May 18, 2020

SUBMITTED VIA REGULATIONS.GOV

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

ATTN: DOCKET NO. EPA-HQ-OA-2018-0259

RE: COMMENTS OF ENVIRONMENTAL DEFENSE FUND ON EPA'S SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING: "STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE," 85 FED. REG. 15,396 (MAR. 18, 2020) ("SUPPLEMENTAL NOTICE")

Administrator Wheeler:

On behalf of our over 2.5 million members and supporters, Environmental Defense Fund (EDF) strongly opposes the Environmental Protection Agency's (EPA) March 18, 2020, Supplemental Notice to sharply curtail the agency's ability to use the best available science in making decisions about vital public health and environmental protections.[1] Cynically presented under the guise of promoting "transparency" in EPA's use of science, the Supplemental Notice would in fact *censor* science at EPA by radically expanding upon an April 2018 proposal to bar the agency from using rigorous, peer-reviewed health studies that rely on confidential data. Like its predecessor proposal, the Supplemental Notice lacks any legal or factual basis; would undermine the scientific integrity of the agency's decisions; and would do deep damage to public health by blinding the agency to life-saving research and hobbling the agency's ability to carry out our nation's bedrock health and environmental laws. EPA must immediately withdraw this harmful, misguided, and fatally deficient proposal.

[1] Strengthening Transparency in Regulatory Science, 85 Fed. Reg. 15,396 (Mar. 18, 2020).

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As we explain in these comments, the Supplemental Notice fails to rectify any of the fundamental flaws in the original proposal. Rather, it exacerbates them by expanding the scope of that flawed proposal to *all* data and models used by the agency, and to a vast universe of influential scientific information produced by EPA. Ignoring concerns that the original proposal would either require researchers to disclose confidential personal and medical information or restrict EPA from using those studies, the Supplemental Notice alters the definitions in the original proposal to make explicit that "[p]ersonnel and medical information . . . the disclosure of which would constitute a clearly unwarranted invasion of personal privacy . . . are intended to be subject to this rulemaking."[2]

Other changes to the original proposal that are reflected in the Supplemental Notice likewise do nothing to mitigate the concerns that numerous commenters, including EDF, pointed out in prior comments. For example, the Supplemental Notice's suggested new approaches for implementing restrictions on the agency's use of science amount to a disingenuous attempt to arrive at the same unlawful and arbitrary result as the original proposal, through only superficially different means, and lack either the reasoned justification or level of detail needed to allow for meaningful comment.

Our comments, among other things, point to these central defects in the Supplemental Notice:

- Like the original proposal, the Supplemental Notice fails to identify a problem that it is needed to address, and rests on the false premise that studies that draw on confidential data are not sufficiently reliable to inform agency decisions. Nowhere does the Supplemental Notice acknowledge or respond to the voluminous evidence in the record—including statements by leading scientific institutions and scientific publications—reaffirming that the availability of underlying data is neither necessary nor sufficient to assure the reliability of a study.

- EPA's novel claim that the federal "housekeeping" statute authorizes the agency to issue a substantive rule permitting it to ignore the best available science is preposterous—contradicting both the plain language of the statute and case law indicating that a sweeping, binding rule of this kind is not a "housekeeping" rule within the scope of the statute. The Supplemental Notice, like the original proposal, would also violate numerous statutes that require EPA to either use "best available science" or to otherwise examine all available data when issuing health or environmental protections. The housekeeping statute provides no authority for EPA to violate those statutes.

[2] *Id.* at 15,401 (alteration in original).

- EPA's new proposals to permit consideration of studies only where the underlying data has either been publicly disclosed or shared through "tiered access" arrangements, or to give less weight to studies where the underlying data has not been disclosed, would result in arbitrary and unjustified exclusion of studies based solely on the availability of data—including in situations where those studies have been validated by other means, and where there are legitimate legal, ethical or practical constraints that prevent disclosure of the underlying data. EPA has also failed to acknowledge or consider important and relevant factors such as the cost of implementation and the impacts of these options on the studies it may consider.

- The Supplemental Notice, like the original proposal, has "entirely failed to consider" virtually every "important aspect of the problem" it purports to address,[3] including the costs of the proposal for researchers, EPA, and the public; the numerous practical, legal, and ethical constraints that make it difficult or impossible for researchers to disclose data and models in many cases; and the effectiveness of reasonable alternatives to EPA's draconian proposal, including traditional methods of peer review and consultation with expert advisory boards. Despite having worked on this proposal for two years, EPA has *still* failed to assess the number and type of studies the agency would no longer be able to consider under this rule—even though the Congressional Budget Office has previously found that similar legislative proposals could sharply curtail the agency's ability to use thousands of scientific studies and cost the agency hundreds of millions of dollars per year.[4] That the Supplemental Notice vastly extends the scope of the original proposal, to cover a far larger range of data and models and a much broader universe of EPA actions and work products,[5] only exacerbates EPA's continued failure to evaluate the costs and impacts of this proposal.

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

[4] *See* Susanne S. Mehlman, Jon Sperl & Amy Petz, Cong. Budget Office, Cost Estimate for H.R. 1030: Secret Science Reform Act of 2015 at 2-3 (Mar. 11, 2015) ("CBO expects that EPA . . . would base its future work on fewer scientific studies . . . . CBO expects that the agency would probably cut the number of studies it relies on by about one-half . . . ."); Susanne S. Mehlman, Jon Sperl & Amy Petz, Cong. Budget Office, Cost Estimate for S. 544, Secret Science Reform Act of 2015 (June 5, 2015) ("CBO Estimate for S. 544") (estimating that another similar congressional proposal would cost up to $250 million per year).

[5] The original proposal only covered studies and dose-response data and models used to support "significant regulatory actions." 83 Fed. Reg. 18,768, 18,771 (Apr. 30, 2018). As noted above, the Supplemental Notice would expand that coverage by (a) applying to all data and models, not just those in dose-response studies, and defining "model" about as broadly as is conceptually possible, as "a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic, or social system," 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2); and (b) applying the proposed requirements not just to data and models supporting significant regulatory actions, but to data and models supporting "influential scientific information" as well, *id.*, a broadly defined category of EPA products that includes numerous documents that are vital to EPA regulations and policies.

- The Supplemental Notice's revised provisions allowing the Administrator to waive the requirements of the proposal on a case-by-case basis continue to leave the door open to selective and biased application of its requirements—allowing the Administrator to arbitrarily consider only those studies that support a desired conclusion.

- The Supplemental Notice, like the original proposal, suffers from numerous procedural deficiencies—including EPA's failure to undertake required consultations with other federal agencies and with EPA advisory boards.

Finally, we reiterate that EPA's decision to issue this attack on public health in the midst of a global pandemic and economic crisis—with *no* opportunity for public hearing and an unreasonably short 61-day window for public comment—fails to satisfy its obligation to provide a meaningful opportunity for public input. As we explained in our March 18, 2020, request for suspension of the comment period,[6] the Supplemental Notice radically alters the scope of the April 2018 proposal and dramatically expands its practical implications; introduces an entirely new legal theory in support of EPA's effort to censor science; presents two new implementation alternatives; and makes other significant amendments to the proposal, including a slew of new regulatory definitions. Under ordinary circumstances, changes this sweeping to a proposal this consequential would require a comment period *at least* as long as the 108 days provided on the April 2018 proposal. And as EPA is aware, these are no ordinary circumstances: the same public health experts and scientists whose input is essential to this Supplemental Notice are occupied in fighting a global pandemic. Moreover, EPA has pointed to no health or environmental benefit that would justify moving forward with this rulemaking: to the contrary, this proposal would harm the public by undermining vital health and environmental protections. For these reasons, EPA's rushed comment process—and its rejection of a legally-required opportunity for hearing—violates the agency's statutory duty to provide the public with a meaningful opportunity to weigh in.

EPA must abandon this irretrievably unlawful and misguided attack on public health.

Respectfully submitted,

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[6] EDF, Request to Immediately Halt and Withdraw EPA's Censored Science Rulemaking Action, and Suspend Deadline for Public Comments on EPA's Supplemental Notice of Proposed Rulemaking, Docket ID No. EPA-HQ-OA-2018-0259-9336 (Mar. 18, 2020).

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I. EPA'S SUPPLEMENTAL NOTICE FAILS TO REMEDY FUNDAMENTAL DEFECTS IN THE ORIGINAL PROPOSAL

EDF's 2018 comments on the original proposal documented numerous deficiencies in the agency's reasoning and a near-total lack of factual support for the proposition that EPA should be barred from considering studies where the underlying data or models cannot be publicly disclosed. Among other things, our comments noted that the proposal failed to identify an actual problem that needed to be addressed, or to point to even a single example of an EPA action or rulemaking that was later found to be defective because it rested on a study for which data was not publicly available.[7] We pointed to statements by leading scientists and scientific institutions indicating that the central premise of the proposal—that studies resting on confidential data or models are somehow not reliable enough to inform agency decision-making—is false, and ignores the many other methods and safeguards that agencies and the scientific community routinely use to validate scientific studies.[8] And we demonstrated that almost all of the documents EPA cited in support of the proposal—including EPA policies, Office of Management and Budget (OMB) guidance, and policies adopted by scientific journals and institutions—either failed to support the proposal or flatly contradicted it.[9]

These errors amount to a clear violation of EPA's obligation to ground its decisions in reasoned decision-making, and constitute fatal legal deficiencies.[10] Despite the nearly two years that elapsed since EPA issued the original proposal, however, the Supplemental Notice fails to acknowledge—much less rectify—any of the gaping holes in logic and evidence that we identified in our comments. Compounding these deficiencies, the Supplemental Notice drastically expands the scope of the original proposal to all data and models used by the agency (not just dose-response data and models), and to data and models supporting "influential scientific information" as well as the regulatory actions that were the focus of the original proposal. For these reasons, all of the deficiencies we documented in the original proposal are even more fatal to the Supplemental Notice—and would render any final rule issued on this record unlawful, arbitrary, and capricious.

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[7] EDF, Comments on the Environmental Protection Agency's *Proposed Rule: Strengthening Transparency in Regulatory Science*, Docket ID No. EPA-HQ-OA-2018-0259-9227, at 64 (Aug. 16, 2018) ("EDF 2018 Comments").

[8] *Id.* at 17-18.

[9] *Id.* at 86-91, App. A.

[10] *State Farm*, 463 U.S. at 43 ("[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.") (citations and quotation marks omitted).

A. THE SUPPLEMENTAL NOTICE REMAINS A "SOLUTION IN SEARCH OF A PROBLEM."

An agency action is arbitrary and capricious where it fails to identify a problem that it is needed to address.[11] The Supplemental Notice, like the original proposal, runs afoul of this basic principle of administrative law.

As EDF explained in its initial comments, EPA has developed a well-earned reputation for grounding its decisions in rigorous science over approximately five decades of operation spanning administrations of both parties.[12] This reputation has not come by accident—rather, it has resulted from deliberate efforts by EPA to utilize time-tested tools including formal peer review; close scrutiny of agency policies, decisions, and studies by the agency's advisory committees and external bodies such as the National Academies; and systematic frameworks that govern the agency's review and evaluation of the scientific studies that inform its work (such as the Preamble to the Integrated Science Assessment and systematic review protocols accompanying Integrated Risk Information System (IRIS) toxicological reviews). On top of these well-established mechanisms, the ability of the public to comment on the agency's use of science—and seek judicial review of arbitrary actions—constitutes a further safeguard to ensure the agency acts on the basis of the best available science.[13]

Like the original proposal, the Supplemental Notice fails to explain why these mechanisms are insufficient—or to address other information that has emerged since the publication of the original proposal that underscores this basic flaw in the rule. EPA's own Science Advisory Board (SAB) issued a final report on this proposal in April 2020 that sharply criticized EPA's failure to consider the effectiveness of existing transparency mechanisms—and warned that the proposal could "reduce scientific integrity" and "decrease efficiency":

> There appears to be consistency among analyses of how to address transparency that are orthogonal to the Proposed Rule. There is minimal justification provided in the Proposed Rule for why EPA finds that 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. It is plausible that in some situations, the Proposed Rule will decrease efficiency and

[11] *See, e.g.*, *Nat'l Ass'n of Fed. Employees v. Vilsac*k, 681 F. 3d 483, 485-86 (D.C. Cir. 2012) (concluding that identifying a legitimate governmental interest without foundation that the problem exists is "a solution in search of a problem" and arbitrary).

[12] EDF 2018 Comments at 64.

[13] *Id.* at 65.

> 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.[14]

Nor does the Supplemental Notice explain what problem would be solved by barring the agency from using studies where the underlying data is not available for reanalysis—no matter what ethical, legal, or practical barriers to disclosure might exist or what other methods have been used to validate the study. EPA has still failed to cite a single example, in either the Supplemental Notice or original proposal, where an EPA action, model, or other data underlying a regulatory action has proved deficient due to lack of public access to all underlying data.[15] The Supplemental Notice likewise fails to point to a single example where influential scientific information has proven to be faulty because it was based on data that was not made available for reanalysis—even as it proposes for the first time to bar consideration of data and models in the large volume of influential scientific information that EPA produces. The Supplemental Notice, like the original proposal, is therefore a classic instance of an arbitrary "solution in search of a problem."[16]

B. The Supplemental Notice Continues to Rest on the Arbitrary Premise that a Study Is Unreliable if It Relies on Data or Models that Cannot Be Disclosed.

EDF also pointed out in its comments that the central premise of the proposal—that a study is somehow inherently unreliable if the underlying data or models have not been disclosed—is false. As leading scientists and scientific institutions have concluded, the ability to reanalyze the

[14] Science Advisory Board, EPA-SAB-20-005, Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled *Strengthening Transparency in Regulatory Science*, at 18 (Apr. 14, 2020) ("Final SAB Report").

[15] A dissenting opinion in the SAB's final report in this proposal points to a recently-settled claim of data fraud associated with EPA-funded research conducted at Duke University. Final SAB Report, at A-1. However, the dissent fails to provide any evidence that the fraudulent data materially affected any EPA regulatory action or influential scientific information. Nor does the dissent provide any evidence that the requirements in this proposal—which merely restrict EPA from using certain studies and do nothing to assure that any data disclosed by researchers is authentic—would have assisted in identifying or preventing the incident. To the contrary, the incident demonstrates that current safeguards are effective in assuring scientific integrity and provide strong incentives against fraud: the fraudulent data was discovered and reported by a fellow researcher at Duke, who ultimately received a substantial reward as part of a $112.5 million settlement with the Department of Justice. *See* Sheila Kaplan, *Duke University to Pay $112.5 million to Settle Claims of Research Misconduct*, N.Y. TIMES (Mar. 25, 2019), https://www.nytimes.com/2019/03/25/science/duke-settlement-research.html.

[16] *Nat'l Ass'n of Fed. Employees*, 681 F. 3d at 485-86; *Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F. 3d 831, 840-41 (D.C. Cir. 2006) ("Professing that an order ameliorates a real industry problem but then citing no evidence demonstrating that there is in fact an industry problem is not reasoned decisionmaking."); *Sorenson Commc'ns v. FCC*, 755 F.3d 702, 709-10 (D.C. Cir. 2011) (similar).

data underlying a study is neither necessary nor sufficient to assure the validity of the study.[17] Reanalysis addresses only one aspect of a study's reliability—the possibility of certain types of errors or misrepresentations in the study's results—and is neither the only way to validate a study nor is it even close to being the most relevant or compelling factor in gauging a study's reliability.[18] Key aspects of reasoned decision making are the requirements that an agency explain reasonably why it is exercising its discretion in a given manner, and the concomitant responsibility to consider alternatives which may be more congruent with an agency's core responsibilities.[19] A rulemaking is irredeemably arbitrary where, as here, it proceeds from an incorrect premise.[20] Likewise, rules lacking in factual support are impermissibly arbitrary.[21]

The Supplemental Notice does not in any way address this fundamental defect in the proposal. Meanwhile, information that has become available since the 2018 proposal's publication only underscores that it proceeds from a false premise. In November 2019, the editors of the nation's leading science journals issued a statement underscoring that the notion of discounting studies based on the availability of underlying data is contrary to good scientific practice and would be a "catastrophe" for public health:

> As leaders of peer-reviewed journals, we support open sharing of research data, but we also recognize the validity of scientific studies that, for confidentiality reasons, cannot indiscriminately share absolutely all data. . . . *Discounting evidence from the decision-making process on the basis that some data are confidential runs counter to the EPA stated mission "to reduce environmental risks . . . based on the best available scientific information."* . . . We urge the EPA to continue to adopt an approach that ensures the data used in decision-making are the best available, which will at times require consideration of peer-reviewed scientific data, not all of which may be open to all members of the public. The most relevant science, vetted through

[17] EDF 2018 Comments at 17-21.

[18] *Id.* at 17 & n.47.

[19] *State Farm*, 463 U.S. at 48-49 (reasoned explanation requirement), 43 (failure to consider other alternative safety measures after rejecting passive restraints was arbitrary); *see also U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 571 (D.C. Cir. 2004) (agency action overturned where agency failed to explore reasonable alternatives, including tailored alternatives to nationwide rule).

[20] *See Clean Air Council v. Pruitt*, 862 F.3d 1, 10 (D.C. Cir. 2017) (summarily vacating EPA action as arbitrary and capricious where it was based on determinations that were plainly "inaccurate and thus unreasonable").

[21] *See, e.g., Util. Solid Waste Activities Grp. v. EPA*, 901 F. 3d 414, 431, 432 (D.C. Cir. 2018) (concluding rule resting on "unsupported suppositions" where there was "no evidence in the record supporting the EPA's assumption" was arbitrary); *Chemical Mfrs. Ass'n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994) (finding EPA cannot rely on general factual assertion in the face of specific contrary evidence).

> peer review, should inform public policy. Anything less will harm decision-making that claims to protect our health.[22]

Likewise, the SAB report mentioned above questions the very basis for the proposed rule in light of the alternative methods available to validate scientific studies:

> The SAB notes that there are legitimate legal, ethical, professional and financial reasons why researchers may be unable or unwilling to fully share "data" - including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data. The EPA, the U.S. Office of Management and Budget, and scientific institutions have recognized these legitimate concerns, and recognized that such constraints on availability of data do not prevent studies from being verified in other ways - or preclude those studies from being considered in regulatory decisions.[23]

This damning commentary from the scientific community itself, on a proposal that EPA has ostensibly advanced for the purpose of strengthening regulatory and influential science, merits a meaningful response from the agency. Instead, the Supplemental Notice ignores the concerns raised by the scientific community since April 2018 and proposes to dramatically expand the rule's scope. EPA's utter failure to engage these critiques underscores the proposal's arbitrariness.

C. THE SUPPLEMENTAL NOTICE FAILS TO CURE THE TOTAL LACK OF FACTUAL SUPPORT FOR THE ORIGINAL PROPOSAL.

EPA's original proposal cited seventeen sources as support for its action. As EDF thoroughly documented in its comments on the original proposal, none of these references supported the proposal. Each source cited proved to be either inapplicable, irrelevant, or contrary to EPA's proposed action.[24] Further, EPA's failure to explain its proposed departure from current agency policies and its reversal of prior agency conclusions on data availability are a hallmark of arbitrary decision-making.[25]

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[22] H. Holden Thorp et al., *Joint Statement On EPA Proposed Rule and Public Availability of Data*, SCIENCE, Dec. 6, 2019, https://science.sciencemag.org/content/366/6470/eaba3197 (emphasis added).

[23] Final SAB Report at 17.

[24] EDF 2018 Comments at 138-82; Environmental Protection Network, Comments on EPA's Proposal entitled "Strengthening Transparency in Regulatory Science," Docket ID No. EPA-HQ-OA-2018-0259-6125, at App. D (Aug. 14, 2018).

[25] *See Physicians for Soc. Responsibility v. Wheeler*, 2020 U.S. App. LEXIS 12727, at *26 (D.C. Cir. Apr. 21, 2020) ("An agency's wholesale failure to address 'past practice and formal policies regarding [an issue], let alone to explain

The Supplemental Notice drastically expands the scope of the original proposal, yet it rectifies neither its earlier citation of inapplicable, non-supportive authorities nor its failure to acknowledge or explain contradictions with current policies and prior conclusions. Nor does the Supplemental Notice cite any new authorities that support its deeply flawed approach. Although the Supplemental Notice claims that EPA's proposal is "consistent" with OMB memorandum M-19-15,[26] that memorandum says nothing about precluding the use of, or downgrading consideration given to, scientific information for which data are not publicly accessible. The memorandum in fact continues to recognize that agencies must "ensure that privacy and confidentiality are fully protected and that data are properly secure so that open data do not disclose personally identifiable information."[27] And although the memorandum discusses circumstances under which the tiered access approaches that are vaguely described in the Supplemental Notice can sometimes mitigate privacy and confidentiality concerns, the memorandum provides no support for EPA's proposal to simply ignore studies where such tiered access has not been created. As we noted in our August 2018 comments, prior OMB IQA guidance and implementing regulations make clear that studies and models are not to be *a priori* rejected or downgraded due to the mere fact that the data underlying them cannot be made public due to protections for privacy, confidential business information, or other data safeguards.[28] EPA's failure to provide adequate support for its proposed course of action is the antithesis of reasoned decision making.[29]

Not only do EPA's purported supporting authorities provide no support for the proposed rule, but there is also a plethora of evidence that EPA's existing approaches to evaluation of scientific studies, models, and other information underlying influential scientific information (ISI) are not only functioning well, but are exemplary. EPA's requirement of peer review of all ISI

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its reversal of course . . . [is] arbitrary and capricious.'") (quoting *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 927 (D.C. Cir. 2017)) (alterations in original).

[26] 85 Fed. Reg. at 15,398.

[27] Office of Mgmt. & Budget, M-19-15, Memorandum for the Heads of Executive Departments and Agencies, at 5 (Apr. 24, 2019).

[28] The OMB Guidelines recognize that data availability is not necessary to high quality science, but is one among many factors. While imposing high standards of quality, objectivity, utility, and integrity of information disseminated by Federal Agencies, the Guidelines recognize the need to implement controls "flexibly, and in a manner appropriate to the nature . . . of the information to be disseminated." Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002). As part of ensuring "objectivity," these guidelines encourage agencies that disseminate influential scientific, financial, or statistical information to "include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." *Id.* at 8460. In particular, OMB has made clear that interest in making data publicly available "does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections." *Id.*

[29] *See, e.g.*, *AT&T v. FCC*, 86 F.3d 242, 298 (D.C. Cir. 1996) (reliance on conclusory assertion without supporting evidence is arbitrary); *Chemical Mfrs. Ass'n v. EPA*, 28 F.3d at 1266 (stubborn adherence to conclusion without supporting evidence is arbitrary); *Fred Meyer Stores, Inc. v. NLRB*, 865 F.3d 630, 639 (D.C. Cir. 2017) (similar).

assures that ISI and underlying information are rigorously examined both within and without the agency before dissemination or other utilization.[30] Furthermore, EPA's *Scientific Integrity Policy* successfully promotes use of best science by not imposing *a priori* constraints on which information is to be used, but rather by considering data on its individual merits, unconstrained by political or other interference.[31] Although the policy recognizes the importance of the ability to independently validate scientific information and methods, as well as the importance of access to data and non-proprietary models used to support agency action, these values are not absolute rules barring or downgrading consideration of legitimate data and information.[32] EPA's traditional weight-of-evidence approach to data evaluation has express judicial imprimatur, as does its decision to consider studies for which not all underlying data are publicly available for legitimate reasons.[33] EPA's failure to even acknowledge its prior policies, much less rationally explain its proposed radical deviation from them, is a fundamental legal error.[34]

D. Recent Information Only Reinforces the Arbitrariness of the Original Proposal.

Other information that has emerged since August 2018 reinforces the deficiencies that EDF highlighted in its initial comments.

Risk of Re-identification. For example, our initial comments pointed out that EPA had failed to meaningfully address concerns that even partial public disclosure of the data underlying health studies could undermine the guarantees of privacy and confidentiality that are usually provided to participants in those studies. As we documented with extensive record evidence, advances in computing have made it possible to identify participants in studies and details about their personal and medical histories, even where researchers have taken steps to mask that information or otherwise "de-identify" the data before disclosing it.[35] In July 2019, a major new study published in the journal *Nature Communications* provided a rigorous assessment that underscores these concerns.[36] Working with datasets of personal attributes drawn from the Census

[30] EPA, Peer Review Handbook, EPA/100/B-15/001, at 20-21, B-12, B-37 (4th ed. 2015).

[31] EPA, Scientific Integrity Policy 3, 5 (2012).

[32] *Id.* at 4.

