Proposal, the SNPRM actually introduces more uncertainty by adding vague new provisions in the form of the tiered access system and alternative weighing approach. The SNPRM's discussion of these new provisions is not nearly sufficient to understand how they would actually be implemented.

EPA continues to fail to identify any valid statutory authority for what it is doing in this rulemaking. That lack of clear statutory authority for the rule renders it ultra vires, and therefore unlawful. Instead, this appears to be an exercise in ungrounded and results-oriented policymaking, aimed at creating obstacles that would prevent the agency from giving full consideration (or even any consideration at all) to well-regarded and long-standing public health studies. Those studies are in fact more valuable because they are based on deep analysis of human health data—and EPA's proposal to reject them because that data is confidential health information that cannot be made available in raw form to "stakeholders" undermines the Agency's mandate to promote and protect public health and welfare. EPA would make significant environmental and public health regulations more difficult to justify, skewing any considerations of costs and benefits against protecting public health and the environment by ignoring or discounting the estimated human health benefits of reducing pollution. Despite the proposal's Orwellian title, it does not contain any mechanism to encourage increased transparency between the government, the public, and the scientific community.

Furthermore, finalizing this rule would be arbitrary and capricious because it lacks a legitimate purpose. It represents a significant and unwarranted departure from established rulemaking practice, without justification, or reasoned explanation, or even clarity. Given the major changes it would require in how EPA conducts its regulatory work, and in the likely outcomes of that work, EPA's failure to do any cost analysis for the rule is particularly egregious.

This effort to inject transparently politically motivated criteria into EPA's consideration of science, to "preclude…EPA from using" science,[6] represents a serious threat to the Agency's mission. As the D.C. Circuit recently noted, "EPA operates pursuant to multiple statutory mandates requiring that its decisions rest on various formulations of the best available science."[7] Finalizing a rule that would prevent the Agency from considering such science would run counter to those statutory mandates by significantly impairing EPA's ability to protect human health and the environment.

I. EPA lacks statutory authority to promulgate the SNPRM

EPA fails to provide any clear or plausible statutory authority for this rule. While the agency asserts it is basing this effort on the "Federal Housekeeping Statute," 5 U.S.C. § 301, that reliance is misplaced, because even if the agency has the authority EPA claims it has (which it does not), that housekeeping authority cannot be the basis for a substantive rule that is in conflict with and limits the scope of substantive environmental statutes. Without the requisite statutory authority, the effort is ultra vires and unlawful.

[6] 83 Fed. Reg. 18,769, 18,769 n.3.

[7] *Physicians for Social Responsibility v. Wheeler*, No. 19-5104, 2020 U.S. App. LEXIS 12727 at *27 (D.C. Cir. Apr. 21, 2020).

A. EPA lacks the necessary authority to promulgate this rule under the Federal Housekeeping Statute.

As EPA admits in the SNPRM, the Agency "is not one of the 15 'Executive Departments' listed at 5 U.S.C. 101."[8] Therefore, on its face the Federal Housekeeping Statute does not even apply to EPA. EPA claims authority based on Reorganization Plan No. 3 of 1970, which transferred functions previously vested in other agencies to EPA, as well as functions "incidental to or necessary for the performance by or under the Administrator of the functions transferred."[9] However, EPA provides no reason to believe this rule is incidental or necessary for performance of the functions transferred. In fact, the rule conflicts with EPA's performance of its statutory duties, including under the Clean Air Act, by preventing the Agency from relying on the latest and best available science for its rulemakings.

B. Even if the Federal Housekeeping Statute applied to EPA, that authority does not extend to substantive rules that limit the Agency's ability to implement other statutes.

Any authority EPA does have under the Federal Housekeeping Statute is too limited to be the basis for this rule. In *Chrysler v. Brown*, the Supreme Court held that the Federal Housekeeping Statute "authoriz[es] what the APA terms 'rules of agency organization, procedure or practice' as opposed to 'substantive rules.'"[10] The Court also held that the Federal Housekeeping Statute does not authorize rules that limit the scope of a separate statute.[11] Because this rulemaking effort will have significant substantive effects, it cannot be authorized by the housekeeping statute.

i. The proposed rule is substantive, not procedural, and therefore cannot be authorized by the housekeeping statute.