[33] *Mississippi v. EPA*, 744 F.3d 1334, 1344 (D.C. Cir. 2013); *Am. Trucking Ass'n v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002); *Coal. of Battery Recyclers Ass'n v. EPA,* 604 F.3d 613, 622-23 (D.C. Cir. 2010).

[34] *Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *26.

[35] EDF 2018 Comments at 45-47.

[36] Luc Rocher, Julien M. Hendrickx & Yves-Alexandre de Montjoye, Estimating the Success of Re-Identifications in Incomplete Datasets Using Generative Models, Nature Commc'n, July 23, 2019; *see also* Gina Kolata, *Your Data Were 'Anonymized'? These Scientists Can Still Identify You,* N.Y. Times (July 23, 2019), https://www.nytimes.com/2019/07/23/health/data-privacy-protection.html.

and other sources, the authors were able to demonstrate that 99.98% of Americans could be correctly re-identified using a combination of just 15 demographic attributes.[37] As the authors state, their results "reject the claims that, first, re-identification is not a practical risk and, second, sampling or releasing partial datasets provide plausible deniability."[38] The authors further conclude that their results "question whether current de-identification practices satisfy the anonymization standards of modern data protection laws."[39]

Likewise, comments submitted by the Health Effects Institute (HEI) to the SAB in advance of the Board's August 27, 2019, teleconference on data privacy issues underscored that "depersonalized" datasets cannot be made available in a way that enables useful re-analysis of the data. As the comments note, "it is not possible to conduct a high-quality air pollution and health study without knowing the locations of those being studied, i.e. where they live, and what are the sources and levels of their air pollution exposure. . . . [O]nce that information is available at smaller spatial scale, it is possible to disclose extensive medical information for individual study subjects."[40] A member of the SAB, Dr. Richard Smith, echoed this concern in the consultation document—observing that "even de-identified data might not be sufficient to confirm the analysis" because location-specific data is essential to many environmental epidemiology studies.[41] As Dr. Smith pointed out to EPA, this is why "major datasets that include individual participant addresses (for example, the Women's Health Initiative) maintain strict rules on the confidentiality of that information. I don't see how this is going to be reversed."[42]

Finally, SAB's report on this proposal echoes these concerns, concluding that:

> Although the Proposed Rule suggests that privacy and confidentiality issues can be addressed through anonymization or de-identification, this is not always the case. The U.S. Office of Management and Budget (OMB, 2013), Health Effects Institute, National Academies of Science (NRC, 2005), and independent experts (Rothstein, 2010; Commission on Evidence-Based Policy Making, 2017; Rocher et al., 2019) have all found that even de-identified datasets present significant risks of

[37] Rocher et al., *supra* note 36, at 1.

[38] *Id.* at 2.

[39] *Id.*

[40] Letter from Daniel Greenbaum, President, HEI, to Michael Honeycutt, Chair, Science Advisory Board (Aug. 20, 2019).

[41] SAB, Consultation on Mechanisms for Secure Access to Personally Identifying Information (PII) and Confidential Business Information (CBI) Under the Proposed Rule, *Strengthening Transparency in Regulatory Science*, EPA-SAB-19-005, at B-33 (Sept. 20, 2019) ("SAB Consultation").

[42] *Id.*

reidentification given modern techniques for combining these datasets with other sources of individual information (also known as a "mosaic effect").[43]

Risk that EPA Will Lose Access to Valuable Research, Both Past and Future. EDF's August 2018 comments also noted that EPA had utterly failed to acknowledge—much less seriously assess or consider—the possibility that its proposal would undermine scientific integrity at the agency by constricting the agency's ability to utilize valuable data and research that legitimately or ethically cannot be disclosed (even in a controlled setting, such as a tiered-access arrangement).[44] Comments submitted by Bernard Goldstein of the Environmental Protection Network for the SAB's August 2019 consultation underscore these concerns. Goldstein's comments pointed to the example of a 2010 study on the effects of formaldehyde exposure that had 34 co-authors from seven different institutions and three different countries.[45] Goldstein observed that sharing the underlying data from that study would potentially require the unanimous agreement of all 34 co-authors, many of which answer to different Institutional Review Boards that must approve such sharing, and some of whom are subject to different privacy laws than those that apply in the United States.[46] As Goldstein also observed, "international studies with or without significant U.S. collaboration are becoming an increasing percentage of total environmental health research. Isn't one of the inevitable outcomes of EPA's proposal a cumbersome barrier to being able to put together a team of international investigators for studies of humans that are potentially relevant to EPA's environmental regulations?"[47] Neither the original proposal nor the Supplemental Notice meaningfully considers this critical question and the implications that it poses for EPA's ability to consider regulatory science.

Similarly, Dr. Janice Chambers—a member of the SAB—commented in response to EPA's charge questions that even a "tiered access" approach to disclosing data would not be possible to apply retroactively to studies carried out in the past. Based on her personal experience, Dr. Chambers opined that "many of the older epidemiology studies would not have considered this option in their Informed Consent Forms" and that the researchers who conducted those studies (assuming they are even available) would therefore not have consent to share the data for reanalysis.[48] Dr. Chambers also noted that the "option of [personally identifiable information] being released to unknown people in the future would have caused some participants to decline participation," suggesting that a tiered access requirement would inhibit participation in future

[43] Final SAB Report at 11-12.

[44] EDF 2018 Comments at 67, 85-94.

[45] Bernard D. Goldstein, Presentation to the EPA Science Advisory Board 2 (Aug. 27, 2019).

[46] *Id.*

[47] *Id.* at 2-3.

[48] SAB Consultation at B-10.

health studies and potentially damage the quantity and quality of future research that is relevant to regulatory action.[49] Dr. Kenneth Portier's comments as a member of the SAB echo this concern and note that participants in past health studies may either have died or be unable to provide consent due to age or illness—and that even participants who are reachable may be unwilling to release subsets of their data even to "safe harbor data archives."[50]

SAB's final report on the proposed rule—though it was issued after the publication of the Supplemental Notice—pointedly underscores EPA's failure to consider these central concerns. For example, SAB noted that "[i]t is not clear: (1) how many of the studies EPA currently relies upon to take important regulatory actions would meet the public disclosure standards stated in the Proposed Rule, and (2) whether EPA has assessed the feasibility of making underlying information from the studies publicly available, or what the impact of precluding those studies would be on EPA's decision making and its ability to protect public health/environment."[51] EPA thus continues to disregard the likelihood that its rule would severely erode the best available science available to the agency, which it recognizes "must serve as the foundation of [its] regulatory actions."[52] The proposal remains arbitrary in ignoring this obvious—and now expanded—counterproductive effect.[53]

Practical and Economic Impediments to Tiered Access Arrangements and Retrospective Application. As also referenced in Section V.A and .B of these comments, EPA's proposed "tiered access" approach fails to engage with or even acknowledge concerns that have been presented multiple times to the agency regarding the cost and feasibility of establishing such arrangements on a routine basis. The HEI comments to SAB noted that tiered-access arrangements, such as proposed in the Supplemental Notice, require the consent and collaboration of researchers and can be "challenging" to establish.[54] Further, Dr. Richard Smith's feedback to EPA in the SAB consultation on tiered access issues notes that the federal tiered-access models EPA has pointed to are relevant only to "a small fraction of published epidemiology research" and that these platforms do not address access to datasets held by universities or by private organizations like the American

[49] *Id.*

[50] *Id.* at B-28.

[51] SAB Final Report at 15.

[52] 83 Fed. Reg. at 18,769.

[53] *See Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *27 ("Even the Directive itself agrees that 'it is in the public interest to select the most qualified, knowledgeable, and experienced candidates.' Yet the Directive nowhere confronts the possibility that excluding grant recipients—that is, individuals who EPA has independently deemed qualified enough to receive competitive funding—from advisory committees might exclude those very candidates." (citations omitted)).

[54] Letter from Daniel Greenbaum, *supra* note 40.

Cancer Society.[55] Dr. Smith also highlighted that federal research centers allowing tiered access require researchers to visit in person and require a federal employee to approve all outputs taken from the research center; Center for Medicare and Medicaid Services allows for remote use of data, but only after the researcher signs a contract with CMS that provides for the data to be maintained on a secure server—a process that in Dr. Smith's experience "took some months to set up and (as I understand) a considerable sum of money."[56] EPA's Supplemental Notice makes no mention of and gives no consideration to these practical impediments to tiered access.

Recent information has also underscored EPA's failure to consider the costs to researchers of demanding that older data be made available for reanalysis (either to the public or through a tiered access mechanism), and the implications that cost would have on EPA's access to regulatory science. For example, SAB member Robert W. Merritt commented in the SAB's September 2019 consultation that data from older studies may be located in obsolete storage media or data formats that are either impossible or very costly to convert to a shareable form.[57] Moreover, because the grants funding older studies have already lapsed, there would likely be little to no funding available for datasets owned by academic and non-profit institutions to be shared—meaning that much of this research would not be eligible for EPA's consideration, and that EPA might be drawing from a biased pool of for-profit industry studies.[58] Previously, EPA had accepted some responsibility for making information publicly available in a "cost-effective" way.[59] Now, it has disclaimed this role and abandoned any pretense of contributing to the transparency and validity it supposedly seeks, opting simply to discard studies out of hand.[60]

SAB's final report on the proposed rule underscores these concerns. As the SAB concluded, "the retrospective application of modern transparency standards is a challenge. A large amount of work would be required to locate, curate and retrospectively make datasets available for public access. This requirement could adversely affect the ability to move this program forward in a meaningful capacity."[61] A separate passage of the SAB report cautioned that "[a]nother aspect to consider is the practical aspect of actually conducting a reanalysis of a major epidemiological study. Such an enterprise requires an enormous amount of work even for a well-qualified

[55] SAB Consultation at B-32.

[56] *Id.*

[57] *Id.* at B-24 to -25.

[58] *Id.*

[59] 83 Fed. Reg. at 18,771 ("EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective.").

[60] 85 Fed. Reg. at 15,402.

[61] Final SAB Report at 15.

researcher. The Health Effects Institute (HEI) established a model for conducting such a reanalysis in its 2000 reanalysis of the Six Cities and American Cancer Society datasets (HEI, 2000). However, HEI has not repeated this kind of exercise."[62] EPA now clarifies that it could consider a study even if no one has independently validated it.[63] The SAB's critique, however, highlights the minimal value of public disclosure in "[e]nhancing the transparency and validity of the scientific information relied upon by EPA" to "strengthen[] the integrity of EPA's regulatory actions."[64] Because EPA has not explained how a public disclosure requirement, alone, would appreciably enhance the validity of the scientific information supporting its actions—or, on balance, strengthen their integrity—its proposal remains arbitrary.[65]

E. The New Proposed Regulatory Language in the Supplemental Notice Confirms That the Rule Would Arbitrarily Apply Retroactively.

At the time of the 2018 proposal, EPA had not clearly indicated whether it would apply the proposed rule retroactively to data and models completed or updated prior to the rule. EDF commented that *any* retroactive application of the proposed rule to models and data completed or updated prior to this rule would be both unlawful and bad policy. Unfortunately, the revised regulatory language proposed in the Supplemental Notice indicates that EPA does intend to apply the rule retroactively. First, both the tiered-access proposal and the weighting alternative proposed for inclusion in section 30.5 would apply "regardless of when the data and models were generated."[66] Second, new language in proposed section 30.9 would authorize the Administrator to exempt a study from the rule's public availability requirements if "the development of the data or model was completed or updated before" the effective date of the final rule.[67] While EPA implies that including the age of data and models as an exemption criterion would soften the rule's impact (e.g., describing older studies as being "eligible for consideration" under the proposed

[62] *Id.* at 19.

[63] 85 Fed. Reg. at 15,403 ("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.").

[64] 83 Fed. Reg. at 18,769.

[65] *See Physicians for Soc. Responsibility v. Wheeler*, 2020 U.S. App. LEXIS 12727, at *27 ("Even the Directive itself agrees that 'it is in the public interest to select the most qualified, knowledgeable, and experienced candidates.' Yet the Directive nowhere confronts the possibility that excluding grant recipients—that is, individuals who EPA has independently deemed qualified enough to receive competitive funding—from advisory committees might exclude those very candidates." (citation omitted)).

[66] 85 Fed. Reg. at 15,403. EPA solicits comment on "whether this [requirement] should apply only to data and models that are generated . . . after the effective date of this rulemaking." *Id.* It does not elaborate on the reasons for prospective application, nor does it propose prospective application as an alternative approach.

[67] *Id.* at 15,406.

rule's exemption provisions[68]), in reality, this new language would confirm that the rule's requirements do in fact apply to pre-existing data and studies unless the Administrator exercises his or her discretion to exempt them. EDF strongly opposes this proposed regulatory language. If EPA persists in finalizing this unlawful and arbitrary rule, EPA must expressly not apply it to data and models completed or updated prior to this rulemaking.

As discussed below and in EDF's 2018 comments, EPA has not demonstrated—and cannot demonstrate—that a study cannot be scientifically valid unless the underlying data and models are publicly disclosed. And, while scientists might be aware of the rule's public disclosure requirements in the future, such requirements did not apply in the past, and it often will not be possible to make data and models underlying older studies publicly available.[69] EDF's 2018 comments provided many reasons why data and models from past research might not be available (or amenable to tiered access), including data loss over time, multiple owners of data, and inability to obtain participant consent.[70] In fact, EPA acknowledges in the Supplemental Notice that "[t]he underlying data, models and computer code for some studies, particularly older studies, may not be readily publicly available because of the technological barriers to data and model sharing (e.g., differences in data storage devices or data retention practices) that existed when they were developed."[71] Thus, applying the rule retroactively would result in excluding valid and reliable studies from EPA's consideration when promulgating rules and adopting policies.[72] And even where it is technically possible to comply with the proposed public disclosure requirements, such disclosure would be prohibitively expensive and time-consuming. As the SAB explains, "[a] large amount of work would be required to locate, curate and retrospectively make datasets available for public access."[73] Thus, it is unrealistic to expect that a significant number of older studies will be reviewed and brought into compliance with the proposed data and disclosure requirements.

Incentivizing scientists to make the data and models underlying their studies publicly available where it is lawful, feasible, and ethical to do so is a worthwhile goal, to the limited extent

[68] *Id.* at 15,403.

[69] *See* Final SAB Report at 15 ("[I]t will not always be possible to apply these same standards retrospectively.").

[70] EDF 2018 Comments at 38-39. The possibility that the Administrator would grant an exemption, on a case-by-case basis, because of the age of the data, 85 Fed. Reg. at 15,403, does not remove the presumption that EPA will ignore or downgrade valid historical studies.

[71] 85 Fed. Reg. at 15,403.

[72] EDF's 2018 comments identify several studies that likely would be eliminated from EPA's consideration if this rule were finalized—or at least downgraded in importance—despite the fact that each has been validated using approaches that did not require public disclosure of underlying data and models. EDF 2018 Comments at 58, 70-75; *see also* Harvard Law School Emmett Environmental Law & Policy Clinic, Comments on Proposed Rule, Strengthening Transparency in Regulatory Science, Docket ID No. EPA-HQ-OA-2018-0259-6111, at 9-12 and Att. 1 (Aug. 7, 2018).

[73] Final SAB Report at 15.

that it improves the reliability of the science the agency relies on to fulfill its statutory duties. But doing so in a way that prevents EPA from considering (or allows EPA to ignore) otherwise valid and reliable studies when formulating rules and policies is plainly unlawful. And applying that approach retroactively to studies for which public disclosure of underlying data and models is impracticable, if not impossible, fails even to achieve the goal of marginally improving the quality of the science on which the agency relies. As explained in the Final SAB Report on this rulemaking, "retrospective application of the requirement would be difficult to implement, could be expensive with no clear responsibility regarding who would cover the added cost, and could arbitrarily impact the conclusions drawn."[74] In sum, retroactive application of the proposed rule would only serve to unlawfully eliminate or impair EPA's ability to consider valid, relevant science when seeking to fulfill its mission of protecting public health and the environment. EDF opposes this misguided and unlawful proposal in its entirety, but if EPA does move forward with finalizing it, EPA must eliminate the proposed regulatory language indicating that the rule applies retroactively. Instead, EPA must confirm in section 30.5 that there will be no retroactive application of the rule.

II. EPA DOES NOT HAVE AUTHORITY TO ISSUE THE PROPOSED RULE AND THE SUPPLEMENTAL NOTICE FAILS TO REMEDY THIS DEFECT

The Supplemental Notice fails to identify any viable additional sources of authority for the 2018 Proposal. None of the discussed authorities under the Federal Housekeeping Act, referenced environmental statutes, or the Information Quality Act support the 2018 proposal or rectify its numerous statutory violations identified in previous comments. Since "an agency literally has no power to act . . . unless and until Congress confers power upon it," the 2018 proposal must be withdrawn for a lack of statutory authority.[75]

A. THE FEDERAL HOUSEKEEPING ACT PROVIDES NO AUTHORIZATION FOR EPA'S PROPOSED REGULATION.

In the Supplemental Notice, EPA asserts that an obscure federal law known as the "Housekeeping Act" authorizes its sweeping attack on health science. This novel legal theory flouts the plain language and history of this statute, both of which make clear that EPA is not an "executive department" with the associated authorities under this statute. Equally important, even if EPA *were* an executive department, the 2018 proposal is clearly substantive and has "binding effects" on the public and the agency itself, which profoundly influence EPA's implementation of multiple environmental laws and capacity to protect public health and the environment. It is black

[74] *Id.* at 17.

[75] *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).

letter law that the Housekeeping Act cannot be used to authorize such substantive rules. The proposal is therefore beyond the housekeeping powers granted by the statute for *any* agency.

1. EPA Is Not an "Executive Department" Under the Housekeeping Act.

EPA's attempt to rely on the Housekeeping Act[76] as a source of authority directly contradicts the statute's explicit allocation of these housekeeping authorities to "Executive departments"—which EPA is not. The statute provides that "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."[77] By its terms, this statute authorizes an executive department "to regulate its own affairs" through "rules of agency organization procedure or practice."[78]

EPA is not an "Executive department" within the meaning of section 301. As EPA acknowledges in the Supplemental Notice, section 101 of Title 5 explicitly lists the fifteen entities considered "Executive departments" under section 301,[79] and EPA is not among them.[80] The statute instead designates EPA as an "independent establishment," under section 104. Section 104 defines an "independent establishment" as "an establishment in the executive branch . . . which is not an Executive department, military department, Government corporation, or part thereof, or part of an independent establishment."[81] Since EPA is an "independent establishment" rather than an "Executive department," the agency cannot rely on section 301 as the source of its authority for the 2018 Proposal.[82]

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[76] 5 U.S.C. § 301.

[77] *Id.*

[78] *Chrysler Corp. v. Brown*, 441 U.S. 281, 309-10 (1979).

[79] Section 101 lists 15 executive departments (which are the 15 cabinet-level departments): the Department of State, the Department of the Treasury, the Department of Defense, the Department of Justice, the Department of the Interior, the Department of Agriculture, the Department of Commerce, the Department of Labor, the Department of Health and Human Services, the Department of Housing and Urban Development, the Department of Transportation, the Department of Energy, the Department of Education, the Department of Veterans Affairs, and the Department of Homeland Security.

[80] 5 U.S.C. § 101; 85 Fed. Reg. at 15,397 ("EPA is not one of the 15 'Executive Departments' listed at 5 U.S.C. 101.").

[81] 5 U.S.C. § 104.

[82] *See also* William Funk, *Is the Environmental Appeals Board Unconstitutional or Unlawful?*, 49 Envtl. L. 737, 742-43 (2019) (stating that EPA is not an executive department under the Housekeeping Act so was not authorized to issue a proposal under section 301).

EPA incorrectly asserts that EPA has gained the authorities of an "Executive department" through delegation and reorganization. In the Supplemental Notice, EPA claims that Reorganization Plan No. 3, which established EPA—and contains no mention of the Housekeeping Act—implicitly granted EPA this status when it transferred programs and authorities from the Departments of Interior and Health, Education, and Welfare to the newly formed EPA.[83] Admitting that nothing in Reorganization Plan No. 3 explicitly grants this authority, EPA points to a 2008 OLC opinion, on the entirely unrelated topic of whether federal employees should be held responsible for lost or damaged federal property, which contends that section 2(a)(9) of the plan implicitly confers this authority alongside the explicit transfer of various functions.[84]

Such a strained interpretation clearly contradicts the requirement for Congress to amend the statute, if it so wills, to recognize additional executive departments. Congress has demonstrated its capacity to grant newly created government entities the status of executive departments with housekeeping authorities when it so chooses. In 2002, Congress created the Department of Homeland Security and, similar to EPA's Reorganization Plan No. 3, laid out the functions transferred from existing departments to the new department. In section 101 of the Homeland Security Act, Congress specifically provided that the Department of Homeland Security was being "established . . . as an executive department of the United States within the meaning of title 5."[85] Congress has had decades to take equivalent action with regard to EPA, and Congress's choice to not update the "Executive department" list cannot be conveniently ignored. To this day, EPA remains an "independent establishment" under the Housekeeping Act. It defies any reasonable interpretation for EPA to be simultaneously designated as an "executive department" and an "independent establishment," when the latter is defined as an entity not listed among the former. To construe EPA as an "executive department" contradicts the plain language of the statute and congressional intent.

EPA attempts to skirt around this glaring omission by scraping together two cases in which it claims courts recognized EPA to have section 301 housekeeping authority. The first case EPA cites for support, *EPA* v. *General Electric Co.*,[86] concerns the judicial reviewability of EPA's refusal to comply with a third-party subpoena under the APA. The court found the refusal reviewable;[87] it did not find that EPA's regulations, which claimed section 301 among other

[83] *See* Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970).

[84] *See Authority of the Environmental Protection Agency to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property*, 32 Op. O.L.C. 79 (2008).

[85] 6 U.S.C. § 111(a).

[86] 197 F.3d 592 (2d Cir. 1999); *see also* 85 Fed. Reg. at 15,397.

[87] *Gen. Elec. Co.*, 197 F.3d at 598-99.

authorities, applied to the subpoena as issued. The court referenced EPA's potential housekeeping authority only in dicta without any further discussion or analysis.[88]

In the second case EPA references for support, *Boron Oil Co.* v. *Downie*,[89] the court held that the lower courts lacked jurisdiction to compel an EPA employee to appear and testify in a state court action to which the government is not a party as EPA was protected by sovereign immunity.[90] While finding the grant of sovereign immunity sufficient on its own merit, the court explained that the principle of federal supremacy supports the protection of sovereign immunity such that the state court could not compel testimony in violation of EPA's housekeeping regulations.[91] But the court provided no explication of how EPA could be construed as an "Executive department" under the Housekeeping Act with relevant authority to issue such regulations. Moreover, the EPA regulations there in question claim an assortment of authorities, not only the Housekeeping Act.[92]

The Supplemental Notice also broadly cites *Chrysler Corp. v. Brown*.[93] But that case provides no additional basis to apply section 301 authority to an "independent establishment," as the case concerns the Department of Labor—a listed executive department under the Housekeeping Act. It also holds that the Housekeeping Act does not authorize issuance of substantive rules, as discussed *infra*.

None of the cited cases hold that EPA is an executive department under the Act. As EDF has argued in other contexts, EPA undoubtedly has administrative authority to undertake its statutory obligations. This comment argues only that section 301 is not the source of that authority. However, even if EPA were to be recognized to have section 301 authority, section 301 does not provide authority for *any* executive department to issue a substantive rule such as the Supplemental Notice.

2. The Housekeeping Act Does Not Authorize Substantive Rules.

In the primary case EPA cites for its alleged authority under the Housekeeping Act to issue the proposal, *Chrysler Corp. v. Brown*, the Supreme Court makes explicit that the Housekeeping Act cannot authorize substantive rules such as the current proposal. *Chrysler Corp.* concerned a

[88] *Id.* at 595-97.

[89] 873 F.2d 67 (4th Cir. 1989); *see also* 85 Fed. Reg. at 15,397.

[90] *Boron Oil Co.*, 873 F.2d at 70.

[91] *Id.* at 71.

[92] *Id.* at 69; *see also* 40 C.F.R. § 2.401(c).

[93] 441 U.S. 281 (1979); *see also* 85 Fed. Reg. at 15,397.

government contractor who asked the court to enjoin release of documents regarding petitioner's employment practices. The documents had been requested under FOIA, and a division of the Department of Labor had determined they should be released, consistent with FOIA and disclosure regulations from the Department of Labor's Office of Federal Contract Compliance Programs (OFCCP). The court concluded that section 301 did not authorize the OFCCP regulations, explaining that section 301 is a "housekeeping statute," authorizing only rules of agency organization, procedure, or practice as opposed to "substantive rules."[94] It found "nothing in the legislative history of § 301 to indicate it is a substantive grant of legislative power to promulgate rules authorizing the release of trade secrets or confidential business information."[95] The case offers no support for a more expansive reading of what constitutes non-substantive rules of agency organization, procedure, or practice for even an executive department—which, as explained above, EPA is not.

Congress took explicit action in 1958 to amend section 301 to "correct" agencies from abusing the Housekeeping Act by attempting to use its authority as a substantive basis to withhold information from the public.[96] The Supreme Court noted in *Chrysler Corp.* "that Congress had looked carefully at the statute in 1958; that the Special Subcommittee on Government Information had 'unanimously agreed that [§ 301] originally was adopted in 1789 to provide for the day-to-day office housekeeping in the Government departments,' and that attempts to construe it as something more was 'misuse' which 'twisted' the statute."[97] The courts have repeatedly checked subsequent agency attempts to "twist" the statute to a range of substantive purposes and found those efforts illegal, including halting government's extralegal efforts to limit disclosure and inclusion of information in the scientific process [98] The Supplemental Notice now attempts to similarly and

[94] *Chrysler Corp.*, 444 U.S. at 310.

[95] *Id*. (emphasis omitted); *see also United States ex rel. O'Keefe v. McDonnell Douglas Corp.*, 132 F.3d 1252, 1255 (8th Cir. 1998) (applying *Chrysler Corp.* and finding that the housekeeping statute did not provide authority for substantive regulations).

[96] H.R. No. 1461, 85th Cong., 2d Sess. (1958), *reprinted in* 1958 U.S.C.C.A.N. 3352, 3353.

[97] *U.S. ex rel. O'Keefe*, 132 F.3d at 1255 (quoting *Chrysler Corp.*, 441 U.S. at 310 n.41).

[98] *See City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1023 (N.D. Cal. 2019) (vacating regulations from the Department of Health and Human Services and explaining that defendants "mistakenly rely on their 'housekeeping authority' to support their authority to promulgate the rule" but "[n]one of the statutes cited by defendants provide HHS with the authority to promulgate substantive rules" including the Housekeeping Act); *United States ex rel. O'Keefe*, 132 F.3d at 1255 ("In recent years, several agencies have unsuccessfully attempted to find statutory authority for substantive regulations in the Housekeeping Statute."); *In re Bankers Trust Co.*, 61 F.3d 465, 470 (6th Cir. 1995) (holding regulation requiring subpoenaed party to refuse production of confidential information was not authorized by the Housekeeping Statute and "exceeded the congressional delegation of authority"), *cert. dismissed*, 517 U.S. 1205 (1996); *Exxon Shipping Co. v. United States Dep't of Interior*, 34 F.3d 774, 776-78 (9th Cir. 1994) (holding that the Housekeeping Act did not authorize regulations allowing agency to withhold deposition testimony of federal employees); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 826-27 (S.D. Ohio 1995) (holding that the Housekeeping Act did not authorize a 1953 Defense Department directive on the use of human volunteers in

illegally twist the statute to withhold science from consideration in rulemakings that broadly affect the public interest.

3. The Proposal Is a Substantive Rule and Hence Not Authorized by the Housekeeping Act.

The 2018 proposal and Supplemental Notice meet the court-determined criteria for a substantive regulation, refuting EPA's claim that it is proposing merely an "internal rule of agency procedure."[99] A "substantive rule" is not defined in the APA, but in distinguishing between "substantive rules" and "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice," courts have described "substantive rules" as those "affecting individual rights and obligations," a quality which helps identify which rules are "binding" or "have the force of law."[100] By contrast, courts have held that regulations issued pursuant to the authority under the Housekeeping Act "do not have the force and effect of law,"[101] and are "directory, not mandatory in nature."[102] Courts have not been shy in finding executive departments' regulations to be substantive rules exceeding authorities under the Housekeeping Act.[103]

In *CropLife Am. v. EPA*,[104] the D.C. Circuit Court of Appeals considered whether an EPA press release, which stated that the agency would not consider third-party-controlled human exposure studies for purposes of pesticide registration subject to case-by-case consideration of individual studies, was a substantive rule. The court held that the press release bound both EPA and registrants during pesticide registrations and so was a binding "substantive rule."[105] In reaching its decision, the court considered two established case law formulations for determining

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experimental research); *McElya v. Sterling Med. Inc.*, 129 F.R.D. 510, 514 (W.D. Tenn. 1990) (concluding that the Housekeeping Act did not give the Department of Navy authority to create general discovery privilege for persons under its jurisdiction).

[99] 85 Fed. Reg. at 15,398.

[100] *Chrysler Corp.*, 441 U.S. at 301-302 (quoting *Morton* v. *Ruiz*, 415 U.S. 199, 232, 235-236 (1974)).

[101] *See, e.g.*, *Einhorn v. DeWitt*, 618 F.2d 347, 350 (5th Cir. 1980) (reviewing regulations arising from the Internal Revenue Service's Statement of Procedural Rules promulgated under 5 U.S.C. §§ 301, 552 and finding that "[t]heir purpose is to govern the internal affairs of the Internal Revenue Service. They do not have the force and effect of law.").

[102] *Boulez v. Comm'r*, 810 F.2d 209, 215 (D.C. Cir. 1987).

[103] *See supra* note 98.

[104] 329 F.3d 876 (D.C. Cir. 2003).

[105] *Id.* at 883.

whether an agency action constitutes a substantive regulation: the effects of the agency's action;[106] and the agency's expressed intentions regarding the action.[107] Consistent with *Chrysler Corp.*, the two analyses overlap in recognizing that a substantive action "binds private parties or the agency itself with the 'force of law.'"[108] In *Croplife*, the court determined: "EPA's stated rule is binding on petitioners, who are now barred from relying on third-party human studies (even in cases where such studies formerly were approved), and is binding on the agency because EPA has made it clear that it simply 'will not consider' human studies."[109]

Like the action at issue in *Croplife*, both the original proposal and the Supplemental Notice would bind EPA to not consider or to discount a scientific study it could have previously given full consideration, all else being equal, if the study fails to meet the new requirement that underlying data and models be publicly available (or available through tiered access). The only possible exception would be if an otherwise disqualified study met the proposal's exemption criteria and the Administrator exercised his or her discretion to grant an exemption. Likewise, the proposed rule would bind the public, including organizations such as EDF, who can no longer receive the benefit of EPA's full consideration of valid but non-complying studies that they submit to the agency as part of an administrative record for an agency action, which EPA would previously have been required to consider as part of the rulemaking process. Furthermore, EPA's rule would require researchers interested in contributing to regulatory protections and influential scientific information to alter their conduct or risk having their efforts deemed unusable. Ultimately, the rule would diminish the public's statutorily protected interests in regulations informed by the best available science, an outcome that results from substantive choices about the scientific evidence it will consider.[110]

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[106] *See Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (quoting *Am. Bus Ass'n v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980)) (considering whether the agency action (1) "impose[s] any rights and obligations," or (2) "genuinely leaves the agency and its decisionmakers free to exercise discretion").

[107] *See Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999) (stating that the court considers "(1) the Agency's own characterization of the action; (2) whether the action was published in the Federal Register or the Code of Federal Regulations; and (3) whether the action has binding effects on private parties or on the agency").

[108] *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 382 (D.C. Cir. 2002); *see also Natural Resources Defense Council v. Wheeler*, 955 F.3d 68, 83 (D.C. Cir. 2020) ("A legislative rule is one that has legal effect or, alternately, one that an agency promulgates with the intent to exercise its delegated legislative power by speaking with the force of law. . . . Here, the 2018 Rule has independent legal effect beyond that compelled by *Mexichem* and reflects EPA's intent to exercise its delegated legislative power." (internal citation and quotation marks omitted)).

[109] *Croplife*, 329 F.3d at 881.

[110] EPA itself has recently argued as much. *See* Brief for Appellees at 19, *Union of Concerned Scientists v. Wheeler*, No. 19-1383 (1st Cir. filed Oct. 7, 2019) (describing EPA's policy of disqualifying any researcher who has accepted funding from EPA from serving on a scientific advisory committee, because of concerns about the appearance of conflicts of interest, as a "substantive choice[] concerning [EPA's] advisers").

When evaluating additional factors courts use to distinguish substantive rules, the proposal identifies itself even more definitively as a substantive rule than the EPA action reviewed in *Croplife*. First, both the 2018 proposal and the Supplemental Notice were published according to notice-and-comment procedures in the Federal Register, unlike the EPA action evaluated in *Croplife*. Courts have considered whether the agency used full public notice-and-comment procedures, which an agency need not use when producing an "interpretive" rule or rule of agency procedure, as an indicator of a substantive rule.[111] While courts consider an agency's own characterization of its action, they disregard claims that conflict with the record such as EPA's contention here that the 2018 proposal as supplemented "would not regulate the conduct or determine the rights of any entity outside the federal government."[112] "The agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a rule with the "force of law," but the record indicates otherwise."[113] And instead of a paragraph in a mere press release, EPA proposes to publish in the Code of Federal Regulations criteria for barring studies from both regulatory and non-regulatory use—a hallmark of a substantive regulation.[114] EPA's choice to put the rule through notice-and-comment rulemaking provides further evidence that EPA regards the rule as substantive. Lastly, EPA's consideration of individual exceptions to its proposed general principle is as unavailing here as it was in *CropLife*.

Argued in the inverse, the 2018 proposal and Supplemental Notice do not meet the requirements for a rule of agency organization, procedure, or practice, for purposes of the APA. Agency actions in this category are the opposite of substantive rules; they are those "that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints to the agency."[115] An agency action that "trenches on substantial private rights and interests" cannot be a rule of agency organization, procedure, or practice.[116] A federal court recently vacated substantive regulations issued by the Department of Health and Human Services under their "mistaken[]" claim of authority under the Housekeeping Act, finding that "[t]he challenged rule is not . . . a mere housekeeping rule. The expansive definitions in the rule depart from the federal statutes, as explained above, changing the rights and responsibilities of health care providers."[117]

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[111] *See, e.g.*, *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 172–73 (2007); *see also* 5 U.S.C. § 553(b)(3)(A); *Molycorp*, 197 F.3d at 545.

[112] 85 Fed. Reg. at 15,398.

[113] *Croplife*, 329 F.3d at 883 (citing *Gen. Elec. Co.*, 290 F.3d at 383-85); *see also, e.g.*, *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 95-96 (D.C. Cir. 2002).

[114] *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 19 (D.C. Cir. 2019); *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993).

[115] *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980).

[116] *Id.* at 708.

[117] *City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1023 (N.D. Cal. 2019).

By the same framework, the 2018 proposal and Supplemental Notice must be a substantive rule, exceeding the powers of the Housekeeping Act, because they affect private rights and interests. By restricting the scientific studies on which EPA may base final significant regulatory actions, EPA severely limits parties from relying on excluded studies in advocating for particular safeguards, or petitioning the agency to take a specific action, as the statute authorizes them to do. As noted in EDF's prior comments, because the rule would substantively impact agency conclusions and regulations, it impacts private rights and interests. The proposal does not allow private individuals to submit for consideration (or renders such submittal a nullity) studies that they would have been permitted to prior to the proposal, thus impacting the substantive standards that EPA is able to justify setting—which has implications for the regulated community as well as for public health.[118] EPA's proposed action "encodes a substantive value judgment [and] puts a stamp of approval or disapproval on a given type of behavior" by requiring regulatory actions to be supported only by certain scientific information deemed acceptable by the proposal.[119]

EPA has even acknowledged that the "the bulk of the responsibility for instituting new methods for access to data and models" will "fall[] on outside parties"—including both researchers and the Centers for Disease Control—according to a memorandum prepared by committee staff to capture recent briefings on the rule before the House Committee on Science, Space, and Technology.[120] For example, the memorandum records EPA's opinion that researchers, "would be responsible for managing the logistics of making the data and models publicly available in a manner that complies with the rule, in consultation with EPA staff," and the Centers for Disease Control would shoulder the burden of "hosting the data and models on its own servers, with CDC personnel working at the secure data enclave reviewing research proposals submitted by members of the public seeking to conduct their own analyses of study data and determining the level of

[118] *See, e.g.*, Comments of 88 Environmental, Farmworker, Environmental Justice, Public Health, and Animal Protection Organizations on Proposed Regulations on "Transparency" in Regulatory Science, Docket ID No. EPA-HQ-OA-2018-0259-6137, at 6-14 (Aug. 15, 2018) ("Earthjustice 2018 Comments") (discussing the substantial impacts on public health that could result from the rule as originally proposed). The public health impacts would be even greater under the expanded scope of the Supplemental Notice.

[119] *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987); *see also Pharm. Mfrs. Ass'n v. Finch*, 307 F. Supp. 858, 865 (D. Del. 1970) (finding that a regulation promulgating new criteria for clinical investigations that will meet the standards of evidence necessary to demonstrate the effectiveness of drug products, and excluding certain kinds of clinical investigations, was not merely a procedural rule, because it "did effect a material narrowing of the range of evidence which previously had been considered relevant in evaluating a drug's efficacy," "[b]ecause of the important clarification of acceptable testing standards effected by the . . . regulations," and "because of the substantial impact of the[] regulations on the drug industry. . . . ").

[120] Memorandum from Democratic Staff, H.R. Committee on Science, Space, and Technology, to Chairwoman Johnson, Re: Summary of Staff-Level Briefings from the Environmental Protection Agency on the "Strengthening Transparency in Regulatory Science" Supplemental Proposed Rule, at 2 (Apr. 30, 2020) ("Memo to Chairwoman Johnson").

access to grant on a case-by-case basis."[121] These substantial impacts on parties outside of EPA further confirm that the proposal is not an internal or procedural rule, but a substantive rule which cannot be issued under the Housekeeping Act.

The 2018 proposal and Supplemental Notice clearly meet the criteria for a substantive rule and cannot be disguised as a procedural rule through EPA's feeble whitewashing. The Supplemental Notice expands the scope of affected regulations, thereby increasing the extent to which private rights are affected and the impacts on public health and the environment. The 2018 proposal and Supplemental Notice would have direct and appreciable legal consequences that have immediate and pervasive impacts on the information that private individuals can submit for consideration in rulemakings, and on EPA's ability to justify setting substantive standards that comply with statutory requirements specifying how to use science to protect public health and the environment.[122] In *Croplife*, the court found that a rule preventing petitioners' submission of third-party human studies to rulemakings did concretely injure the petitioners by precluding the agencies' consideration of studies that petitioners had previously been able to submit. EPA's action to prohibit consideration of any third-party studies presented a "purely legal question that does not depend upon consideration . . . particularized facts"[123] or the subsequent implementation of the rule.

B. THE HOUSEKEEPING ACT CANNOT AUTHORIZE VIOLATIONS OF OTHER STATUTES.

The Housekeeping Act provides no basis to violate other statutes, including landmark environmental laws and the Information Quality Act. As discussed above, the Housekeeping Act authorizes only procedural rules regarding "the custody, use, and preservation of [agency] records, papers, and property,"[124] as opposed to "substantive rules." Regulations issued under the Housekeeping Act "do not have the force and effect of law,"[125] and have been "held to be directory,

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[121] *Id.*

[122] *See Natural Resources Defense Council*, 955 F.3d at 90 (stating that a rule is final when it has "an immediate and practical" impact on rights and obligations).

[123] *Croplife*, 329 F.3d at 885 (quoting *Mountain States Tel. & Tel. Co. v. FCC*, 939 F.2d 1035, 1041 (D.C. Cir. 1991)) (internal quotation marks omitted).

[124] 5 U.S.C. § 301.

[125] *See Einhorn*, 618 F.2d at 350 (reviewing regulations arising from the Internal Revenue Service's Statement of Procedural Rules promulgated under 5 U.S.C. §§ 301, 552 and finding that "[t]heir purpose is to govern the internal affairs of the Internal Revenue Service. They do not have the force and effect of law." (citations omitted)); *see also* James F. Ponsoldt, *Balancing Government Efficiency and the Protection of Individual Liberties: An Analysis of the Conflict Between Executive Branch "Housekeeping" Regulations and Criminal Defendants' Rights to a Constitutionally Fair Trial*, 19 Harv. C.R.-C.L. L. Rev. 349, 370 (1984) ("The Housekeeping Statute only authorizes

not mandatory in nature."[126] While an agency is bound to adhere to all the laws it is required to administer, it is particularly egregious that EPA claims that a procedural housekeeping rule, which lacks legal force, would somehow supersede other binding statutory authorities and allow EPA to rewrite bedrock environmental statutes. The 2018 proposal and Supplemental Notice would require EPA to weigh the extra-statutory factor of data availability and disregard other high-quality data which EPA is required to review under the scientific standards of multiple environmental statutes.[127] The courts have barred previous unlawful efforts to amend binding statutory and regulatory requirements via the Housekeeping Act. Treasury Department rules derived under the Housekeeping Act were found explicitly unable to "override" other binding Treasury Department regulations promulgated pursuant to specific statutory delegation.[128] Similar logic was at work in *Chrysler Corp*. Concluding that section 301 did not authorize regulations limiting the scope of the Trade Secrets Act, the Supreme Court found the "greatest significance" to be "the 'housekeeping' nature of § 301 itself."[129]

As discussed above, EPA has styled the 2018 proposal and Supplemental Notice as a substantive rule that would bind the agency from considering scientific studies without publicly available datasets during rulemakings. However, even if the proposal was found to be validly issued under the Housekeeping Act, it could not in any way authorize violating environmental statutes or binding regulations implementing these statutes. Like the Trade Secrets Act, the major environmental statutes are binding authorities that cannot be limited by the regulations issued under the Housekeeping Act. Nor can the Housekeeping Act authorize rules that would supersede implementing regulations for environmental statutes which have been issued by specific statutory delegation in the same manner as the Treasury Department regulations discussed above.

C. NONE OF THE ENVIRONMENTAL STATUTES ORIGINALLY CITED AUTHORIZE EPA'S PROPOSED RULE OR ITS EXPANSION THROUGH THE SUPPLEMENTAL NOTICE.

As EDF explained in its comments on the 2018 proposal, none of the environmental statutes EPA identifies in the original proposal authorize EPA to issue the proposed rule or otherwise promulgate a one-size-fits-all regulation governing how the agency will consider science

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regulations consistent with law. In fact, regulations promulgated pursuant to the statute which relate to the internal operations of an agency have been held not to have the force of law even with respect to the rights of third parties.").

[126] *Boulez*, 810 F.2d at 215.

[127] For a more detailed explanation of how the 2018 proposal would violate EPA's statutory requirements under a range of environmental laws, *see* EDF 2018 Comments at 13-34 *and* Earthjustice 2018 Comments at 33-53.

[128] *Flynn v. Comm'r*, 269 F.3d 1064, 1072 (D.C. Cir. 2001).

[129] *Chrysler Corp.*, 441 U.S. at 311-12.

under its various statutory authorities.[130] EPA gives no explanation of how *any* of the provisions it cites provide authority for the 2018 proposal and Supplemental Notice, much less how all of them authorize identical requirements despite their varied obligations for considering science. Not only is there still no authority for EPA's pan-statutory proposal, but the 2018 proposal as supplemented would force EPA to more broadly violate a diversity of obligations to consider science under the different environmental laws.[131] While the specifics of the requirements vary, Congress has often commanded EPA to utilize the "best available science" for its policies, which necessitates consideration of the full range of available science. The proposal would restrict consideration of science and cause EPA to violate both its general statutory obligations to consider all available data when undertaking rulemakings as well as the specific requirements to consider science under the respective environmental statutes.[132]

The Supplemental Notice multiplies this defect, broadly expanding the regulation to cover "data and models underlying pivotal regulatory science and pivotal science used to support significant regulatory decisions and influential scientific information, respectively, not simply dose-response data and dose-response models"—effectively hamstringing the agency from considering the best available science across its full portfolio of actions to protect the environment and public health, and impeding its ability to gain a better understanding of the threats to public health and the environment.[133] Nothing in the Supplemental Notice remedies this expansive defect or even attempts to reduce it. The Supplemental Notice adds a reference to the Clean Water Act (CWA), and amends its references to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Resource Conservation and Recovery Act (RCRA),[134] but these additions provide no additional support or authorization for the proposal.

The references to CWA and CERCLA cite to the general authorities of the EPA Administrator to issue regulations to fulfill the respective requirements of the statutes. These authorities cannot authorize the proposal's efforts to violate those statutes or act beyond the scope of their requirements.[135] Similarly, the cited provision of RCRA contains the Administrator's general authorities to promote research and training, offering no basis for the proposal's

[130] EDF 2018 Comments at 13-14; *see also* Earthjustice 2018 Comments at 18-31.

[131] *See supra* note 127.

[132] *Id*.

[133] 85 Fed. Reg. at 15,401.

[134] 85 Fed. Reg. at 15,397.

[135] *See Chrysler Corp.*, 441 U.S. at 302 ("The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes."). For discussion of how the 2018 proposal exceeds the authorities of these statutes and violates the requirements of these statutes, *see* Earthjustice 2018 Comments at 26-27, 48 (CERCLA), *and id.* at 24-25, 45-47 (CWA).

requirements or reconciliation of where it may conflict with RCRA's obligations—even requirements in the very same subsection it presumes to cite for authority.[136]

D. OMB'S 2019 MEMO PROVIDES NO ADDITIONAL AUTHORITY FOR THE PROPOSAL TO VIOLATE STATUTORY OBLIGATIONS, NOR REMEDIES THE PROPOSAL'S VIOLATION OF THE INFORMATION QUALITY ACT.

As noted above, EPA claims the Supplemental Notice has been issued, at least in part, "to ensure consistency with" a memorandum issued in April 2019 by the White House's Office of Management and Budget (OMB) intended to update implementation of the Information Quality Act ("2019 OMB Memo").[137] This non-binding policy statement provides no legal authority for the proposal's numerous substantive violations of environmental statutes. Further, the Supplemental Notice and its citation to the non-binding 2019 OMB Memo fail to remedy the proposal's violation of the Information Quality Act and OMB's binding 2002 guidance on the Information Quality Act ("2002 Guidelines")[138] appropriately established through notice-and-comment rulemaking.[139]

As discussed in EDF's comments on the 2018 proposal, by prohibiting EPA from relying on a study to support a significant rulemaking if that study's underlying data and models are not publicly available, EPA's proposed rule departs from OMB's unambiguous language in its 2002 Guidelines. Specifically, EDF explained that though the 2002 Guidelines seek to ensure objectivity and transparency by encouraging agencies to make data and methods publicly available to facilitate reproducibility, they explicitly state that "agency guidelines *shall not* require that all disseminated data be subjected to a reproducibility requirement."[140] Rather, the 2002 Guidelines instruct that data shall only be subjected to a reproducibility requirement if practicable "given ethical, feasibility, or confidentiality constraints."[141] The 2002 Guidelines emphatically declare that "the objectivity standard does not override other compelling interests such as privacy . . . and other

[136] *See* Earthjustice 2018 Comments at 53.

[137] 85 Fed. Reg. at 15,398 (citing OMB, Memorandum for the Heads of Executive Departments and Agencies, Re: 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).

[138] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8451 (Feb. 22, 2002).

[139] *Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010) ("[B]ecause Congress delegated to OMB authority to develop binding guidelines implementing the IQA, we defer to OMB's reasonable construction of the statute."). EPA's publication of the 2002 Guidelines through notice-and-comment rulemaking, as required by the APA for substantive and binding rules, helps distinguish it from the 2019 OMB Memo.

[140] 67 Fed. Reg. at 8460 (emphasis added).

[141] *Id.*

confidentiality protections."[142] Nothing in EPA's Supplemental Notice remedies the 2018 proposal's violation of the Information Quality Act and OMB's binding 2002 Guidelines.

The Supplemental Notice cannot overcome these violations through reference to the 2019 OMB Memo. The 2019 OMB Memo did not replace OMB's original 2002 Guidelines and did not change the requirement that agencies require disclosure of a study's underlying data only where practicable in light of "ethical, feasibility, or confidentiality constraints."[143] Nor could it. Even though the 2019 OMB Memo is intended to update the 2002 Guidelines, the memo is merely a non-binding policy statement sent to the heads of executive departments,[144] whereas OMB issued the 2002 Guidelines as a binding rule through the required notice-and-comment rulemaking process.[145]

Even absent the clear legal precedence of the 2002 Guidelines, the 2019 OMB Memo lacks the mandate that EPA seeks to support its 2018 proposal. The 2019 OMB Memo is clear that the updated expectations regarding public accessibility and reproducibility do not compel public disclosure of underlying data. First, though the 2019 OMB Memo recommends that agencies "prioritize increased access to the data and analytic frameworks (e.g., models) used to generate influential information,"[146] nowhere does it authorize agencies to require public disclosure of a study's underlying data and models as a prerequisite to the agency's consideration of the study when promulgating rules or developing influential information. Rather, the memo states only that "[a]gencies *should explore* methods that provide wider access to datasets while reducing the risk of disclosure of personally identifiable information."[147]

Second, in discussing reproducibility requirements for non-government information used by an agency, the 2019 OMB Memo states in implementation update 3.3 that:

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[142] *Id.*; *see also* EDF 2018 Comments at 34-35 (explaining how the 2018 proposal violates the 2002 OMB Regulations).