This rule is not procedural. If finalized it will have substantial effects on EPA decisions that impact regulated entities. For example, under the Clean Air Act's National Ambient Air Quality Standards program, EPA is required to issue air quality criteria for pollutants that "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."[12] If EPA were to ignore or diminish the value of the latest scientific studies because they involve human health data that cannot be made publicly available, that would significantly impact the health-protectiveness of the resulting ambient air quality standards, which would have a substantial effect on both regulatory beneficiaries and regulated industries.

[8] 85 Fed. Reg. at 15,397.

[9] Reorganization Plan No. 3 Section 2(a)(9).

[10] *Chrysler v. Brown*, 441 U.S. 281, 310 (1979).

[11] *Id.* at 312.

[12] 42 U.S.C. 7408(a)(2).

In addition to the *Chrysler* Court's decision,[13] the D.C. Circuit held in *Pickus v. United States Bd. Of Parole*, that rules of practice or procedure "should not be deemed to include any action which goes beyond formality and substantially affects the rights of those over whom the agency exercises authority," and that "adherence to congressional purpose counsels a construction of this exemption [for procedural rules] that excludes from its operation action which is likely to have considerable impact on ultimate agency decisions."[14] By restricting EPA's consideration of science in regulatory decision-making based only on the public availability of underlying data, this rule would have a clear and substantial effect on ultimate agency decisions, including decisions that affect the rights of regulated entities, and therefore it is not a procedural rule.

Nor is this a proposed "internal rule of agency procedure" that "exclusively pertains to the internal practices of the EPA."[15] According to details provided to staff of the House Committee on Science, Space, and Technology,[16] EPA's proposed tiered access system would not be implemented internally at EPA, but rather the Agency expects that the bulk of the burden of implementing such a system would fall on the researchers who conduct (or conducted, as this relates to retroactive application of this new policy) the study. According to information shared with committee staff, EPA anticipates that researchers would be responsible for managing the logistics of making data and models publicly available in compliance with the rule, for judging the sensitivity of study data and models and what information can or cannot be made publicly available through tiered access, and what tier of access should be designated for different types of information.[17] It is unclear how EPA would ensure compliance with this rule, or whether after this rule is finalized, it will in effect ban all studies based on confidential human health data. However, what is clear is that this rule would have significant impacts beyond the Agency's internal practices and procedures.

ii. This rule would undermine EPA's ability to implement environmental statutes, including the Clean Air Act, and therefore cannot be authorized by the Federal Housekeeping Statute or the Information Quality Act.

[13] *Chrysler v. Brown*, 441 U.S. 281 (1979).

[14] *Pickus v. United States Bd. of Parole*, 507 F.2d 1107, 1114 (D.C. Cir. 1974).

[15] 85 Fed. Reg. at 15,398.

[16] Democratic Staff, Committee on Science, Space, and Technology, Summary of Staff-Level Briefings from the Environmental Protection Agency on the "Strengthening Transparency in Regulatory Science" Supplemental Proposed Rule (Apr. 30, 2020), https://science.house.gov/imo/media/doc/Letter%20and%20Memo%20-%20EBJ%20to%20SST%20Dem%20Caucus%20re%20Transparency%20Rule.pdf.

[17] *Id.*

Nor can the Federal Housekeeping Statute be used to authorize rules that limit the scope of EPA's responsibilities under other statutes. The *Chrysler* Court was clear that "[section] 301 does not authorize regulations limiting the scope of [the Trade Secrets Act]" (the statute under consideration in that case), or of any other substantive statutory authority.[18] Similarly, the Federal Housekeeping Statute cannot authorize regulations limiting the scope of environmental statutes.[19] If finalized, this rule would limit EPA's ability to evaluate and use the best available science to support its regulatory decisions, thereby undermining its ability to fully implement its responsibilities as mandated under environmental statutes. It therefore cannot be a valid exercise of the authority granted by the Federal Housekeeping Statute.