[143] 67 Fed. Reg. at 8460.

[144] *Panhandle Producers & Royalty Owners Ass'n v. Econ. Regulatory Admin.*, 822 F.2d 1105, 1110, (D.C. Cir. 1987) ("[W]hen an agency announces a policy shift in a nonbinding policy statement, the new policy is not 'binding precedent,' but 'is subject to complete attack before it is finally applied in future cases.'" (quoting *Pac. Gas & Elec. Co. v. FPC*, 506 F.2d 33, 39 (D.C. Cir. 1974)).

[145] *See* Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 66 Fed. Reg. 34,489 (June 28, 2001); 67 Fed. Reg. 8451; *see also* 5 U.S.C. § 553(b)-(d).

[146] 2019 OMB Memo at 8.

[147] *Id.* at 9 (emphasis added).

> Agencies should ensure that when using non-government sources to create influential information they communicate to the public sufficient information on the characteristics of the data and analysis, including its scope (e.g., temporal or demographic), generation protocols, and any other information necessary to allow the public *to reproduce the agencies' conclusions*.[148]

However, the 2019 OMB Memo is clear that to reproduce an agency's conclusions, the public need not access an entire underlying dataset or recreate the entire original study. Rather, "[t]he standard requires that influential analyses must be disseminated *with sufficient descriptions* of data and methods to allow them to be reproduced by qualified third parties who may want to test the sensitivity of agency analyses."[149] In other words, the 2019 OMB Memo states no requirement to publicly share the actual data underlying studies. Moreover, the language of the memo in no way authorizes EPA to prohibit consideration of, or discount, studies with underlying data that cannot be shared publicly. The proposed rule's automatic exclusion or discounting of studies for which underlying data and models are unavailable cannot be justified by this memo's language.

EPA's proposed regulations also directly conflict with the 2019 OMB Memo's clear instruction that "OMB policy requires agencies to ensure that privacy and confidentiality are fully protected."[150] Specifically, the memo confirms that "*[a]ll data disclosures must be consistent with statutory, regulatory, and policy requirements for protections of privacy and confidentiality, proprietary data, and confidential business information*."[151] Thus, even if the 2019 OMB Memo could override the OMB's 2002 Guidelines—which it cannot—there is no indication that OMB desired to alter the 2002 Guidelines' express declaration that data shall only be subjected to a reproducibility requirement if practicable "given ethical, feasibility, or confidentiality constraints" and that an agency "*shall not* require that all disseminated data be subjected to a reproducibility requirement."[152] In sum, the 2018 proposal and Supplemental Notice conflict with the plain meaning and intent of both the 2019 OMB Memo and the 2002 Guidelines. Thus, contrary to EPA's declared intention, the revised draft regulations presented in the Supplemental Notice continue to violate the Information Quality Act.[153]

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[148] *Id.* at 8.

[149] *Id*. at 7 (emphasis added).

[150] *Id.* at 5.

[151] *Id.* at 8 (emphasis added).

[152] 67 Fed. Reg. at 8,460 (emphasis added).

[153] Finally, although the IQA itself does not create a cause of action, *see Mississippi Comm'n on Envtl. Quality v. EPA*, 790 F. 3d 138, 184-85 (D.C. Cir. 2015), the IQA and OMB's implementing rules do create "meaningful standards" which are "judicially manageable" such that violation of these provisions can be held arbitrary and capricious under the Administrative Procedure Act. *See Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *16; *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 17-20 (1st Cir. 2020) (although FACA itself does not create

III. THE SUPPLEMENTAL NOTICE CONTINUES TO VIOLATE NUMEROUS SUBSTANTIVE STATUTORY REQUIREMENTS

A. THE REVISED PROPOSED REGULATIONS CONTRAVENE REQUIREMENTS IN GOVERNING ENVIRONMENTAL AND PUBLIC HEALTH STATUTES REGARDING EPA'S OBLIGATION TO CONSIDER AVAILABLE SCIENTIFIC INFORMATION.

EPA's statutory authorities generally require the agency to consider all available science when undertaking significant rulemakings.[154] As the D.C. Circuit recently explained in *Physicians for Social Responsibility v. Wheeler*:

> Several environmental statutes require EPA to ground its decision-making in scientific evidence. The Clean Air Act, for example, mandates that "[a]ir quality criteria . . . accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare," 42 U.S.C. § 7408(a)(2), and the Toxic Substances Control Act requires the Administrator to "make decisions . . . based on the weight of the scientific evidence," 15 U.S.C. § 2625(i).[155]

The originally proposed regulatory language (§§ 30.3, 30.5) violated these statutory commands by preventing EPA from relying on a study as "pivotal regulatory science . . . used to justify significant regulatory decisions" if dose-response data or models underlying the study were not publicly available, without regard to whether the study had been validated by other means.[156] The Supplemental Notice exacerbates these violations by expanding the proposed regulation's scope (§§ 30.3, 30.5) to not just pivotal *regulatory* science used to justify significant *regulatory* decisions, but also "pivotal science supporting influential scientific information."[157]

Like the original proposal, the Supplemental Notice lacks any demonstration that the public unavailability of a study's underlying data or models necessarily—or even likely—renders the study invalid or unreliable. To the contrary, EDF and others argued extensively in comments on the original proposal that mechanisms are already in place to validate studies for which disclosure

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a cause of action, it supplies meaningful law to apply such that violation of its terms can be found arbitrary under the APA).

[154] EDF 2018 Comments at 14-32.

[155] *Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *3-4; *see also id.* at *26 ("EPA operates pursuant to multiple statutory mandates requiring that its decisions rest on various formulations of 'the best available science.' 15 U.S.C. § 2625(h).").

[156] 83 Fed. Reg. at 18,773 (emphases omitted).

[157] 85 Fed. Reg. at 15,405.

of underlying data and models is either illegal or impracticable.[158] Thus, EPA's automatic exclusion from consideration of (or, at least, diminished reliance upon) studies based solely on the public unavailability of underlying data or models would result in the agency failing to consider all available science—and even the best available science in some cases—in direct contravention of statutory requirements.

Just as EPA is required to consider all available science when making its regulatory decisions, governing environmental and public health statutes likewise require EPA to consider all available science when releasing "influential scientific information" (ISI), which often forms the basis for the agency's regulatory decisions. For example:

- Clean Air Act (CAA) section 108 instructs EPA to establish air quality criteria that "accurately reflect the latest scientific knowledge,"[159] which criteria, in turn, must inform national ambient air quality standards (NAAQS).[160] EPA's website identifies as "influential scientific information"[161] numerous products pertaining to the establishment of air quality criteria and revision of the NAAQS, such as the Office of Air and Radiation's "Ozone NAAQS Review: Risk/Exposure Assessment,"[162] and the Office of Research and Development's integrated science assessments for carbon monoxide,[163] lead,[164] oxides of nitrogen,[165] and sulfur oxides.[166]

- The Toxic Substances Control Act (TSCA) directs that, in implementing the Act's testing requirements, manufacturing and processing notice requirements, and requirements for the prioritization, risk evaluation, and regulation of chemical substances and mixtures, EPA must make its decisions "based on the weight of the scientific evidence."[167] Likewise, in carrying out EPA's responsibilities under TSCA, "the Administrator shall use scientific information . . . employed in a

[158] EDF 2018 Comments at 64-66, 70-74.

[159] 42 U.S.C. § 7408(a)(2).

[160] *Id.* § 7409(b).

[161] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

[162] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=OAQPS&dirEntryID=240406.

[163] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=213229.

[164] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=242655.

[165] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=189147.

[166] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=190346.

[167] 15 U.S.C. § 2625(i).

manner consistent with the best available science."[168] Numerous other TSCA provisions emphasize EPA's obligation to consider all reasonably available scientific information when implementing TSCA's requirements.[169] EPA's Science Inventory website identifies many products pertaining to its evaluation of the impact of toxic substances on human health and the environment, including products such as the Office of Chemical Safety and Pollution Prevention's "Exposure and Hazard Information for Five PBT Chemicals."[170]

- The Clean Water Act (CWA) instructs that EPA's water quality criteria must "accurately reflect[] the latest scientific knowledge" on a variety of factors.[171] Examples of CWA-related ISI identified on EPA's website include the Office of Research and Development's "Coral Reef Biological Criteria: Using the Clean Water Act to Protect a National Treasure," and "The Effects of Mountaintop Mines and Valley Fills on Aquatic Ecosystems of the Central Appalachian Coalfields."[172]

- The Safe Drinking Water Act (SDWA) generally requires EPA to use "the best available, peer-reviewed science,"[173] and to use the "best available public health information" when deciding whether to regulate a particular contaminant.[174] These standards certainly extend to EPA's SDWA-related ISI, such as the Office of Research and Development's "Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources" posted on EPA's Science Inventory website.[175]

- The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) states, among other things, that EPA and the Agency for Toxic Substances and Disease Registry (ATSDR) must annually update a list of hazardous substances commonly found at facilities on the National Priorities List that the agencies determine "pos[e] the most significant potential threat to human health due to their known or suspected toxicity to humans and the potential for human

[168] *Id.* § 2625(h).

[169] *See* EDF 2018 Comments at 25-31.

[170] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=OPPT&dirEntryID=342954.

[171] 33 U.S.C. § 1314(a)(1).

[172] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=215267.

[173] 42 U.S.C. § 300g-1(b)(3)(A)(i).

[174] *Id.* § 300g-1(b)(1)(B)(ii)(II).

[175] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=244651.

> exposure to such substances . . .”[176] For each listed substance, ATSDR must develop a toxicological profile based on guidelines prepared by the EPA and ATSDR.[177] The profile must include examination of “available toxicological information and epidemiologic evaluations . . . to ascertain the levels of significant human exposure for the substance and the associated acute, subacute, and chronic health effects.”[178] Many products relating to CERCLA implementation, especially regarding the establishment of appropriate cleanup standards, are classified as ISI, such as the Office of Solid Waste and Emergency Response’s “Alternative Approach to Estimating Cancer Potency for Asbestos.”[179]

A rule that prohibits EPA from considering (or that downgrades) valid, high quality scientific studies when generating ISI such as the products identified above would contravene the above-noted statutory directives regarding EPA’s obligation to consider all available science.

While the ISI examples provided above involve scientific studies (or surveys of available information) designed to enable effective implementation of specific statutes, there are also many circumstances under which EPA develops ISI with broad applicability to multiple programs or varying governmental actions that have yet to be identified. Such products include Integrated Risk Information System (IRIS) chemical reviews by EPA’s Office of Research and Development (ORD) (*e.g.*, the 2019 “IRIS Toxicological Review of Ethyl Tertiary Butyl Ether (ETBE)”[180] and “IRIS Toxicological Review of Tert-Butyl Alcohol (TBA)”[181]), and reports by EPA’s Office of Chemical Safety and Pollution Prevention (*e.g.,* “Continuing Development of Alternative High-Throughput Screens to Determine Endocrine Disruption, Focusing on Androgen Receptor, Steroidogenesis, and Thyroid Pathways”[182]). EPA’s application of the proposed public disclosure regulations to such products is especially pernicious because it would likely be impossible—or at least, immensely burdensome—to determine at the time that the ISI is utilized in agency decision-making whether, in developing the ISI, EPA omitted from consideration (or gave lesser weight to) valid scientific studies that EPA is obligated to consider fully under the relevant statutory or regulatory provisions.

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[176] 42 U.S.C. § 9604(i)(2)(A), (B).

[177] *Id.* § 9604(i)(3).

[178] *Id.* § 9604(i)(3)(A).

[179] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=OPM&dirEntryID=134104.

[180] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=326410.

[181] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=322481.

[182] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=OSCP&dirEntryID=338571https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryID=226723.

For example, the purpose of ORD's IRIS chemical reviews is to support EPA's mission of protecting public health and the environment by identifying and characterizing the health hazards of chemicals found in the environment.[183] According to EPA's website, these reports "[a]re the preferred source of toxicity information used by EPA," and "[a]re an important source of toxicity information used by state and local health agencies, other federal agencies, and international health organizations."[184] The availability of these reports enables government regulators to act effectively and efficiently in promulgating rules and taking other actions needed to protect public health and the environment from toxic chemicals.[185] In particular, EPA's program and regional offices identify human exposure pathways and estimate the amount of human exposure under different exposure scenarios. They are then able to combine their exposure assessment with the hazard information and toxicity values from IRIS chemical reviews to characterize potential public health risks.[186] Among other things, EPA uses this information to help set national standards under TSCA,[187] the CAA,[188] the SDWA,[189] and the Emergency Planning and Community Right-to-Know Act,[190] and to clean up hazardous sites under CERCLA.[191] But none of these statutes allow EPA to ignore valid, pivotal scientific studies based solely on the fact that underlying data or models are not publicly available. If ORD is forced to exclude consideration of such studies when developing its IRIS chemical reviews, EPA's reliance on these reviews when taking actions under these statutes would be unlawful and arbitrary unless EPA combs through the report and available science to confirm that all valid studies have been considered.[192] The need to undertake such a comprehensive review of ISI before relying upon it would fundamentally undermine the purpose of preparing ISI for general use by EPA's various programs, offices, and regions. Thus, beyond the numerous statutory violations described above, EPA's failure to consider how its proposed rule could interfere with its ability to discharge its statutory duties and fulfill its mission of protecting

[183] EPA, Basic Information about the Integrated Risk Information System, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system.

[184] *Id.*

[185] *Id.*

[186] *Id.*

[187] *See, e.g.*, 82 Fed. Reg. 7432, 7446 (Jan. 19, 2017).

[188] *See, e.g.*, 79 Fed. Reg. 60,238, 60,246 (Oct. 6, 2014).

[189] *See, e.g.*, 79 Fed. Reg. 62,716, 62,735-36 (Oct. 20, 2014).

[190] *See, e.g.*, 59 Fed. Reg. 61,432, 61,444-45 (Nov. 30, 1994).

[191] *See, e.g.*, 53 Fed. Reg. 51,962 (Dec. 23, 1988) (§ 2.2.1.1).

[192] This outcome is especially likely if EPA succeeds in promulgating the proposed rule solely under the Housekeeping Statute and deferring any analysis of whether the rule violates the requirements of federal environmental and public health statutes until EPA takes an action specifically under one of these statutes. Unfortunately, by the time EPA is taking action that relies upon ISI like an IRIS report, it would be extremely difficult to remedy the violation, since the entire report would need to be reviewed and likely redone.

public health and the environment renders its proposed action arbitrary and capricious under the APA.[193]

B. THE SUPPLEMENTAL NOTICE WOULD VIOLATE THE APA AND EPA'S AUTHORIZING STATUTES BY DEPRIVING THE PUBLIC OF AN ADEQUATE OPPORTUNITY TO COMMENT ON FUTURE RULEMAKINGS.

The Supplemental Notice would prevent the public from commenting meaningfully on future rulemakings by withholding information on the studies the agency is considering or will consider. In order to comment in an informed way, it is essential for the public to understand the agency's rationale for ignoring otherwise relevant information. If the agency fails to explain why it has excluded a study in issuing a proposal, or will not consider it when submitted by commenters, the public cannot object to its exclusion and has no indication whether the agency has rejected it because of the requirements of this rule or because the agency deemed the study irrelevant to its regulation. The latter, if true, would be crucial to an understanding of the agency's view of the scope and purpose of its regulation. Yet the Supplemental Notice suggests that EPA will only provide an explanation for disregarding or discounting a study under its alternative "weighting" option.[194] It has not indicated that it will identify the studies it has entirely ruled out under the preferred "tiered access" approach.[195] Without an understanding of how this rule is operating to suppress scientific information in future rulemakings, commenters cannot understand the basis of the agency's proposals and may develop and submit information that the agency will discard out of hand. They would also be unable to oppose EPA's disregard of otherwise relevant information, which it may be required to consider under the controlling statute. This 'black box' precludes fully informed comment on future rulemakings and therefore violates the APA and EPA's authorizing statutes.[196]

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[193] *See Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *27 ("[I]n failing to grapple with how EPA's policy affected its statutory scientific mandates, the Directive 'failed to consider an important aspect of the problem.' *State Farm*, 463 U.S. at 42.").

[194] 85 Fed. Reg. at 15,402.

[195] *See id.* at 15,402-03.

[196] *See, e.g., Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 239-40 (D.C. Cir. 2008) ("It is [acceptable] for the Commission to give notice and make available for comment the studies on which it relied in formulating the rule while explaining its non-reliance on certain parts." (emphasis added)); *cf. Appalachian Power Co. v. EPA*, 249 F.3d 1032, 1060 (D.C. Cir. 2001) (upholding EPA's fully explained determination that a report did not need to be included in the docket because it was not of central relevance to the rulemaking).

C. EPA CANNOT ISSUE A RULE THAT VIOLATES OTHER STATUTES BY NOTING THAT THE OTHER STATUTES ARE CONTROLLING ONLY WHEN THEY APPLY.

Facing the plethora of statutory violations documented above, EPA must withdraw the Supplemental Notice as inconsistent with its substantive obligations to use the best available science. Apparently anticipating these conflicts, EPA concedes that:

> This internal agency procedure is intended to be consistent with the statutes that EPA administers and EPA plans to implement this procedural rulemaking in accordance with all applicable statutory and regulatory requirements. . . . Nonetheless, in the event the procedures outlined in the proposed rulemaking conflict with the statutes that EPA administers, or their implementing regulations, the statutes and regulations will control.[197]

This rationale is vague and meaningless. As an initial matter, EPA has not explained how its rule is "intended to be consistent with" the statutes it administers, nor has it attempted to identify the areas of conflict it anticipates, which renders its promise to yield to their requirements arbitrary.[198] Even if it had offered some indication of the conflicts it foresees, its protean response is ineffectual: to the extent that the agency seeks to inoculate its rule against legal challenges based on these statutory violations, any invalid application—of the many that would proliferate upon implementation—would doom the rule.[199] EPA cannot insulate its unlawful policy from challenges by promising to yield in the future to statutory and regulatory requirements.[200]

Nor does EPA enhance its rule with the mere suggestion that its options for considering studies in some circumstances "improve consistency" with statutes requiring use of the best available science.[201] Aside from the inherent flaws in these approaches, discussed in greater detail

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[197] 85 Fed. Reg. at 15,398; *see also id.* at 15,405 (proposed 40 C.F.R. § 30.3).

[198] *See Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *27 ("[I]n failing to grapple with how EPA's policy affected its statutory scientific mandates, the Directive 'failed to consider an important aspect of the problem.' State Farm, 463 U.S. at 42."). EPA's expectation that its proposed rule would contravene the statutes it administers also calls into question any reliance on them as authority for this action.

[199] *See Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998); *District of Columbia v. U.S. Dep't of Agric.*, No. 20-119 (BAH), 2020 U.S. Dist. LEXIS 43853, at *100-04 (D.D.C. Mar. 13, 2020).

[200] *See Ameren Servs. Co. v. FERC*, 880 F.3d 571, 584 (D.C. Cir. 2018) ("We once described an agency's effort to offer future rulemaking as a response to a claim of agency illegality as an 'administrative law shell game,' *Am. Tel. & Tel. Co. v. FCC*, 978 F.2d 727, 732, 298 U.S. App. D.C. 230 (D.C. Cir. 1992), a phrase the Supreme Court thought apt. *See MCI Telecomm. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 222, 114 S. Ct. 2223, 129 L. Ed. 2d 182 (1994).").

[201] 85 Fed. Reg. at 15,398.

below, occasional compliance with statutory requirements cannot render its rule lawful.[202] To correct the numerous statutory violations documented above,[203] EPA must conform its actions to the directives Congress imposed; partial alignment will not suffice.

IV. THE SUPPLEMENTAL NOTICE'S EXPANDED SCOPE COMPOUNDS ITS ARBITRARINESS AND UNLAWFULNESS

A. EPA DRAMATICALLY EXTENDS THE REACH OF ITS PROPOSAL WITHOUT ADEQUATE EXPLANATION.

1. EPA Fails to Provide a Sufficient Description and Explanation of Its Proposal to Exclude Studies for Which Any of the Underlying Data and Models Are Not Publicly Available.

The original proposal applied to "dose response data and models that underlie . . . pivotal regulatory science."[204] The Supplemental Notice expands its application to all "data and models" underlying "pivotal regulatory science and pivotal science,"[205] but leaves considerable and unacceptable uncertainty as to the breadth of this expansion. EPA offers only a sampling of the types of scientific information that it might disregard:

> Some, but not the only, examples of information that would be considered to be data and models, in addition to dose-response data and dose-response models, include environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on environmental releases,

[202] *See U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 643 (D.C. Cir. 2016).

[203] *See* Section III.A, *supra*.

[204] 83 Fed. Reg. at 18,770. "Pivotal regulatory science" is described in the preamble of the original proposal as "the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based." *Id.* The proposed regulatory definition of "pivotal regulatory science" in the original proposal is "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions." *Id.* at 18,773.

[205] 85 Fed. Reg. 15,396. The proposed regulatory definition of "pivotal science" in the Supplemental Notice is "the specific scientific studies or analyses that underly [sic] influential scientific information" and the proposed regulatory definition for "influential scientific information" in the Supplemental Notice is "scientific information that will have or does have a clear and substantial impact on important public policies or private sector decisions." *Id.* at 15,405.

exposure estimates, quantitative structure activity relationship data, and environmental studies.[206]

EPA admits that this list is incomplete—and it is plainly incoherent, ranging from data to models to studies to estimates. Further, upon review of the Supplemental Notice, the SAB has concluded that the definitions of "data and models" "are not adequate."[207] By failing comprehensively to describe the scope of its proposal, EPA has denied the public the information it needs to comment in an informed way.[208]

Nonetheless, EDF has investigated potential areas of application—an exercise that explores the serious consequences the rule could have, but which cannot fulfill the agency's obligation to provide adequate notice of the scope of its rule. Examples we've identified include:

Integrated Science Assessment for Particulate Matter

In April 2020, EPA proposed to retain the existing National Ambient Air Quality Standards (NAAQS) for particulate matter (PM), one of the six criteria air pollutants.[209] EPA's proposal is based in part on the agency's Integrated Science Assessment (ISA) for PM[210] that surveyed and synthesized the body of scientific evidence on the health and welfare effects of PM, including data and studies published since the previous review of the NAAQS in 2012.[211] The ISA is identified by EPA as highly influential scientific information, and as such would have been subject to the proposed rule's requirements if they had been in place.[212]

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[206] *Id.* at 15,400; *see also id.* at 15,401 ("This list is not exhaustive but is intended to provide examples of the range of information that would be considered to be within the scope of data and models.").

[207] Final SAB Report at 3; *see also id.* at 11 (stating that EPA "should define and clarify when the requirements are applicable to animal toxicity studies or environmental epidemiology studies"). The SAB suggests that EPA could elaborate on these definitions in a guidance document. *Id.* For the reasons discussed above, however, subsequently issued guidance would not provide the requisite notice and allow for informed public comment on the scope of EPA's proposed rule.

[208] *See Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983) ("Agency notice must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking."); *see also id*. ("This is doubly true under Clean Air Act § 307(d)(3), which requires EPA to issue a specific 'proposed rule' as a focus for comments.").

[209] Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094 (Apr. 30, 2020).

[210] Integrated Science Assessment for Particulate Matter, 85 Fed. Reg. 4655 (Jan. 27, 2020).

[211] National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3086 (Jan. 15, 2013).

[212] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

PM is associated with several adverse health effects, including eye and respiratory irritation, breathing issues, asthma, and lung cancer, and poses particular risks to certain susceptible subpopulations such as those with heart and lung diseases, children, and the elderly.[213] Despite the evidence that PM negatively affects human health and welfare, including new studies published since the previous review of the NAAQS, EPA's decision to retain the existing NAAQS for PM fails to adequately protect public health.[214] These comments do not address the merits of EPA's proposal to retain the existing NAAQS for PM nor the PM ISA, and instead focus solely on illustrating the significant effects the proposal would have on a recent EPA product.