Neither the Federal Housekeeping Statute nor the Information Quality Act (IQA) provide authority or justification for a rule that would significantly impede and disrupt EPA's ability to fulfill its statutory mandates. For example, the air quality criteria EPA is required to issue when reviewing the National Ambient Air Quality Standards under the Clean Air Act takes the form of an integrated science assessment (ISA), in which the Agency evaluates the latest science on public health and environmental effects of criteria pollutants. The ISA document is considered a highly influential scientific assessment (HISA), which is a subset of the influential scientific information governed by the IQA guidance.[20] Subjecting the ISA to the requirements of this rule and SNPRM would result in the exclusion of important, longstanding public health studies from consideration, because the human health data on which they are based, and which makes them of value, is not publicly available as contemplated by the proposed rule. Such a result would directly conflict with the CAA's mandate that the air quality criteria reflect the latest scientific knowledge.

The Agency claims that "[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."[21] EPA fails, however, to explain how the Agency will define and identify such conflicts and ensure that staff do not follow the proposed rule. This is a significant question that EPA entirely fails to discuss.[22]

iii. EPA provides no other authority for this rule.

Not one of the other environmental statutes cited as potential authority by EPA actually authorizes this rule.[23] At most, many of the provisions cited by EPA generally allow the agency to promulgate regulations in order to implement various statutes, with many requiring that the regulations be

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[18] *Chrysler v. Brown*, 441 U.S. 281, 312 (1979) (internal citation omitted).

[19] *Chrysler v. Brown.*

[20] Office of Management and Budget, *Improving Implementation of the Information Quality*

Act. Memorandum for the Heads of Executive Departments and Agencies, at 4 (Apr. 24, 2019), https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf.

[21] 85 Fed. Reg. at 15,398.

[22] *Motor Vehicle Mfrs Ass'n v. State Farm Mut. Life Ins. Co.*, 463 U.S. 29, 43 (1983).

[23] *See* Earthjustice, *et al.*, Comments on "Transparency" in Regulatory Science, at 18-31 (Aug. 15, 2018), Doc. ID No. EPA-HQ-OA-2018-0259-6137.

necessary.[24] However, EPA has not shown how this rule would further the implementation of any statute, much less how the rule is necessary to fulfill any statutory responsibilities, and the fact that the Agency has not considered such a rule necessary until now suggests the opposite. Under the Clean Air Act, the most important scientific studies and models for use in evaluating the public health effects of air pollution are those that are based on actual human health data—much of which cannot be publicly available due to the confidentiality requirements imposed by other federal statutes and the agreements under which the data is provided to researchers. For Clean Air Act rulemaking then, any of the approaches EPA is proposing actively undermine the Agency's use of the best science in making decisions that promote and protect the public health and welfare—the fundamental purpose of the Clean Air Act.

If Congress had intended EPA to prioritize data transparency over the quality of scientific information in its regulatory decision-making, it could have written that requirement into the statutes. In the absence of such a requirement and as required by law, EPA should prioritize quality in accordance with the various "mandates requiring that its decisions rest on various formulations of the best available science."[25]

II. Finalizing this rule would constitute an arbitrary and capricious decision and an abuse of the Agency's discretion

In addition to EPA's lack of legal authority discussed above, EPA's proposal also still lacks sufficient clarity, justification, and rationality to constitute reasoned decision-making. Vague references to transparency do not provide sufficient identification of a "problem" with existing policies, requiring a remedy of the sort provided by EPA's 2018 Proposal and the SNPRM. EPA simply has not justified the radical and drastic measures it advances. The SNPRM also suffers from significant procedural flaws as it fails to provide sufficient information regarding the new provisions in the rule to offer a meaningful opportunity to comment on them. Without a reasoned explanation for moving off established and robust Agency practices supporting the use of the best available science in decision-making, the SNPRM is arbitrary, capricious, and an unlawful abuse of discretion.

A. EPA has not identified a problem with existing longstanding and robust policies and procedures sufficient to justify the radical changes it promotes in this rulemaking.

EPA claims to be taking this action to address concerns raised about its 2018 Proposal, but the SNPRM compounds those problems by expanding the rule's scope. EPA continues to fail to justify its rule—even failing to identify the problem it is supposedly meant to solve.