The PM ISA reviews thousands of studies relevant to the pollutant, ranging from its sources and atmospheric chemistry to its associations with various adverse health outcomes. A broad assessment that synthesizes a large body of evidence, the ISA for PM would be significantly affected by EPA's proposal, especially given the proposal's expansion to *all* data and models not only dose-response data and models. For example, in the section on sources, atmospheric chemistry, and ambient concentrations, the data underlying two of the studies cited as evidence that vehicle emissions are the primary source of PM pollution in the United States are not publicly available.[215] Similarly, the underlying data are not publicly available for a large fraction of the studies that EPA relies on to characterize chemical transport and national-level ambient concentrations of PM. As just a few examples, Crippa et al. 2009, Paciorek & Liu 2009, and Matte et al. 2013 provide critical information on the accuracy of regional chemical transport models, the efficacy of using remote sensing data to estimate ground-level PM, and the patterns of air pollution across an urban landscape, respectively, yet the data underlying these studies are not publicly available.[216]

Exposure information is another critical component of ISAs. In the case of PM, there are numerous exposure studies for which the underlying data are not publicly available. Among these

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[213] CDC, Particle Pollution, https://www.cdc.gov/air/particulate_matter.html.

[214] Press Release, American Lung Association, 19 Health and Medical Organizations Strongly Oppose EPA's Move to Keep Weak Limits on Particle Pollution, Placing Health of Millions at Risk (Apr. 14, 2020), https://www.lung.org/media/press-releases/health-organizations-epa-particle-pollution; Clean Air Task Force, Statement on EPA Proposal on NAAQS (Apr. 14, 2020), https://www.catf.us/2020/04/catf-statement-on-epa-proposal-on-naaqs/.

[215] A. Fushimi et al., *Chemical Composition and Source of Fine and Nanoparticles from Recent Direct Injection Gasoline Passenger Cars: Effects of Fuel and Ambient Temperature*, 124 ATMOSPHERIC ENV'T 77 (2016); L. Morawska et al., *Ambient Nano and Ultrafine Particles from Motor Vehicle Emissions: Characteristics, Ambient Processing and Implications on Human Exposure*, 42 ATMOSPHERIC ENV'T 35 (2008).

[216] P. Crippa et al., *Evaluating the Skill of High-Resolution WRF-Chem Simulations in Describing Drivers of Aerosol Direct Climate Forcing on the Regional Scale*, 16 ATMOSPHERIC CHEMISTRY AND PHYSICS 1 (2016); .D. Matte et al., *Monitoring Intraurban Spatial Patterns of Multiple Combustion Air Pollutants in New York City: Design and Implementation*, 23 J. EXPOSURE SCI. AND ENVTL. EPIDEMIOLOGY 3 (2013); C.J. Paciorek & Y. Liu, *Limitations of Remotely-Sensed Aerosol as a Spatial Proxy for Fine Particulate Matter*, 117 ENVTL. HEALTH PERSPECTIVES 6 (2009).

are studies that explore differences in personal exposure based on an individual's surrounding environment,[217] as well as those that explore exposure levels among certain vulnerable populations[218] and that characterize the relationship between long-term exposure to PM and adverse health outcomes.[219]

All of the studies cited here have been vetted through established, peer-reviewed processes and EPA has relied upon them to develop the PM ISA. The two alternative approaches outlined in EPA's proposal would not resolve the limitations imposed on the agency's use of these studies by the proposal. Under the tiered access approach, those studies that do not utilize restricted data or models would be immediately excluded; while studies that contain restricted data or models would be excluded unless the authors are somehow able to miraculously comply with the agency's entirely ambiguous tiered access regime. As discussed in Section I.D, *supra*, and Section V.B, *infra*, researchers would be unable or unlikely to surmount the massive obstacles involved in providing tiered access to restricted data assuming they would even attempt it. Under the differential weighting approach, the studies cited here would either be excluded outright or be given less consideration, either outcome of which would result in the agency's failure to use the best available science, ultimately violating the Clean Air Act when revising the NAAQS.[220]

Integrated Science Assessment for Sulfur Oxides

In 2019, EPA issued a decision to retain the previous primary NAAQS for sulfur oxides (SOx), another of the six criteria air pollutants.[221] As with particulate matter, the NAAQS decision for SOx was based in part on an ISA that reviewed and synthesized the body of scientific evidence on the health and welfare effects of this pollutant.[222] EPA identified the SOx ISA as highly

[217] R.W. Allen et al., *Modeling the Residential Infiltration of Outdoor PM(2.5) in the Multi-Ethnic Study of Atherosclerosis and Air Pollution (MESA Air)*, 120 ENVTL. HEALTH PERSPECTIVES 6 (2012); M.L. Bell et al., *Adverse Health Effects of Particulate Air Pollution: Modification by Air Conditioning*, 20 EPIDEMIOLOGY 5 (2009); Q. Meng et al., *Determinants of the Associations Between Ambient Concentrations and Personal Exposures to Ambient PM2.5, NO2, and O3 During DEARS*, 63 ATMOSPHERIC ENV'T 109 (2012).

[218] L. Liu et al., *Acute Effects of Air Pollution on Pulmonary Function, Airway Inflammation, and Oxidative Stress in Asthmatic Children*, 117 ENVTL. HEALTH PERSPECTIVES 4 (2009).

[219] M. Jerrett et al., *Comparing the Health Effects of Ambient Particulate Matter Estimated Using Ground-Based Versus Remote Sensing Exposure Estimates*, 125 ENVTL. HEALTH PERSPECTIVES 4 (2016); J. Madrigano et al., *Long-Term Exposure to PM2.5 and Incidence of Acute Myocardial Infarction*, 121 ENVTL. HEALTH PERSPECTIVES 2 (2013).

[220] 42 U.S.C. §§ 7408(a)(2), 7409(d)(1).

[221] Review of the Primary National Ambient Air Quality Standards for Sulfur Oxides, 84 Fed. Reg. 9866 (Mar. 18, 2019).

[222] Integrated Science Assessment for Sulfur Oxide—Health Criteria, 82 Fed. Reg. 58,600 (Dec. 13, 2017).

influential scientific information,[223] and as such the ISA would have been subject to the proposed rule's requirements if they had been in place.

Sulfur oxides are associated with harmful health effects, including irritation of the respiratory tract and asthma exacerbation, while high levels of exposure are associated with difficulty breathing, adverse effects on lung function, and exacerbations of existing heart disease.[224] Especially vulnerable groups include those with lung diseases, children, and the elderly.

The SOx ISA reviews thousands of studies, models, and technical reports relevant to the pollutant. As with the PM ISA, the ISA for SOx would be significantly affected by EPA's proposal, as a number of studies that the assessment relies upon do not have publicly available underlying data. Again, this includes non-dose response studies now captured by the Supplemental Notice. For example, the underlying data are not publicly available for Horowitz et al. 2003, a study that developed a chemical transport model used to inform conclusions about the effects of atmospheric chemistry on large-scale changes in ambient concentrations of various air pollutants.[225] Among the subset of SOx exposure studies that EDF reviewed, a large fraction did not have publicly available underlying data, including studies the ISA cites when describing individual exposure to sulfur dioxide, the connection between SOx pollution and mortality, and the relationship between ambient environmental conditions and individual exposure levels to SOx.[226] Key studies examining the health effects of SOx and identifying vulnerable subpopulations would also be affected by EPA's proposal as their underlying data are not publicly available. Just a few examples of such studies include those demonstrating the unique susceptibilities of asthmatic individuals, including asthmatic children, to sulfur dioxide, as well as investigations that reveal decreased lung function among otherwise healthy individuals living near an industrial facility that releases sulfur dioxide.[227]

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[223] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

[224] National Park Service, Sulfur Dioxide Effects on Health, https://www.nps.gov/subjects/air/humanhealth-sulfur.htm.

[225] L.W. Horowitz et al., *A Global Simulation of Tropospheric Ozone and Related Tracers: Description and Evaluation of MOZART, Version 2*, 108 J. GEOPHYSICAL RESEARCH D24 (2003).

[226] R. Beelen et al., *Estimated Long-Term Outdoor Air Pollution Concentrations in a Cohort Study*, 41 ATMOSPHERIC ENV'T 7 (2007); K.W. Brown et al., *Factors Influencing Relationships Between Personal and Ambient Concentrations of Gaseous and Particulate Pollutants*, 407 SCI. TOTAL ENV'T 12 (2009); B. Zou et al., *An Emission-Weighted Proximity Model for Air Pollution Exposure Assessment*, 407 SCI. TOTAL ENV'T 17 (2009).

[227] R. Dales et al., *Acute Changes in Lung Function Associated with Proximity to a Steel Plant: A Randomized Study*, 55 ENV'T INTL. 15 (2013); W.S. Linn et al., *Responses to Sulfur Dioxide and Exercise by Medication-Dependent Asthmatics: Effect of Varying Medication Levels*, 45 ARCH. ENVTL. & OCCUPATIONAL HEALTH 1 (1990); H. Velická et al., *Asthma Exacerbations and Symptom Variability in Children Due to Short-Term Ambient Air Pollution Changes in Ostrava, Czech Republic*, 23 CENT. EUR. J. PUB. HEALTH 4 (2015).

All of the studies cited here have been vetted through established, peer-reviewed processes and EPA has relied upon them to develop the SOx ISA. As described above for the PM ISA, the alternative approaches outlined in the proposal, tiered access and differential weighting, would not resolve the limitations imposed on the agency's use of these studies. Both approaches would limit the body of evidence that EPA can use to reach conclusions in the ISA and would therefore prevent the agency from setting NAAQS for sulfur oxides based on the best available science, again violating the Clean Air Act when revising the NAAQS.[228]

Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on U.S. Drinking Water Resources

In 2016, EPA published a report examining the potential impacts of hydraulic fracturing activities on drinking water in the U.S., *Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States*.[229] EPA identified the external review draft and the final report as highly influential scientific information, and as such both would have been subject to the proposed rule's requirements had they been in place.

The report reviews and synthesizes the body of scientific evidence relevant to five major activities in the hydraulic fracturing water cycle—water acquisition, chemical mixing, well injection, flowback and produced water, and wastewater treatment and waste disposal—and characterizes their potential to affect the quality and quantity of drinking water resources. As stated in the report, its purpose is to provide government and other stakeholders with a comprehensive report of the best available science that may be used to support decisions related to hydraulic fracturing and drinking water resources.

The report reviews thousands of studies and other data sources relating to key activities of the hydraulic fracturing water cycle. EDF reviewed a subset of the studies cited in the report and found that a number of them do not make their underlying data publicly available. For example, two of the studies that the report cites when describing the potential for surface water contamination due to oil and gas development, as well as the scale of this potential in locations with intensive development, do not have publicly available underlying data.[230] The same is true

[228] 42 U.S.C. §§ 7408(a)(2), 7409(d)(1).

[229] EPA, *Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States* (2016) ("Hydraulic Fracturing Report"), https://cfpub.epa.gov/ncea/hfstudy/recordisplay.cfm?deid=332990.

[230] S. Entrekin et al., *Rapid Expansion of Natural Gas Development Poses a Threat to Surface Waters*, 9 FRONTIERS IN ECOLOGY ENV'T 9 (2011); A. Vengosh et al., *A Critical Review of the Risks to Water Resources from Unconventional Shale Gas Development and Hydraulic Fracturing in the United States*, 48 ENVTL. SCI. & TOXICOLOGY 5 (2014).

for studies that describe the transport of volatile organic compounds (VOCs) and other byproducts of oil and gas extraction through soil and groundwater.[231] Similarly, two studies that found an association between shale gas development and water quality degradation at local and regional scales, and that the report cites when discussing wastewater treatment and waste disposal, do not have publicly available underlying data.[232]

All of the studies described here have been vetted through established, peer-reviewed processes and EPA has relied upon them to develop this report of the potential impacts of hydraulic fracturing on drinking water resources. In describing this publication EPA indicated that, "the scientific information presented can be used by federal, tribal, state, and local officials; industry; and the public to better understand and address vulnerabilities of drinking water resources to activities in the hydraulic fracturing water cycle."[233] EPA's proposal would undermine comprehensive, foundational scientific reports like this one, undercutting efforts of diverse stakeholders to make robust, health- and environmentally-protective decisions based on the best available science.

Future Influential Scientific Information and Significant Regulatory Decisions Regarding Novel Coronavirus, SARS-CoV-2

The ongoing global pandemic of COVID-19, the disease caused by novel coronavirus SARS-CoV-2, that began in late 2019 has had well-documented, disastrous effects on public health and economic well-being in the US and around the world. While researchers, public health agencies, and healthcare workers have been racing to study the virus and develop treatments, many aspects of this crisis are still not well understood, including what personal and environmental risk factors, such as smoking or living in a region with high levels of air pollution, may make an individual more susceptible to contracting and succumbing to the disease.[234]

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[231] D. Bouchard et al., *Analytical Modelling of Stable Isotope Fractionation of Volatile Organic Compounds in the Unsaturated Zone*, 119 J. CONTAMINANT HYDROLOGY 1-4 (2011); E. Rasa et al., *Impacts of an Ethanol-Blended Fuel Release on Groundwater and Fate of Produced Methane: Simulation of Field Observations*, 48 WATER RESOURCES RES. 8 (2013); M.O. Rivett et al., *Review of Unsaturated-Zone Transport and Attenuation of Volatile Organic Compound (VOC) Plumes Leached from Shallow Source Zones*, 123 J. CONTAMINANT HYDROLOGY 3-4 (2011).

[232] S.M. Olmstead et al., *Shale Gas Development Impacts on Surface Water Quality in Pennsylvania*, 110 PROC. NAT'L ACAD. SCI. 13 (2013); R.D. Vidic et al., *Impact of Shale Gas Development on Regional Water Quality*, 340 SCIENCE 6134 (2013).

[233] Hydraulic Fracturing Report, *supra* note 229, at 10-28.

[234] For discussion of how some of these factors may make an individual more susceptible to COVID-19, *see* Environmental Defense Fund, *The Truth About Coronavirus, Air Pollution and Our Health* (Apr. 7, 2020), https://www.edf.org/blog/2020/04/07/truth-about-coronavirus-air-pollution-and-our-health.

It has become clear that this pandemic will be an ongoing global challenge at least until an effective vaccine is developed and widely distributed. EPA has a number of COVID-related efforts underway,[235] and is likely to produce influential scientific information, if not make significant regulatory decisions, regarding COVID-19. Yet EPA's proposal would hinder the agency's ability to do so using the best available scientific evidence, as many studies in the rapidly growing body of literature on COVID-19 do not provide publicly available underlying data. For example, three early cohort studies examining potential risk factors and outcomes among patients with COVID-19 provide only summary data.[236] Similarly, underlying data are not publicly available for two clinical studies reporting on disease progression and outcomes among COVID-19 patients.[237] Such studies provide valuable data about COVID-19 and the factors that may make certain individuals more susceptible to the disease, critical information to consider when examining the influence of environmental factors on the disease. Yet, EPA would be precluded from using these studies when developing influential scientific information or significant regulatory decisions under its proposal. The fact that EPA's proposal might require the agency to disregard critical studies aimed at better understanding an unprecedented global health threat further highlights the capriciousness and profoundly irresponsible nature of the proposal.

These case studies may be just the tip of the iceberg. Indeed, the scope of the Supplemental Notice's expansion appears well-nigh incalculable. We also looked at one section of a single rulemaking: EPA and NHTSA's October 25, 2016, final rule adopting greenhouse gas emission standards and fuel efficiency standards for medium- and heavy duty engines and vehicles.[238] Specifically, we examined the discussion of the heavy duty rule's potential impacts on a) emissions of greenhouse gases and resulting impacts on the climate;[239] b) criteria pollutant emissions and health effects of those pollutants;[240] c) emissions of air toxics and health effects of those

[235] *See* EPA, Coronavirus (COVID-19), https://www.epa.gov/coronavirus.

[236] W. Liu et al., *Analysis of Factors Associated with Disease Outcomes in Hospitalized Patients with 2019 Novel Coronavirus Disease*, 133 CHINESE MED. J. (ENGLISH) 9 (2020); H. Qiu et al., *Clinical and Epidemiological Features of 36 Children with Coronavirus Disease 2019 (COVID-19) in Zhejiang, China: An Observational Cohort Study*, LANCET INFECTIOUS DISEASES (2020), https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30198-5/fulltext; F. Zhou et al., *Clinical Course and Risk Factors for Mortality of Adult Inpatients with COVID-19 in Wuhan, China: A Retrospective Cohort Study*, 395 LANCET 10229 (2020).

[237] H. Shi et al., *Radiological Findings from 81 Patients with COVID-19 Pneumonia in Wuhan, China: A Descriptive Study*, 20 LANCET INFECTIOUS DISEASES 4 (2020); J. Zhang et al., *Clinical Characteristics of 140 Patients Infected with SARS-CoV-2 in Wuhan, China*, ALLERGY (2020), https://onlinelibrary.wiley.com/doi/full/10.1111/all.14238.

[238] Greenhouse Gas Emissions and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles—Phase 2, 81 Fed. Reg. 73,478 (Oct. 25, 2016).

[239] 81 Fed. Reg. at 73,833-35 nn.554-569; *id.* at 73,875-876 nn.833-35.

[240]81 Fed. Reg. at 73,836-41 nn.570-609. Among these references are the NAAQS ISAs which are themselves compendia of research studies, each of which appears to be influential scientific information under the proposal.

pollutants;[241] d) near road pollution;[242] and e) energy security benefits.[243] The total number of references in this single preamble section of a single rule is massive. Each reference appears to be "influential scientific information"—it has "a clear and substantial impact on important public polic[y] . . . decisions." That is why EPA cited and disseminated it as support for the positive environmental effects and energy security benefits resulting from its action. Each reference, in turn, is supported by bodies of sub-references which may also be influential scientific information. Or perhaps some, most, or even all these thousands of references and embedded sub-references are "pivotal science," since arguably they underlie disseminated influential scientific information,[244] or "pivotal regulatory science," since they apparently drive the requirements or quantitative analysis of EPA final significant regulatory decisions.[245] One cannot reliably answer given the opaque Supplemental Notice text—yet another instance of faulty notice.[246] What is clear is that thousands of items are affected and that EPA has made no analysis which accounts for those impacts.

EPA must, if it is to finalize any rule similar to the proposal, document whether or not these studies could be barred or limited in consideration under the proposed rule, the reasons why, and a rationale for why this is or is not reasonable. Which of the many studies cited in Heavy Duty Vehicle Rule would be barred or downgraded from consideration under the proposal?[247] Then, at a minimum, EPA should do this same analysis and provide a comparable explanation for the references in other of its significant rules. This of course is what EPA should have done already, and is required to do under standard administrative law principles requiring an agency to consider critical issues, and to identify and explain to the public the implications of its proposed actions.[248] Since none of this information is presently available to commenters, this notice is inadequate and

[241] 81 Fed. Reg. at 73,841-44 nn.610-679 (health effects of napthalene, acrolein, toluene, xylene, ethylbenzene, propionaldehyde, benzene, 1,3 butadiene, formaldehyde, polycyclic organic matter, among others; many of the references are IRIS databases, each of which contain many hundreds of supporting references which are also likely influential scientific information under the proposal).

[242] 81 Fed. Reg. at 73,844-46 nn.681-710.

[243] 81 Fed. Reg. at 73,888-92.

[244] *See* 83 Fed. Reg. at 18,773 (proposed 40 C.F.R. § 30.2).

[245] *See* 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[246] *Cf. Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158-59 (2012) ("[I]t is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance.").

[247] Is Karner, A.A. et al., *Near-Roadway Air Quality Data*, 44 ENV. SCI. TECH. 5334 (2010), barred or downgraded from consideration under the proposal (n.681)? Is "Health Effects Institute Panel on the Health Effects of Traffic Related Air Pollution (2010)" (n.689)? Is Zanobetti et al., *T-Wave Alternans, Air Pollution and Traffic in High-Risk Subjects*, 104 AM. J. CARDIOLOGY 665-670 (2009)?

[248] *State Farm*, 463 U.S. at 43; *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 518-19, 550.

the public comment period is insufficient to fulfill EPA's public participation obligations. EPA must produce such analysis and then afford additional public notice and opportunity to comment on its findings.

The Supplemental Notice's extension to all models also has startling implications, to which EPA appears oblivious. The definition is stunningly broad: "Model means a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic, or social system."[249] Given this nearly limitless reach, what are the proposal's implications for such fate and transport models as GREET[250] and MOVES[251]? What are the implications of exposure and monetization models such as BEN-Map CE?[252] Are econometric models including the proprietary Integrated Planning Model (IPM)[253] used in numerous significant rulemakings (including those recently carried out by this EPA) to evaluate impacts of air and water pollution standards[254] on electricity generating units implicated, why and how? Models for assessing effects

[249] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[250] Greenhouse Gases, Regulated Emissions, and Energy Use in Transportation (GREET) is a full life-cycle model sponsored by the Argonne National Laboratory (U.S. Department of Energy's Office of Energy Efficiency and Renewable Energy). It fully evaluates energy and emission impacts of advanced and new transportation fuels, the fuel cycle from well to wheel, the vehicle cycle through material recovery, and vehicle disposal. It allows researchers and analysts to evaluate various vehicle and fuel combinations on a full fuel-cycle/vehicle-cycle basis. GREET includes more than 100 fuel production pathways and more than 70 vehicle/fuel systems.

[251] Motor Vehicle Emission Simulator (MOVES) is a state-of-the-science emission modeling system that estimates emissions for mobile sources at the national, county, and project level for criteria air pollutants, greenhouse gases, and air toxics.

[252] BenMAP-CE is an open-source computer program that calculates the number and economic value of air pollution-related deaths and illnesses. The software incorporates a database that includes many of the concentration-response relationships, population files, and health and economic data needed to quantify these impacts. BenMAP-CE enables users to load their own data or use pre-loaded datasets for the U.S. and China, including air quality data, demographic data, economic values, and concentration-response relationships.

[253] The Integrated Planning Model (IPM) is a multi-regional, dynamic, deterministic linear programming model of the U.S. electric power sector. It provides forecasts of least-cost capacity expansion, electricity dispatch, and emission control strategies for meeting energy demand and environmental, transmission, dispatch, and reliability constraints. IPM can be used to evaluate the cost and emissions impacts of proposed policies to limit emissions of sulfur dioxide (SO2), nitrogen oxides (NOx), carbon dioxide (CO2), hydrogen chloride (HCl), and mercury (Hg) from the electric power sector.

[254] *See* EPA, Regulatory Impact Analysis for the Repeal of the Clean Power Plan, and the Emission Guidelines for Greenhouse Gas Emissions from Existing Electric Utility Generating Units 3-4 (June 2019) ("The EPA has used IPM extensively over the past two decades to analyze options for reducing power sector emissions. Previously, the model has been used to forecast the costs, emission changes, and power sector impacts for the Clean Air Interstate Rule (CAIR), Cross-State Air Pollution Rule (CSAPR), the Mercury and Air Toxics Standards (MATS), and the Clean Power Plan (CPP). IPM has also been used to estimate the air pollution reductions and power sector impacts of water and waste regulations affecting EGUs, including Cooling Water Intakes (316(b)) Rule, Disposal of Coal Combustion Residuals from Electric Utilities (CCR) and Steam Electric Effluent Limitation Guidelines (ELG).").

of climate change, including MAGICC[255] and GCAM[256]? Again, it is incumbent on EPA to evaluate the potential impacts of the Supplemental Notice on all of its standard modeling tools and its reasoning therefor, and then to provide notice and opportunity for comment on these findings.

EPA must also provide a well-reasoned justification for the expansion of its proposal, which it has not done. Previously, commenters objected to EPA's unjustified targeting of dose-response studies for exclusion, without any evidence that these studies are inherently less reliable than other studies.[257] Rather than fill this fundamental gap in the logic of the original proposal, the Supplemental Notice would extend the arbitrary and unsupported exclusion to *all* studies for which any underlying data or models are unavailable.[258] As with dose-response data and models, however, EPA has offered no reason why the additional data and models are also unreliable. Instead, it simply notes that other data and models, beyond dose-response data and models, will also influence its regulatory decisions and influential scientific information.[259] This fact is not an adequate explanation for excluding additional studies, and the Supplemental Notice remains as arbitrary as the original.

2. *EPA Fails to Provide a Sufficient Description and Explanation of Its Proposal to Apply Its Rule to Influential Scientific Information.*

At the same time, the Supplemental Notice expands the reach of the original proposal to all "pivotal science" underpinning influential scientific information, capturing a broad spectrum of scientific products developed by the agency. A review of an EPA webpage providing a chronological listing of published influential scientific information illustrates the breadth of agency activities now captured.[260] Taken from this webpage, examples of influential scientific information already published include all chemical toxicological reviews by the Integrated Risk

[255] Model for the Assessment of Greenhouse Gas Induced Climate Change, often used by the IPCC and cited repeatedly by EPA.