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[24] *See, e.g.*, Clean Air Act § 301(a), 42 U.S.C. § 7601(a) ("The Administrator is authorized to prescribe such regulations as are necessary to carry out his functions under this chapter."); Clean Water Act § 501(a), 33 U.S.C. § 1361(a) (authorizing the Administrator to "prescribe such regulations as are necessary to carry out his functions under this chapter."); Comprehensive Environmental Response, Compensation, and Liability Act § 115, 42 U.S.C. § 9615 (authorizing the President "to promulgate any regulations necessary to carry out the provisions of this subchapter."); Emergency Planning and Community Right-To-Know Act § 328, 42 U.S.C. § 11048 ("The Administrator may prescribe such regulations as may be necessary to carry out this chapter.").

[25] *Physicians for Social Responsibility v. Wheeler*, No. 19-5104, 2020 U.S. App. LEXIS 12727 at *27 (D.C. Cir. Apr. 21, 2020).

i. EPA still fails to identify a problem with existing policies to be solved by the rulemaking.

The basic premise of this rulemaking is that public health data—including human health data—has to be made publicly available to ensure the validity of scientific studies. That premise, simply put, is completely unsupported and totally incorrect. The Agency's long standing position is that "[w]hether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications."[26] EPA fails to explain why it now believes the contrary—that study validity and public data availability are (or should be) connected.

EPA has long relied on peer review and already has extensive policies in place regarding influential scientific information to assess the quality of the scientific research.[27] EPA provides no explanation as to why those policies are not sufficient to allow validation of scientific studies and information relied on by the Agency. Simply stating that "EPA shall conduct independent peer review on all pivotal regulatory science used to justify significant regulatory decisions and on all pivotal science underlying influential scientific information, consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review,"[28] fails to explain why this does not already occur under the Agency's past and current practice. If validation is truly the aim of this rulemaking, EPA must explain why existing practices for peer review are insufficient to validate scientific studies. It has failed to do so, indeed, the SNPRM contains very little discussion of peer review at all.

ii. The EPA Science Advisory Board Report on this proposal highlighted EPA's failure to provide sufficient justification for this change in policy.

Despite being composed largely of the Trump Administration's appointees, EPA's Science Advisory Board (SAB) included scathing criticism of the 2018 Proposal in its report, which also applies to this SNPRM:

> There is minimal justification provided in the Proposed Rule for why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate, and how the Proposed Rule will improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner.[29]

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[26] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research*, at 4-5 (Nov. 29, 2016).

[27] EPA, *Peer Review Handbook*, (October 2015), https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.

[28] 85 Fed. Reg. at 15,406.

[29] Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled *Strengthening Transparency in Regulatory Science*, at 18 (Apr. 24, 2020), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf [hereinafter "SAB Report"].

Not only is the rule insufficiently justified, but the SAB warned EPA that changing transparency requirements could have negative consequences:

> It is plausible that in some situations, the Proposed Rule will decrease efficiency and reduce scientific integrity, determining if in fact that will be the case requires a thorough and thoughtful examination that is currently absent in the Proposed Rule. Moving forward with altered transparency requirements beyond those already in use, in the absence of such a robust analysis, risks serious and perverse outcomes.[30]

The SNPRM does not include the additional "robust analysis" of the need for the changed policy called for by the SAB, and instead continues to leave important details regarding implementation of the rule undecided. At the very least EPA must provide a response to the problems raised by the SAB, including some explanation and justification for this rule.

iii. The SNPRM directs an unwarranted and unlawful standard for release of public health data disclosure.

The supporting private personal information that EPA in the SNPRM proposes[31] would have to be publicly released prior to EPA's reliance on public health studies is the kind of information that EPA itself is generally prohibited from releasing, even when faced with a Freedom of Information Act (FOIA) request. FOIA exempts "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."[32] In the SNPRM, EPA by contrast makes clear that the information subject to this rulemaking would include "[p]ersonnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."[33] Not only is this information exempt from FOIA, but Congress passed the Privacy Act of 1974, 5 U.S.C. § 552a, in order to prohibit agencies from releasing precisely this kind of information. The Privacy Act concerns the release of records, and the definition of "record" explicitly includes medical history.[34] Requiring public disclosure of information, where EPA itself is prohibited from disclosing it, as the threshold to allowing a study's use in regulatory decision-making, is not only unjustified, it is absurd.

B. The SNPRM lacks sufficient detail and clarity to allow a meaningful opportunity to review and comment.

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[30] *Id.*

[31] 85 Fed. Reg. at 15,401.