[256] Global Change Assessment Model (GCAM) is an integrated assessment model that links the world's energy, agriculture and land use systems with a climate model. The model is designed to assess various climate change policies and technology strategies for the globe over long time scales. GCAM runs in 5-year time steps from 1990 to 2100 and includes 14 geographic regions in the energy/economy module and 151 regions in the agriculture and land use module. The model tracks emissions and atmospheric concentrations of greenhouse gases (CO2 and non-CO2), carbonaceous aerosols, sulfur dioxide, and reactive gases and provides estimates of the associated climate impacts, such as global mean temperature rise and sea level rise.

[257] EDF 2018 Comments at 79-80.

[258] *Cf. State Farm*, 463 U.S. at 46-49 (faulting the agency for rescinding an entire safety standard without considering the effectiveness of airbags merely because the agency had determined that one option, automatic seatbelts, was ineffective).

[259] 85 Fed. Reg. at 15,399-400.

[260] EPA, Science Inventory, https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

Information System (IRIS) program; all draft risk evaluations under the Toxic Substances Control Act; all integrated science assessments (ISAs); various EPA models and methods including those relating to hazard identification, exposure estimation, and environmental fate; and significant agency reports detailing the state of knowledge on issues of great import to protecting public health and the environment (e.g., impacts of climate change on human health in the United States, potential impacts of hydraulic fracturing on drinking water in the United States). A separate EPA webpage identifies planned and ongoing influential scientific information.[261] Examples of influential scientific information provided on this webpage include a biologically-based dose response model for perchlorate;[262] a model for estimating blood lead levels in children resulting from exposures via drinking water; and health effects documents for the per- and polyfluoroalkyl substances (PFAS) perfluorooctanoate (PFOA) and perfluorooctane sulfonate (PFOS). Notably, the agency did not identify these webpages to document the scope of its proposal, leaving open the possibility that it extends much further.

As with its incomplete list of examples of data and models, EPA has failed to provide adequate notice of the types of influential scientific information to which its rule could apply. Without such a comprehensive description, commenters are left with an exceedingly broad definition: "*Influential scientific information* means 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."[263] Although some influential scientific information could have been indirectly excluded from use by the agency by the original proposal—e.g., if destined to support a significant regulatory decision—the Supplemental Notice imposes an independent and immediate restriction on the development of *all* influential scientific information. EPA cannot reasonably expect commenters to anticipate the reach of its new proposal or account for any potential overlap with the original. It is EPA's most basic job to evaluate the implications of its actions, yet this most basic of obligations is an abject cipher here.

Strikingly, EPA offers *no* rationale for expanding the scope of its prohibitions to influential scientific information.[264] The closest the agency comes to an explanation is a passing reference to OMB implementation updates recommending that "[a]gencies should prioritize increased access to the data and analytic frameworks (*e.g.*, models) used to generate influential information."[265]

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[261] EPA, Peer Review Agenda, https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

[262] Perchlorate is a highly toxic compound that interferes with normal functioning of the thyroid gland. *See* Tox Town, U.S. National Library of Medicine, Perchlorate, https://toxtown.nlm.nih.gov/chemicals-and-contaminants/perchlorate; EPA, Perchlorate in Drinking Water Frequent Questions, https://www.epa.gov/sdwa/perchlorate-drinking-water-frequent-questions#where-found.

[263] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[264] *See* 85 Fed. Reg. at 15,398.

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

OMB does not suggest that an agency should disregard data and analytic frameworks in developing influential information. Absent any rationale for expanding the scope of its rule to influential scientific information, finalizing the Supplemental Notice would be arbitrary.[266]

* * *

Multiplying these expansions together, all data and models used in pivotal science or pivotal regulatory science, results in a dramatic and even more untenable imposition on the scientific work of the agency with dramatic implications for public health and environmental protection. Section IV.A.1 of these comments provide specific—though by no means comprehensive—applications of these expansions in practice. Ultimately, the indeterminate and unexplained expansion of the Supplemental Notice means that many more high quality studies would be disqualified from full consideration and utilization by the agency unless the underlying data are publicly available,[267] and this phenomenon would occur more often as the agency imposes the proposal's requirements on many more scientific products of the agency. As a result, the scientific rigor and merit of the agency's work would diminish substantially, and with it a failure to adhere to statutory obligations to use the best available science and all available data as well as a failure to protect public health and the environment.[268] More foundationally, EPA continues to fail to articulate the problem it seeks to solve or identify any benefits the proposal would yield.[269]

B. EPA Fails to Acknowledge or Examine the Disastrous Effect of Further Decreasing the Quantity of Studies upon Which It Can Base Its Regulatory Decisions and Influential Scientific Information.

In addition to providing an inadequate description and justification for the proposed expansions, as noted in Section IV.A, EPA has failed to examine the sweeping effects of expanding coverage of the rule to all data and models and to influential scientific information. At a basic level, expanding the requirement for disclosure of all variety of underlying data and models increases the chances that EPA will ignore any given study—even those that include dose-response data and models that have been disclosed per the proposal's requirements, if such studies include other forms of data and models that remain unavailable. It also sweeps in studies that do not examine dose-response relationships at all. EPA has not estimated the proportion of valid, relevant

[266] *See State Farm*, 463 U.S. at 48-49, 55-57; *Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *19 ("It is axiomatic that the APA requires an agency to explain its basis for a decision.").

[267] For discussion of the problems with the tiered access and differential weighting approaches, *see* Section V, *infra*.

[268] *See* Section III.A, *supra*.

[269] *See* Section I, *supra*.

research that it would disregard under the expanded proposal.[270] As discussed in EDF's comments on the original proposal, the Congressional Budget Office has estimated the number of studies that legislative proposals similar to EPA's rule would affect, both overall and at the level of individual actions, such as reviews of the NAAQS.[271] EPA presumably has better information than CBO does about the volume of scientific information it relies on across its programs; indeed, CBO relied on information from EPA on how the agency would implement the legislation, as well as the cost of complying with it, in developing the CBO estimate.[272] Using updated information, EPA must conservatively estimate both the absolute numbers and the proportion of studies it would rule out through this proposal—overall and in each foreseeable individual action—reasonably assuming that tiered access and de-identification are not feasible. Similarly, the agency must conservatively estimate the number of studies that would be given lesser consideration under the alternative approach described in the proposal. The omission of any such analyses renders its rule arbitrary.[273]

At a higher level, EPA has failed to acknowledge or examine the impacts of expanded coverage on its own rulemakings. The problem is not merely additive; some of the actions that EPA intends to cover with this rule, such as integrated science assessments that inform national ambient air quality standards (NAAQS), are based on an assessment of overall confidence in an at-risk factor (i.e., a factor that potentially increases the risk of air-pollutant related health effects for individuals in certain subpopulations), and excluding one or more studies showing a relationship between that factor and adverse health effects could tip the balance toward, for example, recommending a change in the NAAQS.[274] Thus, arbitrarily ignoring rigorous studies at one or multiple stages of the regulatory process could alter critical health and environmental protections and would be illegal.[275]

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[270] *See* Final SAB Report at 15 ("It is not clear: (1) how many of the studies EPA currently relies upon to take important regulatory actions would meet the public disclosure standards stated in the Proposed Rule, and (2) . . . what the impact of precluding . . . studies would be on EPA's decision making and its ability to protect public health/environment.").

[271] *See* Jon Sperl & Amy Petz, Cong. Budget Office, Cost Estimate for H.R. 1430: Honest and Open New EPA Science Treatment (HONEST) Act of 2017 at 2-3 (Mar. 29, 2017) ("CBO Estimate for H.R. 1430"); CBO Estimate for S. 544, *supra* note 4, at 2-3.

[272] *See* CBO Estimate for H.R. 1430, *supra* note 271, at 2-3.

[273] *See State Farm*, 463 U.S. at 43 ("Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem."); *Process Gas Consumers Grp. v. USDA*, 694 F.2d 778, 790-91 (D.C. Cir. 1982) (en banc) (faulting FERC for failing to "assess the consequences of fully incorporating a current requirements methodology" in implementing USDA's certification of essential agricultural uses of natural gas).

[274] EPA, Preamble to the Integrated Science Assessments at 25-27 (Nov. 2015).

[275] *See, e.g.*, *U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1013, 1018-19 (D.C. Cir. 2002) (invalidating the FAA's decision to ignore noise from non-tour aircraft over national parks, when the agency had "given every indication it w[ould] employ [the decision] in future rulemakings").

Moreover, the expanded proposal would irreconcilably conflict with EPA's obligation to regulate emissions of hazardous air pollutants under the Clean Air Act. Section 112 of the Act requires EPA to set emission standards for existing major sources of hazardous air pollutants that are typically no less stringent than "the average emission limitation achieved by the best performing 12 percent of the existing sources (for which the Administrator has emissions information)."[276] This provision does not allow EPA to ignore information that the agency possesses but that qualifies as confidential business information. Indeed, EPA has historically taken such confidential business information into account in calculating the minimum limitation.[277] Now, however, EPA has proposed to define "data and models" to encompass "data on environmental releases" and to eliminate any such data that would underlie pivotal regulatory science driving the level of a standard, such as emission standards under section 112.[278] EPA's proposed rule, as expanded, patently conflicts with the Clean Air Act's well established requirements and cannot be finalized.[279]

By expanding the scope of its 2018 proposal, EPA has also inadvertently and irrationally hampered its ability to cooperate with other agencies in conducting joint or coordinated rulemakings, beyond the examples noted previously.[280] For example, EPA recently finalized emission standards for greenhouse gases from light-duty vehicles, which it intended to harmonize with the National Highway Traffic Safety Administration's (NHTSA) corporate average fuel economy standards (CAFE). Both sets of standards are based on scientific analysis for which underlying data or models are not available.[281] EPA could not have relied on this analysis in setting greenhouse gas standards had the proposal's requirements been in place, even if the analysis did not alter the level of the standards.[282] Presumably, however, there would be instances in which

[276] 42 U.S.C. § 7412(d)(3)(A).

[277] *See, e.g.*, 67 Fed. Reg. 46,028, 46,044-45 (July 11, 2002); 63 Fed. Reg. 68,832, 68,843, tbl. 4 (Dec. 14, 1998).

[278] *See* 85 Fed. Reg. at 15,401-02; 83 Fed. Reg. at 18,773 (proposed 40 C.F.R. § 30.2, defining "[p]ivotal regulatory science").

[279] For the reasons discussed above, *see* Section III.C, *supra*, EPA's promise to yield in its application of the proposed rule whenever clear statutory duties require it to consider otherwise off-limits information cannot cure the rule's fundamental defects. On the contrary, the proposal's incompatibility with a wide array of EPA's governing statutes provides further evidence that the proposal is arbitrary and unlawful.

[280] *See* EDF 2018 Comments at 80-81.

[281] *See, e.g.*, The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021-2026 Passenger Cars and Light Trucks, 85 Fed. Reg. 24,174, 24,551 (Apr. 30, 2020) (noting that the agencies modeled aerodynamic improvement technologies partly "based on confidential business information submitted by the manufacturers"); *see also id.* (using updated cost estimates from the National Academy of Sciences in the same modeling).

[282] *See* 83 Fed. Reg. at 18,773 (defining "[p]ivotal regulatory science" as "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions" (emphasis added)); *see also* 85 Fed. Reg. at 24,271 ("The purpose of the analysis is not to determine the standards, but rather to provide information for consideration in doing so.").

discrepancies in the rulemaking records considered by EPA and NHTSA, respectively, would result in different standards. It would be bizarre if, going forward, EPA and NHTSA were to attempt another harmonized rulemaking and be prevented from doing so by the fact that NHTSA relied on studies without publicly available underlying data or models while EPA would not.

Relatedly, the proposal could impede any EPA rulemaking, or joint rulemaking, for which the National Environmental Policy Act (NEPA) requires an environmental impact statement (EIS). The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule is a case in point. There, NHTSA prepared an EIS examining the emissions, air quality, and health impacts of weakening fuel economy standards, with EPA as a cooperating agency in the preparation of the EIS. NHTSA averred that it prepared the EIS "[t]o inform its development of the final CAFE standards."[283] Thus, to the extent that EPA's GHG standards in the SAFE Vehicles Rule conform to NHTSA's CAFE standards in the same joint rule, the studies considered in the EIS also qualify as "pivotal regulatory science" that "drive[s] the requirements and/or quantitative analysis of [an] EPA final significant regulatory decision."[284] NEPA requires the agency to take a "hard look" at the relevant data and, in some cases, gather more data.[285] At the very least, the agency must explain why data it omitted "would not alter its conclusions in the EIS or the approval of [the action]."[286] The proposal here would summarily rule out data that NEPA requires the agency to include and consider in an EIS.

V. BOTH OF THE SUPPLEMENTAL NOTICE'S ALTERNATIVE OPTIONS ARE ARBITRARY AND UNLAWFUL

The Supplemental Notice offers two alternative approaches that would theoretically allow EPA to consider studies for which underlying data or models are not or cannot be made publicly available. The first provides for tiered access to data or models underlying studies; the second provides for differential weighting of studies based on the extent to which their underlying data or models are publicly available.[287]As with the original proposal, both approaches violate multiple statutory requirements to use the best available science and to consider all available data.[288] Both approaches would *a priori* unjustifiably require or allow the agency to ignore or give less weight

[283] NHTSA, SAFE Rule for Vehicles Rule for Model Year 2021–2026 Passenger Cars and Light Trucks Final Environmental Impact Statement S-1 (Mar. 2020); *see also Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 100 (1983) ("As a general proposition, we can agree with the Court of Appeals' determination that an agency must allow all significant environmental risks to be factored into the decision whether to undertake a proposed action.").

[284] 83 Fed. Reg. at 18,773 (proposed 40 C.F.R. § 30.2).

[285] *Pub. Employees for Envtl. Responsibility v. Hopper*, 827 F.3d 1077, 1083 (D.C. Cir. 2016).

[286] *Vill. of Bensenville v. FAA*, 457 F.3d 52, 71 (D.C. Cir. 2006).

[287] 85 Fed. Reg. at 15,405.

[288] *See* Section III.A, *supra*; *see also* EDF 2018 Comments at 14-34.

to studies based on whether underlying data or models are available for reanalysis—an arbitrary criterion that ignores the rigor and validity of a study, as well as its usefulness for agency decision-making.

As discussed above, EPA has embarked on an expedition to solve a non-existent problem, and it has wandered far off-course by proposing to ignore studies for which underlying data and models are not publicly available. EPA acknowledges "a 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," an error that prompted the Supplemental Notice.[289] Yet the revised approach perpetuates this problem: it continues to exclude or devalue valid studies solely because the underlying data and models are not publicly available. The Supplemental Notice therefore remains arbitrary for the reasons detailed in comments on the original proposal and summarized here.

Public availability of data is not synonymous with reliability: researchers do not make data public to improve the strength or quality of their findings, and EPA has offered no evidence to suggest that studies with publicly available underlying data are more likely to represent strong science than studies without such data availability.[290] Although reanalysis of data may help confirm a study's results, it is not a primary or sufficient way to validate those results.[291] Rather, the scientific community more heavily relies on peer review and reproducing results[292] using different populations or methods to validate findings.[293] EPA has used such means to ensure the studies it relies on are valid, including comparison of findings with the results of other research and strong peer-review processes led by scientific journals, EPA, or advisory bodies such as the SAB.[294] EPA now refuses to acknowledge these proven and preferred methods, while clarifying that its rule would not actually require any reanalysis of data before the agency uses a study.[295]

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[289] 85 Fed. Reg. at 15,401-02.

[290] EDF 2018 Comments at 73.

[291] *Id.*

[292] As described in a workshop report of National Academies of Sciences, Engineering, and Medicine, "when you *reproduce*, you are producing something that is very similar to that research, but it is in a different medium or context . . . . In other words, a researcher who is reproducing an experiment addresses the same research question but from a different angle than the original researcher did." Nat'l Acads. of Sci., Eng'g, & Med., *Principles and Obstacles for Sharing Data from Environmental Health Research: Workshop Summary*, at 6 (2016) (emphasis in original) (internal quotations omitted), available at https://doi.org/10.17226/21703. We note that this report is merely a summary of a workshop convened by the National Academies and does not reflect the views of the National Academies itself.

[293] EDF 2018 Comments at 74-75.

[294] *Id.* at 71-73.

[295] 85 Fed. Reg. at 15,402.

Inexplicably, however, it insists on excluding or devaluing studies for which the underlying data are not available.

Exacerbating the fundamental flaw of continuing to disregard whole swaths of current and future research, the agency's proposed solutions do nothing to allow rigorous consideration of the vast body of historical studies that document the harm that pollutants cause to human health and welfare. EPA acknowledges objections to the original proposal's exclusion of "many older studies" that include valid data and models.[296] The Supplemental Notice does not, however, respond to these concerns. As explained above, both the tiered access approach and the differential weighting approach would apply retroactively to data and models finalized prior to the rule's effective date unless the Administrator grants a case-by-case exemption.[297] Yet, as EPA admits, there are compelling reasons why it may be impossible or infeasible to provide access to data and models underlying older studies.[298] The revised and alternative approaches therefore fail to address one of the most substantial shortcomings of the original proposal—one that EPA has explicitly acknowledged in its Supplemental Notice.[299]

Ultimately, both approaches fail to address numerous concerns and conflicts raised in EDF's comments submitted on the original proposal regarding scientific principles and practices associated with evaluation of study quality and integration of evidence.[300] Of note, in proposing these alternative options, EPA continues to ignore well-established practices effectively used in the scientific community to vet research, opting instead to discard research that does not meet its disclosure requirements.[301] Finally, neither option addresses fundamental concerns raised about the original proposal regarding cost, ethics, and feasibility of disclosing data and models.

[296] 85 Fed. Reg. at 15,401-02.

[297] *See* Section I.E, *supra*.

[298] *See* Section I.E, *supra*.

[299] 85 Fed. Reg. at 15,403.

[300] *See, e.g.*, EDF 2018 Comments at 64-79.

[301] *See* Section I.B, *supra*; *see also* Final SAB Report at 17 ("The EPA, [OMB], and scientific institutions have . . . recognized that . . . constraints on availability of data do not prevent studies from being verified in other ways - or preclude those studies from being considered in regulatory decisions." (citing EPA and OMB policy documents, as well as a letter from the presidents of the National Academies to EPA regarding this rulemaking)).

A. BOTH THE TIERED ACCESS AND DIFFERENTIAL WEIGHTING APPROACHES WOULD RESULT IN ARBITRARY EXCLUSION OF THE BEST AVAILABLE SCIENCE.

1. Relevant Studies Would Be Excluded from Consideration by the Agency Under the Tiered Access Approach.

The tiered access approach would still require that all data and models underlying studies be made publicly available with a provision that for studies "with restricted data and models (i.e., those that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects)," different tiers of access be available to such underlying data and models where more restricted access occurs for more sensitive data and models.[302] While this approach provides for different degrees of access to underlying data and models, the expectation is that all underlying data and models must be available even if under restricted access. As such, EPA's proposal would still ultimately exclude relevant studies from consideration in the development of influential scientific information and significant regulatory decisions unless their underlying data and models are fully available to EPA and those who have been granted access. These exclusions would continue to be arbitrary for reasons discussed at length in Sections I and IV of these comments and Section II of EDF's 2018 comments.

In altering its proposed approach, EPA purports to address objections to the agency's exclusion of valid data and models containing confidential, proprietary, or personal data that cannot be sufficiently de-identified to protect data subjects.[303] Yet EPA's tiered access approach is an inadequate response to these objections. If tiered access does not exist, for whatever reason, the agency will ignore all studies for which data and models are not publicly available.[304] Thus, the tiered access modification to the original proposal fails to cure its essential defect: the agency would continue to disregard valid studies without any rational grounding in its statutory authorities, and in plain violation of numerous statutory requirements.[305]

2. Relevant Studies Would Be Arbitrarily Undervalued or Excluded Under the Differential Weighting Approach.

Under the differential weighting approach, EPA is proposing to devalue or exclude studies if their underlying data and models are not publicly available, or are not fully available via a tiered

[302] 85 Fed. Reg. at 15,399, 15,405.

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

[304] *Id.*

[305] *See* EDF 2018 Comments at 13-94.

access approach. As with the tiered access approach, this requirement would lead to a failure by the agency to use the best available science and consider all available information, in violation of EPA's statutory obligations.[306]

EPA's differential weighting approach would therefore fail to solve the original proposal's fundamental problem. The agency suggests that, while it would give greater weight to studies for which underlying data and models are available (possibly through tiered access), it "*may* still consider studies where there is no access or limited access to underlying data and models."[307] The agency's consideration of relevant, valid studies is not optional.[308] Moreover, EPA indicates the agency could downgrade its consideration of many valid studies, seeking input on how much to diminish their weight.[309] Discarding or discounting otherwise valid studies, for no reason other than an *a priori* judgment made without regard to study quality, is arbitrary and illegal, for the same reason that disregarding such studies altogether is illegal.

B. THE TIERED ACCESS APPROACH IS UNEXPLAINED AND ARBITRARY.

EPA's preferred approach, which "would allow Agency consideration of studies where there is tiered access to data and models," is arbitrarily vague and notional.[310] EPA observes, generally, that:

> Under a tiered approach to accessing data and models . . . access is more restricted for more sensitive data and models. Thus, the amount of information available for analysis is dictated by the tier. The greatest amount of information is made available at the most restricted access tier.[311]

Nowhere does the agency specify the types of data and models it envisions would be encompassed by each tier, or even how many tiers might exist. Regarding potential requirements to gain access, EPA speculates:

> Restricted access for researchers through secure data enclaves for [personally identifiable information] or through non-disclosure agreements for [confidential

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[306] *Id.*

[307] 85 Fed. Reg. at 15,402 (emphasis added).

[308] *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018).

[309] *See* 85 Fed. Reg. at 15,403 ("EPA is also requesting comment on how much consideration should be given to studies when there is limited or no access to the underlying data and models.").

[310] 85 Fed. Reg. at 15,402.

[311] *Id.*

> business information] may result in access to sufficient information about the data and models to allow for independent validation."[312]

The agency does not actually propose either secure data enclaves or non-disclosure agreements—or any other specific arrangement—as a mechanism to implement its preferred approach in the Supplemental Notice. On the contrary, its discussion underscores that EPA is unable to effectuate or define the tiered-access approach. For example, EPA notes that it is "currently conducting a pilot study using the [Research Data Center's] secure data enclave to host EPA datasets in a restricted use environment," access to which is limited to researchers who "submit a research proposal outlining the need for restricted-use data."[313] EPA does not describe any results from its pilot study, nor does it propose any criteria that it would use to evaluate requests for access to a secure data enclave. Similarly, the agency observes that the White House Office of Science and Technology Policy has an open solicitation for comment that could "help federal agencies provide more consistent information on desirable characteristics of data repositories."[314] Yet EPA has not provided any such information here. In fact, EPA's recent briefing to House Science, Space, and Technology Committee staff reveals that the agency remains in utter disarray as to the management of one or more outside enclaves, hypothetically by unspecified third parties or other federal agencies not involved in this rulemaking.[315] This persistent disregard of a key aspect of the agency's preferred approach renders the proposal arbitrary and unlawful.[316] It also prevents the public from meaningfully commenting on the practical feasibility, costs, and impacts of the agency's proposed approach.

Specifically, EPA fails to provide sufficient description or necessary analysis of the agency's envisioned tiered access approach including details relating to the determination of tiers; procedures for granting access to various tiers of data; operation, curation, management and oversight of data repositories; data repository ownership; whether, and if so, how repositories involving personally identifiable information and confidential business information could be legal; safeguards to prevent hacking of web-based repositories; liability implications for researchers handling personally identifiable information or confidential business information; considerations relating to the extent to which study authors would participate generally; and costs.

Instead, EPA's description of a tiered access approach is cursory and comprised of meaningless generalities. For example, regarding protection of personally identifiable information,

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[312] *Id.*

[313] *Id.*

[314] *Id.*

[315] Memo to Chairwoman Johnson, *supra* note 120, at 2.

[316] *State Farm*, 463 U.S. at 43.

EPA merely states that "[a]ccess to data involving [personally identifiable information] would be consistent with the requirements of the Common Rule, the Health Insurance Portability and Accountability Act (HIPPA) [sic], the 21st Century Cures Act, the Privacy Act, and other relevant laws and regulations, and EPA privacy policies."[317]

The closest EPA comes to describing its envisioned tiered access approach is a brief reference to the Research Data Center (RDC), National Center for Health Statistics (NCHS), Centers for Disease Control (CDC).[318] The RDC houses various health data relating to population health, vital records, and healthcare records among other information. EPA's reference to the RDC is wholly inappropriate, as the data features are entirely different from the scope of scientific information EPA is capturing in the Supplemental Notice. The data housed within the RDC are either developed directly by the federal government or collected through federal government-designed and managed programs. These data are highly standardized, and the platforms housing the data are developed and managed by the government. In other words the RDC is a highly controlled, integrated, and coordinated data infrastructure. In contrast, EPA's proposal targets all potential "data and models" to be considered by the agency that are developed by a wide breadth of entities inside and outside government and that are highly variable including in terms of how they are generated, collected, curated, and stored. Furthermore, EPA is entirely silent on who or what entity will create and manage the tiered access approach. EPA certainly doesn't suggest that it will. Any reference to the RDC as an analogous potential model for EPA's tiered access approach is highly inappropriate and disingenuous.

The SAB has identified similar problems with the proposed rule:

> Some individual data (i.e., data associated with individuals in a sample) used in epidemiological studies are held by federal agencies such as the Centers for Disease Control and Prevention or the Department of Health and Human Services (Medicare data), while other data have been developed by state, local or tribal governments, academic institutions or private organizations, among others. Some federal agencies have efficiently developed methods for making data available to the public (e.g., Census Bureau, CDC). *Currently, no comparable system exists for datasets that are owned by non-federal governments (e.g., states, tribes), and/or owned by private societies/organizations or academic institutions, which are themselves protected by strong privacy and confidentiality requirements through their Institutional Review Boards (IRBs).* . . .

[317] 85 Fed. Reg. at 15,402.

[318] *Id.*

> The proposed regulation should clearly address the issue of obtaining public access to datasets while maintaining the privacy of the participants and confidentiality of the data, because without such access, sensitive data and confidential business information could be excluded entirely from consideration as pivotal regulatory science.[319]

Plainly, the Supplemental Notice—which the SAB has considered—does not even begin to address this fundamental inadequacy. Without any specific proposals as to how it would implement its preferred tiered access approach, EPA has failed to provide the requisite notice.[320]

The vagueness of the tiered access approach, if finalized, would render it arbitrary for another reason as well: researchers whose work is relevant to the regulatory process would no longer be able to pursue studies to ensure that EPA could consider their findings. By replacing its prior policy of considering peer reviewed studies with a prerequisite of indeterminate "tiered access" to data and models, the agency has disregarded these stakeholders' reliance interests in a predictable system for accepting and considering scientific information. EPA has failed to provide the more detailed justification necessary for altering its policy in a way that would inject uncertainty into policy-oriented scientific inquiry.[321]

Even presuming some semblance of a defined approach, EPA fails to assess the legal and practical barriers to implementing tiered access. Regarding personally identifiable information, the agency observes:

> Access to data involving [personally identifiable information] would be consistent with the requirements of the Common Rule, the Health Insurance Portability and Accountability Act (HIPPA) [sic], the 21st Century Cures Act, the Privacy Act, and other relevant laws and regulations, and EPA privacy policies. Reanalyzing findings of studies based on data and models that include PII (*e.g.*, residence) or CBI may not be possible given the degree of perturbation caused by deidentification that would be needed for the information to be made publicly available.[322]

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[319] Final SAB Report at 3 (emphasis added).

[320] *See Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 549 ("Agency notice must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking."); *see also id.* ("This is doubly true under Clean Air Act § 307(d)(3), which requires EPA to issue a specific 'proposed rule' as a focus for comments.").

[321] *Cf. Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1114 (D.C. Cir. 2019) (noting that the agency had failed to take into account the reliance interests of certain telecommunications providers and their customers, who could lose access to service).

[322] 85 Fed. Reg. at 15,402.

Nowhere does EPA explain how it would ensure compliance with such statutory requirements or evaluate the extent of the restrictions they might place on its tiered access approach. As for confidential business information, EPA points to its existing regulations on disclosure of CBI as a potential framework that would govern tiered access to such information.[323] Those regulations, however, provide a detailed process for applying the rules and adjudicating disputes as to confidentiality, and EPA has not demonstrated that the agency has the capacity to administer a system of tiered access to the myriad studies that support all of its regulatory decisions and influential scientific information.[324] In sum, EPA has arbitrarily offered no explanation of how and to what extent legal restrictions on the sharing of confidential information would impede its preferred "tiered access" approach.[325]

EPA also failed to consider the likelihood that tiered access would not be practical or ethical if study participants did not consent to their personal information being examined by outside parties, even with restrictions. Several members of the SAB expressed concerns along these lines.[326] The SAB expressed a similar concern in its majority report on the proposed rule:

> It may not be feasible to identify and make available data in epidemiological studies that arise from small datasets or targeted geographic areas, especially if the Informed Consent Form indicated that only the particular researchers who conducted the study would have access to the information and data. If the participants agreed to grant only a select group of researchers access to their personal information, then that consideration should be respected, and such information should not be supplied to additional people for validation. It would probably be impractical, to go back to the participants and request their approval to provide additional people access to personal information.[327]

It would be arbitrary for EPA to ignore this important aspect of the problem,[328] especially in disregarding the comments of its own science advisers on these issues.[329]

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[323] 85 Fed. Reg. at 15,402-03.

[324] *See* 40 C.F.R. §§ 2.204, 2.205.

[325] *Cf. Am. Pub. Power Ass'n v. Fed. Power Comm'n*, 522 F.2d 142, 146 (D.C. Cir. 1975) (upholding a rule for which the Commission explained how it would address antitrust implications).

[326] *See* SAB Consultation at B-10 (statement of Dr. Janice Chambers); *id.* at B-28 (statement of Dr. Kenneth M. Portier); *see also id.* (noting that owners of data may be unwilling to submit the data to a repository with tiered access).

[327] Final SAB Report at 10.

[328] *State Farm*, 463 U.S. at 43.

[329] *See, e.g., NRDC v. EPA*, 808 F.3d 556, 570-71 (2d Cir. 2015).

Indeed, an underlying assumption of the tiered access approach is that researchers involved in the development of pivotal science or pivotal regulatory science will participate, and EPA has provided no analysis indicating the extent to which the agency believes compliance could or would occur. Instead, it is reasonable to assume that many researchers would not engage in a tiered access approach for a variety of reasons, the significant anticipated costs being just one for which EPA has utterly failed to provide any analysis.[330] As mentioned earlier, this outcome would likely lead to the exclusion of studies representing the best available science, and a failure on EPA's part to consider all relevant information.

Finally, EPA has completely disregarded the potential for pro-industry bias by considering studies for which interested parties have arranged for tiered access. EPA's recent briefing to House Science, Space, and Technology Committee staff underscores how the tiered access approach would preference industry interests: researchers would be responsible for managing the logistics of making data and models publicly available and establishing levels of tiered access;[331] a time-consuming and labor-intensive process for investigators who have already concluded their work and published their findings, possibly having expended the full amount of funding available, unless specially interested third parties bankroll the process.[332] Once established, tiered access would also allow financially interested, repeat players such as regulated entities to test the findings of whatever studies they dislike. EPA has thus proposed to establish a requirement that would favor industry interests by compelling disclosure of data and methods that regulated entities can more readily furnish and that only regulated entities will likely have the resources and motivation to scrutinize with any frequency. Such favoritism in the agency's rule would be arbitrary unless somehow grounded in its authorizing statutes.[333] At the very least, EPA would need to assess, consider, and balance the substantial unfair advantage industry would receive against any theoretical, marginal increase in the reliability of scientific information that could result from a tiered access approach. EPA has completely ignored the issue here, yet another reason that it cannot finalize the Supplemental Notice.

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[330] *See* Section I.D, *supra* (noting recent comments on the challenges of establishing and participating in a tiered access system, for both the original researchers and subsequent investigators).

[331] Memo to Chairwoman Johnson, *supra* note 120, at 2.

[332] *See* SAB Consultation at B-25 (comments of Robert W. Merritt).

[333] *See Cent. Fla. Enters., Inc. v. FCC*, 598 F.2d 37, 41 (D.C. Cir. 1978); *cf. Action for Children's Television v. FCC*, 564 F.2d 458, 480 (D.C. Cir. 1977) (upholding a rule against a claim of pro-industry bias); *see also Am. Trucking Ass'ns, Inc. v. EPA*, 175 F.3d 1027, 1052-53 (D.C. Cir. 1999), *rev'd on other grounds sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001) (concluding it was arbitrary for EPA to disregard study based on informational criteria not applied to other such studies).

C. THE DIFFERENTIAL WEIGHTING APPROACH IS ALSO UNEXPLAINED AND ARBITRARY.

As with the tiered access approach, EPA provides no details as to how the differential weighting alternative approach would work in practice. Rather, EPA merely states:

> [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 available in a manner sufficient for independent validation either because the information is publicly available or available through tiered access when the data include CBI, proprietary data, or PII and appropriate techniques have been used to reduce the risk of re-identification. In developing the significant regulatory decision or influential scientific information, the EPA will identify those studies that are given greater consideration and provide a short description of why greater consideration was given. However, the Agency may still consider studies where there is no access or limited access to underlying data and models.[334]

This description is entirely ambiguous, lacking sufficient detail not only as to how EPA would intend to apply this alternative approach in practice (including how much weight it would give to the availability of data and models in assessing studies), but also under what circumstances the agency would or would not decide to apply this alternative approach as EPA maintains it *may* consider studies where underlying data is not available or only available on a limited basis.[335] In EPA's briefing to House Science, Space, and Technology Committee staff, the agency "was unable to expand on how this potential weighted system would operate. The Agency has not identified implementation details for the weighting approach, including any concrete ideas about how the scale of a weighted system would be structured."[336] The fact that EPA itself does not understand how the alternative would work confirms that the agency has not provided adequate notice for public comment,[337] and it cannot finalize any such alternative without first examining the details of its implementation.[338]

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[334] 85 Fed. Reg. at 15,402.

[335] EPA's suggestion that there will be instances where studies will be "equal" with the exception of the availability of underlying data is entirely disingenuous. In reality, underpinning influential scientific information and significant regulation, will be a diverse body of evidence of different methodological design and no two studies will be exactly alike with exception of data availability. EPA's suggestion that this will be the case may be convenient, but in no way reflects the realities of research and science.

[336] Memo to Chairwoman Johnson, *supra* note 120, at 4.

[337] *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 518-19, 549-50.

[338] *State Farm*, 463 U.S. at 43.

Aside from the vagueness of the weighting approach, EPA has also failed to explain how differential weighting of studies based on data availability adds to, modifies, or is needed in light of existing, relevant frameworks at the agency including, for example, frameworks developed for EPA Integrated Risk Information System (IRIS) toxicological reviews,[339] the development of Integrated Science Assessments,[340] and ecological assessments.[341] More broadly, implicit in EPA's differential weighting approach is an indication that the availability of underlying data in and of itself is an indicator of study quality such that this feature alone can determine the weight a study is given within a body of evidence. In fact, EPA has failed to provide any empirical evidence supporting a relationship between data availability and study quality or reliability. Meanwhile, study evaluation criteria used in leading systematic review frameworks that have been developed for environmental health, such as the University of California San Francisco Navigation Guide[342] and the U.S. Toxicology Program Office of Health Assessment and Training systematic review handbook,[343] have been adapted from prominent systematic review methods in medicine, namely the Cochrane Reviews.[344] Cochrane Review study evaluation criteria have been developed and refined over decades, and are supported by empirical evidence[345] and experience in application.[346] In contrast, EPA's failure to provide any factual support for assigning the availability of underlying data controlling weight in its assessment of studies renders the proposal arbitrary.[347]

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[339] *See, e.g.*, EPA, *IRIS Systematic Review Protocol for Polychlorinated Biphenyls (PCBs)*, https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=237359.

[340] EPA, *Preamble To The Integrated Science Assessments (ISA)*, EPA/600/R-15/067 (2015), https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244.

[341] EPA, Risk Assessment Forum, *Weight of Evidence in Ecological Assessment*, EPA/100/R-16/001 (2016), https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/3839851.

[342] Tracy J. Woodruff, & Patrice Sutton, *The Navigation Guide Systematic Review Methodology: A Rigorous and Transparent Method for Translating Environmental Health Science into Better Health Outcomes*, 122 Envtl. Health Persp. 1007 (2014), https://ehp.niehs.nih.gov/doi/10.1289/ehp.1307175.

[343] Nat'l Toxicology Program, *Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration* (2019), https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/handbook/index.html.

[344] Cochrane Database of Systematic Reviews, https://www.cochranelibrary.com/cdsr/about-cdsr (last visited May 15, 2020).

[345] Cochrane, *Revised Cochrane Risk-of-Bias Tool for Randomized Trials (RoB 2)* (Julian Higgins et al. eds., 2019), https://www.researchgate.net/profile/Prachi_Kaistha/post/Do_we_have_the_option_to_choose_one_of_the_two_effects_ITT_and_Per-Protocol_Effect_in_the_New_Cochrane_Risk_of_Bias_Tool_20/attachment/5e9a06d94f9a520001e08c5b/AS%3A881396046393349%401587152601564/download/20190822_RoB_2.0_guidance_parallel_trial.pdf.

[346] *Cochrane Handbook for Systematic Reviews of Interventions*, § I.1.1 (Julian Higgins et al. eds., Version 6, 2019), https://training.cochrane.org/handbook/current/chapter-i#a-i11-a-brief-history-of-cochrane.

[347] *State Farm*, 463 U.S. at 43.

EPA departs without explanation or acknowledgement from its existing, well-established approaches for assessing the weight of scientific evidence. For example, its Risk Assessment Forum recommends weighting evidence based on relevance, strength, and reliability.[348] Even within reliability, the Forum observes that "scoring the most important component properties" is useful.[349] Transparency is only one such component, and it is merely "*presumed* to increase reliability by reducing the likelihood of hidden faults."[350] EPA offers no reason to give overwhelming importance to one component of reliability in this framework, and, in turn, to reliability over the strength and relevance of a study. In fact, EPA does not discuss existing approaches to weighting evidence at all. EPA has therefore failed to acknowledge that it is changing policies or to provide a good reason for doing so, rendering a final rule that is similarly deficient and unlawful.[351]

With its differential weighting approach, EPA is opting to give substantial weight to data availability relative to other more powerful indicators of study quality including its actual methodological design or the extent to which a study's general findings and conclusions have been corroborated in different studies employing different data or different methodologies. EPA's proposal is at odds with scientific best practices.

VI. EPA'S NEW DEFINITIONS ARE INADEQUATE AND INACCURATE

The definitions EPA proposes are again confusing and fail to match established scientific terminology, including the use of those terms reflected in some of the primary references cited in the Supplemental Notice.[352] Concerns with EPA's definitions are discussed below.

- Capable of being substantially reproduced. EPA proposes to define "capable of being substantially reproduced" to "mean[] that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error."[353] This definition represents an attempt to, once again, bring the word *reproduced* into the realm of *reanalyzed*.

[348] *See* EPA, *Weight of Evidence in Ecological Assessment*, *supra* note 341, at 27.

[349] *Id.* at 33.

[350] *Id.* at 34 (emphasis added); *see also id.* at 36 ("Reliability has at least 11 component properties that are conceptually distinct, ... and more than one can be applied to a piece of evidence.").

[351] *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Physicians for Soc. Responsibility*, 2020 U.S. App. LEXIS 12727, at *22-28.

[352] *See, e.g.*, 85 Fed. Reg. at 15,400 (citing Nat'l Acads. of Sci., Eng'g, & Med., *Principles and Obstacles for Sharing Data from Environmental Health Research: Workshop Summary* (2016)).

[353] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

As EDF discussed in its comments on the original proposal:

> *[W]hen you **reproduce** a scientific experiment, you are producing something that is very similar to that research, but it is in a different medium or context. For example, a researcher who is reproducing an experiment addresses the same research question but from a different angle than the original researcher did.*[354]

and

> *A **reanalysis** is when you conduct a further analysis of data. A person doing a reanalysis of data may use the same programs and statistical methodologies that were originally used to analyze the data or may use alternative methodologies, but the point is to analyze exactly the same data to see if the same result emerges from the analysis.*[355]

EPA's proposed definition for "capable of being substantially reproduced" attempts to make "reanalysis" synonymous with "reproduce," which is wholly inappropriate. To use the term "reproduced" in this context is to mislead the public into believing that some new scientific insights have been applied to an original set of data such that the original research findings are made stronger.

Rather, EPA's definition for "capable of being substantially reproduced" highlights a fundamental misconception underpinning the premise of the proposal—that somehow independent validation is accomplished through reanalysis of study data by other experts. In fact, the strength of scientific findings are not determined by endless reanalysis of a single data set, but rather gained over time through the conduct of separate investigations utilizing different methodologies that yield corroborating conclusions around a hypothesis being explored.

- Data. EPA provides the following proposed regulatory definition for "data":

> [T]he 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.[356]

[354] EDF 2018 Comments at 10.

[355] EDF 2018 Comments at 9.

[356] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

Here again the definition of "data" is tied to the concept of reanalysis rather than the more common definition from Merriam-Webster: "[F]actual information (such as measurements or statistics) used as a basis for reasoning, discussion, or calculation."[357] EPA assumes that this is the "data" that is "necessary to validate research findings." Validation of a research finding involves a determination of whether the scientific findings are *well-grounded, sound and correct*—a much broader inquiry than the narrow type of reanalysis that EPA's proposal is focused on. Validation involves evaluating all of the available science around the hypothesis being explored, not just a determination that no errors or incorrect leaps-of-faith have occurred in reaching a conclusion from a given set of data.

EPA's proposed definition for "data" also suggests that "the scientific community" perceives availability of data to be inherent to study validation. This construct, however, is entirely of EPA's making, and the agency is incorrectly attributing its flawed notions of validation to the scientific community. EPA has in fact failed to provide any analysis as to what the scientific community believes to be involved in study validation.

- Independent validation. EPA provides the following proposed regulatory definition for "independent validation":

> [T]he reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced.[358]

The definition of "independent validation" suffers from the same problems as described for "capable of being substantially reproduced" in that EPA is inappropriately conflating "validation" with "reanalysis." Validation of scientific data is not accomplished by simply *independently reanalyzing* the data. False or inappropriately obtained data will be *invalid* regardless of whether it can be *independently reanalyzed*. Reproducing study results using a different population or method is generally considered a stronger approach to validation, rather than simply reanalyzing the results using the same data, as it shows that the results hold across different populations and different study designs.[359] Furthermore, even accepting EPA's focus on reanalysis, the agency has not identified what information would

[357] *Data*, MERRIAM-WEBSTER DICTIONARY ONLINE (last visited May, 17, 2020), https://www.merriam-webster.com/dictionary/data.

[358] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[359] *See, e.g.*, Comments of the International Society for Environmental Epidemiology on EPA's Proposed Rule on Strengthening Transparency in Regulatory Science, Docket ID No. EPA-HQ-OA-2018-0259-1973, at 2 ("However, although data reanalysis has a role to play, ultimately, the key determination of the consistency of scientific evidence comes from replication, not reanalysis."). Note that ISEE uses the term "replicate" to mean what we have defined in these comments as "reproduce."

be needed for independent validation of different areas of research. For example, the Final SAB Report raises additional points regarding the deficiencies in EPA's proposed definition for independent validation, highlighting the significant ambiguity that remains and insufficient attention to other, related considerations:

> EPA's supplemental proposal indicates that independent validation means the reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced. However, the specific definition of independent validation drives the feasibility of whether EPA can make data and models available for independent validation. For example, the EPA should consider the following questions: How much information is sufficient for independent validation? Will this information consist of equations where reviewers can verify the math, more detailed models where assumptions and limitations are described, or code to allow the public to evaluate and run the models if desired? Is this information simply the dose-response data for the endpoint of concern driving a regulatory limit, or is it availability of all data from a pivotal study to allow reviewers to examine the potential contributions of other variables on the primary endpoint of concern? Endpoint data are seldom evaluated in isolation so providing sufficient study information to allow an independent assessment seems important to meet the goals of the Proposed Rule. For example, an effect on pup body weights in a toxicology study should be examined with knowledge of maternal gestational body weight gains, litter size, food consumption, maternal/litter clinical signs, etc. Sample size and variability also play a key role in data interpretation.[360]

- Pivotal science. EPA proposes to define "pivotal science" as "the specific scientific studies or analyses that underly [sic] influential scientific information."[361] This definition is grossly ambiguous and wholly inadequate. It fails to provide any specificity as to what would qualify as a study that *underlies* influential scientific information. Many studies are included in the development of influential scientific information, whether as supporting evidence in a weight of evidence approach or more directly to derive values related to exposure, hazard, or risk or other forms of conclusions. As defined, "pivotal science" could include all studies involved in the development of influential scientific information, both supportive studies and studies used to derive specific values or other final conclusions. Application to all such studies would be entirely infeasible, effectively paralyzing the development of influential scientific information and with it the work of the agency. Conversely, to the extent the agency intends to apply the proposal to some narrower set of

[360] Final SAB Report at 12.

[361] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

studies, the definition is entirely deficient and introduces incredible risk for selective and biased application with no accountability.

- Publicly available. The proposal provides the following definition for "publicly available":

> [L]awfully available to the general public from federal, state, or local government records; the internet; widely distributed media; or disclosures to the general public that are required to be made by federal, state, or local law.[362]

In general scientific usage, "publicly available" means the data, methods, results and summary evaluation are available in a usual form (e.g., a peer-reviewed scientific publication or a technical report). The definition proposed by EPA goes well beyond the generally accepted scientific definition and is likely to mislead the public into believing that the agency's definition is the scientific norm.

VII. EPA'S FAILURE TO ANALYZE THE COSTS AND BENEFITS OF THE SUPPLEMENTAL NOTICE IS ARBITRARY AND UNLAWFUL

A. THE SUPPLEMENTAL NOTICE EXACERBATES EPA'S ARBITRARY FAILURE TO ASSESS COSTS AND BENEFITS DESPITE COMMENTS FILED POINTING OUT THIS FATAL DEFICIENCY OF THE 2018 PROPOSAL.

The Supplemental Notice would effect a major change in how EPA establishes public health protections without any consideration of the impacts or burdens that the policy would inflict upon the agency, the research community, vulnerable populations, or the public at large. In comments on the 2018 proposal, EDF and others demonstrated that EPA failed to provide any assessment of the costs and benefits—either quantitatively or qualitatively—and thus fell gravely short of basic requirements for reasoned decision-making.[363] Far from correcting that fatal shortcoming, the Supplemental Notice exacerbates the problem by conjuring an even more expansive policy from the same deficient record. Indeed, the word "cost" appears nowhere in the Supplemental Notice, except in titles of two documents cited for other purposes.

It is arbitrary and capricious to "'entirely fai[l] to consider an important aspect of the problem' when deciding whether regulation is appropriate."[364] As in *Michigan*, EPA's present failure to consider the costs and benefits of a regulation where there is no statutory bar to doing so

[362] 85 Fed. Reg. at 15,405 (proposed 40 C.F.R. § 30.2).

[363] EDF 2018 Comments at 101-108.

[364] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (quoting *State Farm*, 463 U.S. at 43).

is arbitrary and capricious.[365] Moreover, EPA's failure to characterize costs and benefits necessarily precludes the agency from assessing whether the costs are disproportionate to the benefits, a finding that could render the proposal arbitrary and capricious.[366] As described below, this failure extends to harms that the proposal would inflict upon the public at large, vulnerable populations, the research community, and the agency.[367] EPA does not identify any statutory authority that could justify its failure to assess the costs and benefits of the proposed rule, and it is certain that the agency could not rely on a radical use of a generally applicable statute like the Housekeeping Act in order to evade well-established requirements of administrative law.

In addition to defying Supreme Court precedent, EPA has contravened Executive Order 12,866 as well as its own guidance on how to implement that Executive Order. For significant regulatory actions like the instant proposal, agencies are required to prepare "[a]n assessment, including the underlying analysis," of both the costs and the benefits.[368] The Executive Order expressly contemplates a wide range of costs, including costs "to the government in administering the regulation" and "any adverse effects on health, safety, and the natural environment."[369] These requirements are especially important in the context of this proposal, which is not only a significant regulatory action in its own right, but also explicitly applies to future "final regulations determined to be 'significant regulatory actions' under E.O. 12866."[370] It is indefensible for the agency not to analyze the costs and benefits of a significant regulatory action that is in turn intended to affect an untold number of additional significant regulatory actions in perpetuity. EPA's failure to do so is arbitrary, capricious, and unlawful.

It is no defense that EPA characterizes this rulemaking (wrongly) as pertaining to internal organization or procedure. The costs to the public are significant and foreseeable. As this policy would likely result in weaker protections from pollutants, toxicants, and other threats, costs would manifest in the form of illness, premature death, medical expenses, missed school and work days, and more. Additionally, as discussed below, the rule would inflict costs upon the research community whose work has long formed the foundation for EPA's public health protections. Even

[365] *See id.* ("Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions.").

[366] *See id.* at 2710.

[367] *See id.* at 2707 ("'[C]ost' includes more than the expense of complying with regulations; any disadvantage could be termed a cost.").