[32] 5 U.S.C. § 552(b)(6).

[33] 85 Fed. Reg. at 15,401.

[34] 5 U.S.C. § 552a(a)(4).

EPA has failed to provide a meaningful opportunity to review and comment on the proposed rule as required by the APA,[35] because many of the provisions in the SNPRM are described only in vague terms, with very little detail provided about the proposed policies and how they would be implemented. This continued failure to address critical details ignores significant problems that will arise on implementation of a final rule. For example, EPA in the SNPRM proposes to apply its data release requirements across the board, without distinguishing between types of studies and the data they rely on, which may or may not include confidential information. Additionally, while the 2018 Proposal was limited to dose-response data and models, the SNPRM expands that to all data and models broadly and without justification. The SAB's report on the 2018 Proposal stated that:

> … the requirement to make data available for public inspection will be more easily implemented for some datasets than others (e.g., [certain] studies include individual sample data as part of standard reporting). The expectation that data and methods will be available for all endpoints may be unrealistic.[36]

The SAB was clearly concerned that the rule's requirements could not even be put into practice, never mind whether they are lawful or rational or adequately justified. And, although the SNPRM allows the Administrator to grant an exception to the requirements, the SNPRM provides no reason to believe that provision will sufficiently address the concern identified by the SAB. Nor is there any safeguard included to ensure that the EPA Administrator, in exercising his discretion, will not bring extra-statutory political considerations into the decision-making process.

EPA's discussion of the so-called "tiered access" approach is especially vague and problematic. The proposed rule would allow studies to be considered in decision-making "if there is tiered access to these data and models in a manner sufficient for independent validation."[37] However, neither the rule nor the preamble provide sufficient detail on how such a system would be actually be implemented. For example, the SNPRM references models in the Research Data Center (RDC), National Center for Health Statistics, and Centers for Disease Control, mentioning that EPA is currently conducting a pilot study using the RDC's secure data enclave, but then the Agency also asserts that "[d]evelopment of standard data repositories is still ongoing."[38] In other words, even EPA acknowledges that it is far from clear how this would actually work.

EPA's failure to offer a reasoned explanation about how its proposed tiered access system would actually be implemented under this rule renders it unsupported and arbitrary. It is not enough for EPA in the SNPRM to introduce and vaguely discuss "tiered access." And asserting that "[i]nformation received during this public comment period will, among other things, help inform improved guidance and best practices related to preserving and providing access to data,"[39] does not allow commenters access to sufficient information about the course the Agency's final rule will take

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[35] 5 U.S.C. § 553.

[36] SAB Report at 19.

[37] 85 Fed. Reg. at 15,405.

[38] *Id.* 15,402.

[39] *Id.* at 15,402.

to permit meaningful comment. The whole point of an SNPRM is to clear things up and to allow enough release of information to permit the public to evaluate fully what the agency is proposing. But EPA has failed in that regard concerning its proposed tiered access approach.

C. EPA's so-called "alternative approach" would require the agency to assign greater weight to studies based on arbitrary criteria unrelated to scientific merit and quality.

While the details of EPA's alternative approach are unclear, assigning preferential treatment to certain studies based on criteria that are unrelated to the studies' scientific merit and quality would also be arbitrary and capricious. The SNPRM states that "[w]hen promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will, other things equal, give greater consideration to studies where the underlying data and models are publicly available."[40] However, the agency does not explain what it means by "other things equal" such that one study would be given greater weight, nor is the fact that data can be made publicly available tied in any way to the actual scientific merit or quality of the study results. Notably, the SNPRM places great importance on having publicly available data for reanalysis of peer-reviewed studies, but the Agency provides minimal detail regarding how it will determine whether researchers have actually fulfilled this reanalysis requirement. Giving the Administrator or staff leeway to "consider" one study more valuable than another based on criteria unrelated to quality clearly provides opportunity to inject politics into public health and environmental decision-making. While no two studies are likely to be identical, this vague approach would actually force the Agency to rely on one more than another (whether or not the study receiving the greater weight is actually more accurate or up to date), and is arbitrary and capricious.

Neither the 2018 Proposal nor the SNPRM provides any details as to how this provision would be implemented. How much additional weight will certain studies receive? How will that be determined? These are critically important questions that neither the Proposal nor the SNPRM answers or explains. The limited information provided about the alternative approach suggests that it would be arbitrary because, like the original approach, it would force the Agency to distinguish between studies and treat them differently based on arbitrary criteria. Data availability, as previously discussed, has no connection to the validity and quality of science.

D. Expanding the scope of the rule to include Influential Scientific Information (ISI) is unwarranted and inconsistent with the Information Quality Act.

The SNPRM clearly prioritizes information (data) availability, at the expense of information quality, and therefore is neither justified nor authorized by the Information Quality Act (IQA). The IQA requires agencies to "issue guidelines ensuring and *maximizing* the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency."[41] This proposal is entirely inconsistent with the IQA's mandate to maximize the quality of information disseminated by the agency. To the extent that complying with Office of Management and Budget's

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

[41] Treasury and General Government Appropriation Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515, 114 Stat. 2763 (2000) (emphasis added).

[OMB] memorandum[42] on implementing the IQA requires EPA to implement a rule that sacrifices information quality for data availability, the memorandum itself may be inconsistent with the IQA. The OMB redline of the proposal, found in the docket materials at EPA-HQ-OA-2018-0259-932, makes clear that OMB itself added in provisions related to the IQA during 12866 review.[43] Whatever its source, the additions are highly ironic, as this proposal is plainly *not* intended to improve the quality of information used or disseminated by EPA.

E. EPA has failed to offer a rational connection between the facts found and the choice made and does not provide a satisfactory explanation for changing the Agency's policy on the use of science.

Under the APA and CAA, agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" are to be held unlawful and set aside.[44] Agencies are required to "articulate a satisfactory explanation for [the] action including a 'rational connection between the facts found and the choice made.'"[45] Here, however, EPA is proposing to exclude or devalue scientific studies based on criteria that are unrelated to scientific value or merit, and that would eliminate the Agency's ability to rely on research that may be the best available science.

The Agency's newly claimed statutory authority under the housekeeping statute does not save this rule, and actually undermines any transparency justification for the rule. Many of the studies EPA relies on are done outside of the Agency, and therefore must be beyond the reach of the housekeeping statute. The Agency's conflation of transparency in EPA's processes with data availability in scientific research outside the Agency cannot be used to provide satisfactory justification for this rule.

EPA seems to believe that by wielding the terms "validation" and "reanalysis" it shows concern about the quality of studies relied on by the Agency. But EPA's real intention in the SNPRM, as in the Proposal, is to limit the Agency's access to public health science, not to ensure the quality of the studies the Agency relies on. That is made abundantly clear by the Agency's statement that if "multiple high-quality studies exist but only two studies have data and models that are available for independent validation and reanalysis, EPA would *only* include those two studies as pivotal regulatory science and/or pivotal science."[46] By acknowledging that the highest quality studies will be ignored if confidential data and models are not made available for validation and reanalysis, EPA is admitting that this rule is not concerned with improving the quality of studies relied on by the Agency. The SNPRM is instead laser-focused on information availability, even if it comes at the expense of the quality of scientific work. The best studies may not rely on available underlying

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[42] Office of Management and Budget, *Improving Implementation of the Information Quality Act. Memorandum for the Heads of Executive Departments and Agencies*, at 4-5 (Apr. 24, 2019), https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf.

[43] OMB, "Documentation of EO 12866 Review, Strengthening Transparency in Regulatory Science; Supplemental Proposed Rule (RIN 2080-AA14)," Doc. ID No. EPA-HQ-OA-2018-0259-9321.

[44] APA 706; CAA 307

[45] *State Farm*, 463 U.S. 29, 42-44 (1983).

[46] 85 Fed. Reg. at 15399 (emphasis added).

data—precisely because they are human health studies that requires the maintenance of the privacy of the study participants —and in those situations this rule would clearly prioritize data availability over quality.

Unlike the 2018 Proposal, the SNPRM does not include any acknowledgement that EPA must use the "best available science" for regulatory actions—but it must.[47] This lack of concern for quality is evident throughout the SNPRM and is particularly alarming in an agency that relies heavily on science—as it must, given its statutory mandates. Additionally, the suggestion that the rule could apply to studies retroactively if the Administrator does not grant an exemption further illustrates the intention to undermine longstanding reliance on the human health studies that have done the most to advance air quality and public health. The SNPRM states that the "proposal would apply to reviews of data, models, and studies at the time a rule is developed or influential scientific information is finalized, regardless of when the data and models were generated."[48] EPA has provided no reasoning to explain how retroactive application to past studies—including the Harvard Six Cities and American Cancer Society particulate matter health studies and subsequent work that links exposures to air pollution with declines and damages to human health—is justified. It certainly has not provided any information to suggest that this rule would *encourage* the release of more data from those studies. This proposal's focus is clearly on arbitrarily excluding or diminishing the value of quality scientific research rather than any real commitment to transparency.

The SNPRM also creates a new artificial and unnecessary conflict between EPA's reliance on its own Influential Scientific Information (ISI) and its statutory mandates to use the best available science. By broadening the scope of the rule to apply to ISI, EPA opens the door to two adverse outcomes. Either EPA would arbitrarily erode the usefulness of its peer-reviewed ISI and limit the Agency's ability to rely on ISI in situations where it is required to use the best available science, or, if the Agency chooses to rely on the ISI despite the exclusion of the best available science, potentially allow the Agency to circumvent statutory requirements. Neither of these outcomes is justified.

III. EPA failed to follow established practices in the rulemaking process

While the Science Advisory Board conducted a review of the 2018 Proposal that includes some discussion of the SNPRM, the board did not receive the text in time to have a meeting to fully deliberate on the SNPRM. Substantive deliberations for a review of the SNPRM would have required an open meeting under the Federal Advisory Committee Act.[49] Also, under the Environmental Research, Development, and Demonstration Authorization Act, the Administrator "shall" make any regulation under the Clean Air Act available to the SAB when it is provided to any other agency for formal review and comment.[50] To the extent this proposal is meant to impact any Clean Air Act rule outcomes, EPA therefore was required to provide the SAB information when the SNPRM was sent to the Office of Management and Budget but it did not.

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[47] 83 Fed. Reg. at 18,769 & n.1.

[48] 85 Fed. Reg. at 15,399.

[49] 5 U.S.C. App. § 10.

[50] 42 U.S.C. § 4365(c)(1)(requiring, inter alia, EPA to make available to the SAB any CAA rule that is provided to any other Federal agency for formal review and comment);

EPA has also failed to provide a regulatory impact analysis of the SNPRM, or include any analysis of the expected costs of the rule. Because this rule has significant substantive implications and involves important policy considerations and a change in longstanding practices, under executive order 12866, the agency is required to do a regulatory impact analysis—at the very least, because the SAB report made clear that "[t]here will be costs associated with assessing and disseminating data as required by the Proposed Rule."[51] The SNPRM applies more broadly and is likely to have even higher costs than the 2018 Proposal, yet EPA provides no discussion of the costs or benefits of the SNPRM under Executive Order 12866. While the 2018 Proposal included some cursory and inadequate discussion of benefits and costs, EPA fails to even discuss costs and benefits of the rule in the SNPRM, much less do a regulatory impact analysis.

IV. Conclusion

This rulemaking effort, including the SNPRM, is clearly not intended to improve the quality, validity, or transparency of the scientific evidence and studies on which the Agency relies in decision-making. Instead it is another aspect of a deregulatory agenda that discounts advances in the understanding of public health and environmental quality—the very purposes for which the Agency was established. EPA provides no legal authority that justifies its actions, and no persuasive reasons why the rule would lead to any improvement in its consideration of robust scientific advances, particularly in the public health realm.

Rather than improving transparency, or confidence in the scientific integrity of EPA actions, this rule would do the opposite—limiting or precluding the agency's use of pivotal public health studies, and allowing the injection of politics into EPA decision-making at the expense of independent science-based actions. If finalized, the rule would undermine EPA's ability to effectuate its statutory responsibilities by using the best available science to achieve its mission to protect human health and the environment. We strongly oppose finalization of any effort to limit EPA's discretion to consider the best available science based on arbitrary or vague criteria, including both of the approaches described in the SNPRM.

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[51] SAB Report at 4.