[368] E.O. 12,866 § 6(a)(3)(C); EPA, Office of Policy, *EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions* at 49 (2011) (EPA proposed rules covered by EO 12,866 are to contain the OMB Circular A-4 economics table and a regulatory impact analysis).

[369] E.O. 12,866 § 6(a)(3)(C)(ii).

[370] 83 Fed. Reg. at 18,771, 18,773.

if there is uncertainty about how costs would materialize, EPA must make a reasonable effort to estimate them. EPA cannot assume the costs to be zero—or ignore the issue altogether.[371]

Here, any inability of EPA to assess costs is largely attributable to the deficiencies in the agency's rulemaking process. As noted elsewhere in these comments, EPA has failed to articulate a defensible rationale for this proposal or to describe what effects the proposal might produce. The SAB recently observed that "[c]osts of processing and documenting data will be difficult to assess in advance until EPA has developed a system for dealing with the requirements of the rule."[372] Basic ambiguities in the proposal might further obscure potential costs, as the SAB noted with respect to the definition of "data."[373]A reasoned decision-making process would have generated more information upon which to analyze costs and benefits, rather than the near-total absence of information that we now face. This lack of information is not carte blanche to forego an analysis, but rather an indication that this rulemaking is arbitrary and unsupported.

That EPA might analyze costs and benefits of future rulemakings that implement this policy is no substitute for analyzing costs now.[374] Moreover, in future rulemakings, the methodology of this policy would already be baked into the process, and disentangling its specific impacts would be virtually impossible. To do so, EPA would have to identify which studies it would have relied on (or weighted differently) but for this rule, the difference in the standards or other outcome that would have resulted, and the costs and benefits the counterfactual standards would have yielded. And even then, this rule would have been long since finalized, so any assessment of costs and benefits would come far too late to influence EPA's decision-making. Moreover, analyzing the costs of this rule only as-applied in future rulemakings would be unlikely to capture costs imposed on the research community or resulting from the public's reluctance to participate in studies as a result of this policy.[375] As described above,[376] the influential scientific information to which this proposal would apply may be utilized in processes other than EPA rulemakings—such as to inform decisions by state and local health agencies—that would not provide even a theoretical opportunity for EPA to assess the costs and benefits of this proposal.

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[371] *See State Farm*, 463 U.S. at 43; *see also Ctr. for Biological Diversity v. NHTSA*, 538 F.3d 1172, 1200 (9th Cir. 2008) (agency acted arbitrarily and capriciously when assigning zero value to benefits which were real but difficult to quantify; failure to account for such benefits is tantamount to assigning zero value).

[372] Final SAB Report at 14.

[373] *Id.* at 17.

[374] *See Michigan v. EPA*, 135 S.Ct. at 2709 ("Cost may become relevant again at a later stage of the regulatory process, but that possibility does not establish its irrelevance at this stage.").

[375] *See id.* at 2710 (noting lack of assurance "that the consideration of cost at subsequent stages will ensure that the costs are not disproportionate to the benefits").

[376] *See* Section III.A, *supra*.

EPA's failure to characterize and consider costs and benefits is especially arbitrary and unlawful in the context of a proposal that ostensibly strengthens regulatory transparency. EPA's 2018 proposal asserted: "By better informing the public, the Agency i[s] enhancing the public's ability to understand and meaningfully participate in the regulatory process."[377] Ironically, in the rulemaking at hand, EPA deprives the public of information that is essential to meaningful participation and accountability. Equally concerning, EPA appears not to have developed that information even for its internal consideration. In the following sections, we describe some of the cost considerations that EPA arbitrarily and unlawfully failed to assess.

B. EPA Fails to Consider Costs to the Research Community Potentially Associated with Making Data Available for Reanalysis.

The costs that this proposal would impose on the research community would likely be significant and pervasive, thoroughly impacting the scientific process. These costs are even higher than those that would have been imposed under the 2018 proposal because of the wider range of studies and EPA actions encompassed by the Supplemental Notice. EPA's failure to consider these costs is arbitrary and unlawful.

EPA cannot disregard these costs by claiming that the Supplemental Notice does not directly impose requirements upon the research community. Researchers performing public health and environmental studies have an ethical, professional, and personal stake in how their studies are utilized. It is untenable for EPA to ignore the impacts that this proposal would have on the research community, as if scientists would—or even could—conduct their research in a vacuum, with complete indifference to whether their work would be deemed unsuitable for consideration by the nation's top environmental regulator.

For researchers who attempt to satisfy the parameters of this rulemaking by restructuring their studies to disclose underlying data, the process would be costly and convoluted. The recent SAB report notes several contexts in which costs for researchers could increase, including "researchers' time to collate data and work with EPA to make these data publicly available," and likely "additional costs that occur at an institutional level (i.e., Institutional Review Boards) that would be substantial."[378] Furthermore, "there are legitimate legal, ethical, professional and financial reasons why researchers may be unable or unwilling to fully share 'data.'"[379] As noted in Section I.D of these comments and further below, individual members of the SAB have also observed that study subjects may decline to participate in studies if researchers may ultimately

[377] 83 Fed. Reg. at 18,769.

[378] Final SAB Report at 15.

[379] *Id.* at 17.

share their data with others, raising serious concerns that researchers who attempt to comply with the requirements of this proposal will have difficulty persuading members of the public to participate in studies, or that participation in such studies may be biased or skewed in ways that would influence the results. As described above, this proposal lacks any discernible benefit, so researchers' efforts to meet EPA's arbitrary strictures would be superfluous to any measures taken to ensure scientific rigor and valid, evidence-based outcomes. Such efforts would increase costs and administrative burdens but provide almost nothing in return except checking off EPA's irrational requirements.

Researchers unable to obtain additional funding would have two options. First, they could continue their study without meeting EPA's requirements (assuming funders would support a study that the agency would ignore), with the bleak awareness that its benefit for public health and the environment—not to mention the researchers' professional advancement—might be arbitrarily thwarted by EPA. Second, they might drop the study entirely in order to avoid the agency's erratic minefield of requirements, which would deprive the entire public of the benefits of their study.

Even if some researchers obtained additional funding in order to meet the proposal's requirements, studies by other researchers may be imperiled. As scientific research becomes more expensive in order to meet the proposal's parameters, there is little reason to expect that the total pool of research funding would increase commensurately. If the cost of each study increases, and the total funding remains constant, then fewer studies could be funded. This financial strain could impede not only studies incompatible with the proposal's arbitrary criteria, but even those that are compatible, drastically winnowing the available body of evidence upon which to base public health protections. As a member of the SAB has noted, organizations that devote resources to meet the proposal's requirements "will have to shift funding from ongoing, vital new research to fund this activity, at the net negative cost to the nation's health."[380] Aside from constraining funds available for new research, the proposal would pose unique challenges when applied retrospectively to prior research, possibly precluding the use of past studies, with distortionary impacts on agency analyses.[381]

It bears noting that not all funders would be equally disinclined to support research meeting EPA's requirements. For instance, research backed by industry that profits from pollutants or toxicants might be adequately resourced to adapt to EPA's new requirements, since such funders would have a financial interest in which studies the agency considers. The proposal could thereby

[380] SAB Consultation at B-25 (comments of Robert W. Merritt).

[381] "[R]etrospective application of the requirement . . . could arbitrarily impact the conclusions drawn." Final SAB Report at 17.

skew the research landscape in favor of studies whose funders hope to reap a monetary benefit from the outcome of the research.[382]

The introduction of the tiered access alternative in the Supplemental Notice raises major additional concerns about the costs to the research community. As explained elsewhere in these comments,[383] the tiered access approach would likely be difficult and costly to administer, but EPA has not explained, even in general terms, how this approach would be implemented, the degree of burden it would impose, or who would bear the costs. However, in a recent briefing with staff on the House Committee on Science, Space, and Technology, EPA staff revealed that "key implementation responsibilities [for tiered access] will fall on the research community."[384] EPA's apparent expectation that it will impose massive new costs on the research community without acknowledging as much in the Supplemental Notice is arbitrary and a violation of notice requirements. It would further privilege EPA's reliance on studies from wealthy organizations or those with a financial incentive to expend the necessary resources for EPA to consider their work.

C. EPA FAILS TO CONSIDER COSTS TO THE PUBLIC RESULTING FROM WEAKER HEALTH AND ENVIRONMENTAL PROTECTIONS.

As EDF explained in its comments on the 2018 proposal, the most important costs of this rule would be associated with public health and environmental regulations that do not reflect the best available science.[385] EPA's failure to consider these costs is arbitrary and unlawful. The proposal would likely result in EPA's exclusion or subordination of research that indicates a link between pollutants and toxicants on the one hand, and human death and morbidity on the other. EPA's regulations would likely be insufficiently protective of public health and the environment due to the exclusion of research demonstrating the harm caused by various substances and activities. In particular, EPA is subject to requirements, ranging from statutes to executive orders, to consider the impacts of its regulations on vulnerable populations.[386] EPA has not addressed how the implementation of this proposal would intersect with those requirements. The proposal would provide EPA with a means to paper over human suffering but weaken the agency's ability to prevent it.

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[382] *See* SAB Consultation at B-25 (comments of Robert W. Merritt) (raising the possibility that "only organizations producing results favorable to deep-pocketed industrial concerns will easily find funding to participate").

[383] *See* Section V.B, *supra*.

[384] Memo to Chairwoman Johnson, *supra* note 120, at 3.

[385] EDF 2018 Comments at 103.

[386] *See, e.g.*, 42 U.S.C. § 7409(b)(1) (requiring EPA to set national ambient air quality standards with "an adequate margin of safety . . . to protect the public health"); Exec. Order 13,045, "Protection of Children from Environmental Health Risks and Safety Risks," 62 Fed. Reg. 19,885 (Apr. 23, 1997); Exec. Order 12,898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-income Populations," 59 Fed. Reg. 7629 (Feb. 16, 1994).

Moreover, as noted above, this proposal could prevent many studies from being performed at all, at a significant cost to society. Many state and local environmental regulators could be expected to continue utilizing the best available science rather than adopt EPA's meritless criteria. In addition, individuals could still use studies spurned by EPA to protect themselves from harm. But by imposing scientifically baseless financial barriers and other disincentives to pursuing these studies, EPA would deprive all stakeholders of the studies' benefits. And as explained above, the proposal could raise the costs and decrease the quantity of even those studies that would meet EPA's requirements, further depriving EPA of a robust scientific record when establishing public health and environmental protections.

D. EPA Fails to Consider the Costs of Discouraging Public Participation in Research Studies.

Another way that EPA's arbitrary fixation on the public availability of underlying data would impair scientific research is the deterrent effect on study participants. As EDF explained in comments on the 2018 proposal, confidentiality pledges to study participants are often essential in order to collect accurate and complete information.[387] This concept was reinforced by an SAB member, who advised EPA that the possibility of disclosure of personally identifiable information would "[c]ertainly . . . cause[] some participants to decline participation."[388] The proposal could encumber the researcher-participant relationship by introducing several unnecessary concerns into the process. First, some subjects in public health studies may lose confidence that their data will remain confidential. Even if researchers withhold the names of study participants, the increased pressure on researchers to release information could instill a reasonable fear in subjects that their data could be traced back to them. Second, if researchers committed to keeping underlying data confidential, subjects might reasonably fear that EPA would arbitrarily disregard the findings of the study, lowering their incentive to participate. In some contexts, EPA seems to acknowledge that study participants are motivated in part by the potential impact of a study on public health protections.[389] And third, by imposing new requirements for data availability that have no scientific basis, EPA may create a false impression that the public release of data is an indicator of study

[387] EDF 2018 Comments at 105.

[388] SAB Consultation at B-10 (comments of Janice Chambers).

[389] *See* EPA, *Clinical Studies in Environmental Health, Questions & Answers*, https://epastudies.org/public/epastudies/QuestionsAndAnswers.aspx#q10 (last updated Mar. 20, 2020) ("Thanks to people like you who have participated in studies at the Human Studies Facility, the EPA has set air pollutant regulations that help improve the health of millions of individuals every year. Your participation will help make the world a better and healthier place for us all."); EPA, *Clinical Studies in Environmental Health, Study Results*, https://epastudies.org/Public/EPAStudies/Results.aspx (date of last update not indicated) ("Results of studies performed by the Human Studies Facility . . . directly impact the creation of regulations responsible for protecting the health and environment of millions of Americans.").

quality. This could deter participants from participating in studies for which data will be kept confidential.

As a result, scientific research would become more arduous and expensive. Fewer studies could be performed, to the detriment of public health policy at EPA and other regulatory bodies. EPA's failure to consider these costs is arbitrary and unlawful. While these concerns also applied to the 2018 proposal, the expanded scope of the Supplemental Notice greatly exacerbates them.

E. EPA FAILS TO CONSIDER COSTS THE AGENCY WOULD INCUR IN REVIEWING STUDIES.

Expanding upon a defect in the 2018 proposal, EPA has failed to estimate the costs the agency would incur to implement the proposal, despite the availability of information upon which to base such estimates. Executive Order 12,866 specifically includes costs "to the government" among the costs the agency "shall consider."[390] It again references costs "to the government" when describing the required assessments for significant regulatory actions.[391] Moreover, the costs of administering a regulation are plainly relevant to the reasonableness of an agency's interpretation of the statutes supposedly authorizing the regulation.[392]

The Congressional Budget Office (CBO) has repeatedly estimated the cost of the failed congressional bills that inspired this proposal, generating estimates exceeding $100 million per year—assuming that EPA takes the necessary steps to bring all the studies it relies upon into compliance with the policy.[393] Alternatively, CBO estimated that EPA might reduce those costs to $5 million over a five-year period, but only by "significantly reduc[ing] the number of studies that the agency relies on."[394] EPA failed to address these costs—including the effects of potentially relying on fewer studies—in the 2018 proposal, and it has failed to do so again in the Supplemental Notice, even though commenters provided these figures in their 2018 comments. EPA's present failure to address the CBO estimates is even more arbitrary than in 2018—and not only because the estimates are now clearly in the record. In addition, the Supplemental Notice more closely

[390] E.O. 12,866 § 1(b)(5).

[391] *Id.* § 6(a)(3)(C)(ii).

[392] *See Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 322-24 (2014).

[393] *See, e.g.*, CBO Estimate for H.R. 1430, *supra* note 271; *see also* CBO Estimate for S. 544, *supra* note 4, at 3 (estimating that another, similar bill would cost up to $250 million per year, even if EPA halved the number of studies it relied upon); Ben Levitan, *Public Records Confirm EPA's "Censored Science" Proposal Was an End-Run Around Congress*, EDF Climate 411 Blog (Nov. 12, 2019) (describing public records showing that the proposal was expressly intended to implement the HONEST Act), http://blogs.edf.org/climate411/2019/11/12/public-records-confirm-epas-censored-science-proposal-was-an-end-run-around-congress/.

[394] CBO Estimate for H.R. 1430, *supra* note 271, at 1-2.

parallels the bills that CBO reviewed due to the expanded scope of agency actions and studies it would encompass.

EPA now disclaims any responsibility to make data and models available for independent validation so that the agency could use them in its regulatory decisions and influential scientific information.[395] Yet significant—and entirely unassessed—administrative costs remain, including those associated with identifying pivotal regulatory science and pivotal science, determining whether underlying data and models are available in a manner sufficient for independent validation, and deciding whether to exempt any of the numerous studies that would otherwise be off-limits. The SAB has recently and repeatedly raised concerns about the complexity of these self-imposed tasks.[396] EPA cannot finalize any rule resembling the proposal until it conducts a thorough accounting of these and other costs to the agency, which could prove impossible given the incoherent nature of its requirements.

F. EPA Fails to Quantify, Characterize, Analyze, or Disclose the Benefits of Its Proposal.

The Supplemental Notice does not cure EPA's failure in the 2018 proposal to articulate the benefits of its policy. The error is even more glaring now that the scope of the proposal has significantly expanded. If the 2018 proposal had any merit, it would have contained at least the seed of benefits that should be all the more obvious now that the proposal covers a wider range of studies and actions. Yet EPA still has not characterized what positive outcomes this proposal would deliver. EPA's failure to characterize or analyze the benefits of its proposal—or to acknowledge the absence of benefits—is arbitrary and unlawful.

VIII. CHANGES TO THE PROPOSED RULE'S EXEMPTION PROVISIONS

A. The Changes to the Proposed Rule's Exemption Provisions Do Nothing to Remedy the Fundamental Unlawfulness of the Proposed Rule.

As explained in EDF's 2018 comments, the originally proposed exemption provisions did nothing to remedy the fundamental unlawfulness of prohibiting EPA from considering valid and

[395] 85 Fed. Reg. at 15,402.

[396] *See* Final SAB Report at 8 ("[I]dentification of all studies and regulatory science supporting regulatory actions . . . will be a complex process."); *id.* at 9 ("It may also be very challenging to identify pivotal studies if holistic judgments and weight-of-evidence frameworks are used."); *id.* at 12 (discussing the difficulty of determining whether data and models are sufficiently available for independent validation); *id.* at 16 (noting that "it may be difficult to develop criteria for exceptions" and that "EPA cannot address all circumstances and scenarios that could limit data sharing").

relevant studies due to the public unavailability of underlying data and methods.[397] The changes to the exemption provisions announced in the Supplemental Notice do nothing to warrant altering that analysis.

Specifically, numerous environmental and public health statutes *require* EPA to consider all available science and other relevant information when making regulatory decisions,[398] but if a study fails to meet the proposed rule's public disclosure requirements, the Supplemental Notice's exemption provisions, like the originally proposed provisions, would merely *allow* the Administrator to exempt a qualifying study. Thus, the proposed exemption provisions would give the Administrator unfettered discretion to ignore a study that fails to satisfy the proposed rule's public availability requirements, even if that study constitutes the best available science (and perhaps, is the *only* available science). Furthermore, there may be circumstances where a study does not meet the rule's disclosure requirements *and* does not qualify for an exemption, but nonetheless constitutes the best available science. Under such circumstances, the Administrator could not consider the study even in the face of his or her statutory obligation to do so.

As EDF explained in its 2018 comments, there are many reasons that underlying study data and models may not be available that have no bearing on the quality or validity of the study, including legal restrictions or concerns about privacy.[399] Indeed, EPA's proposal to allow the Administrator to grant exemptions from the rule's disclosure requirements demonstrates EPA's awareness that a study can be valid and worthy of consideration even if underlying data or models are not publicly available. Where a statute requires that the agency consider certain information in reaching a decision, EPA cannot promulgate a rule that prohibits the Agency from considering such information, that automatically downgrades the value placed on such information regardless of its scientific merit, or that gives the Administrator discretion to decide whether the Agency will consider such information. None of the Supplemental Notice's changes to proposed section 30.9 do anything to resolve this fundamental conflict with the relevant environmental and public health statutes. The mere fact that the Administrator might in the future use his or her exemption authority to allow the agency to consider a particular study does not resolve the rule's unlawfulness.[400]

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[397] EDF 2018 Comments at 32-33.

[398] *Id.* at 14-32.

[399] *Id.* at 36-40; *see also* Final SAB Report at 17 ("[T]here are legitimate legal, ethical, professional and financial reasons why researchers may be unable or unwilling to fully share 'data' - including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data."). In fact, under the Supplemental Notice, the Administrator need not exempt a study from the requirement to make data and models publicly available even under circumstances where such disclosure "would conflict with laws governing privacy, confidentiality, confidential business information, or national and homeland security." 85 Fed. Reg. 15,406.

[400] *Cf. Sierra Club v. EPA*, 536 F.3d 673, 678 (D.C. Cir. 2008) (where the Clean Air Act required source-specific operating permits to include monitoring sufficient to assure compliance with applicable requirements, the court held

B. EVEN IF THE ADMINISTRATOR HAD LEGAL AUTHORITY TO IGNORE A VALID SCIENTIFIC STUDY BASED SOLELY ON THE PUBLIC UNAVAILABILITY OF MODELS AND DATA, THE EXEMPTION PROVISIONS ARE ARBITRARY BECAUSE THEY ARE BOTH TOO VAGUE AND TOO LIMITED.

The proposed exemption provisions are also arbitrary in that they are both too vague and too restricted to ensure that the Administrator considers the most valuable and reliable studies when formulating environmental rules and policies.

As explained in EDF's 2018 comments, the exemption provisions are too vague because they fail to define sufficient criteria or process steps by which the Administrator shall apply the exemption criteria.[401] While the Supplemental Notice clarifies that the exemption for circumstances where it is "infeasible" to make models and studies available pertains only to "technological barriers,"[402] it remains unclear whether this determination could be based on cost or other practical concerns, or whether the exemption would be available only where the necessary technology does not exist. Likewise, while the Supplemental Notice would authorize the Administrator to exempt a study for which the development of the data or model was completed or updated before the effective date of the final rule, it offers no criteria to govern when granting an exemption based on the study's age is appropriate. Thus, the Administrator would possess nearly absolute discretion in deciding whether to grant an exemption from the rule's requirements. In fact, like the originally proposed exemption provisions, the Supplemental Notice's exemption provisions lack any specific requirement for the Administrator to provide a public, written explanation of his or her decision to grant (or deny) an exemption. Thus, there would be no way to hold the Administrator accountable for arbitrarily applying the exemption provisions to consider those studies that are favorable to the current Administration's position while excluding those that are unfavorable but of equal or greater scientific validity. While EPA apparently initially intended to include specific criteria for determining whether application of the exemption provision is warranted with respect to a particular study, OMB directed EPA to remove that criteria for unknown reasons.[403]As the SAB Report on this proposed rulemaking notes, the absence of specific criteria to guide the Administrator's application of the case-by-case exemption provisions "may create concerns about inappropriate exclusion of scientifically important studies."[404] Likewise, the

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that EPA's "vague promises to act in the future" to correct inadequate monitoring in federal regulations was not enough to justify EPA's promulgation of a regulation prohibiting state permitting authorities from supplementing inadequate monitoring in applicable regulations when issuing an operating permit).

[401] EDF 2018 Comments at 33.

[402] 85 Fed. Reg. at 15,403.

[403] EPA, Documentation of Changes Made During EO 12866 Review, Docket ID No. EPA-HQ-OA-2018-0259-9321, at 50-51 (2020).

[404] Final SAB Report at 16.

SAB Report explains that those waivers that the Administrator does grant "might appear to be inconsistent or lacking objectivity."[405]

The Supplemental Notice's exemption provisions are also arbitrarily limited because they fail to provide the Administrator with any general exemption authority to apply when unforeseen circumstances necessitate a deviation from the rule's disclosure provisions. While EPA solicits comment on whether there are additional circumstances where an exemption would be warranted, it is impossible to foresee every such circumstance. As the SAB Report explained, the proposed rule's exemption provisions "may not be an effective mechanism for ensuring that the EPA can appropriately consider important studies."[406] Given the importance of EPA's decisions in ensuring the protection of public health and the environment—and that nothing in this rulemaking demonstrates that a study that fails to meet the rule's model and data availability requirements cannot nonetheless constitute the "best available science"— EPA must have the flexibility to consider a study when presented with a compelling justification that it is infeasible to comply with the rule's requirements.

C. THE SUPPLEMENTAL NOTICE'S EXEMPTION PROVISIONS ARBITRARILY FAIL TO REQUIRE THE ADMINISTRATOR TO CONSIDER THE MOST CRITICAL FACTOR IN WHETHER A SCIENTIFIC STUDY SHOULD BE CONSIDERED: WHETHER THE STUDY HAS BEEN SUFFICIENTLY REVIEWED AND VALIDATED TO MAKE IT RELIABLE DESPITE THE PUBLIC UNAVAILABILITY OF UNDERLYING DATA AND MODELS.

For EPA's proposed rule to be lawful, EPA would have to be able to demonstrate that the public unavailability of underlying data and models can, by itself, be dispositive of a study's validity. As explained in EDF's 2018 comments, EPA has made no such demonstration.[407] The Supplemental Notice's exemption provisions further confirm the unlawfulness of EPA's proposal by omitting from the Administrator's exemption criteria any consideration of whether a study is valid despite the public unavailability of underlying data and models.[408]

No factor could be more central to whether EPA considers a particular scientific study in formulating a rule or policy than whether the study has been sufficiently validated to serve as a reliable foundation for agency decision-making. EPA's failure to identify that consideration as a core criterion in the Administrator's decision as to whether to grant an exemption from the

[405] *Id.*

[406] *Id.*

[407] *See* EDF 2018 Comments at 16-22.

[408] *See* 85 Fed. Reg. at 15,406 (proposed 40 C.F.R. § 30.9).

proposed rule's public disclosure requirements renders the proposed exemption provisions arbitrary.[409]

EPA's failure to identify consideration of whether study is reliable despite the lack of public disclosure of underlying models and data as a prerequisite to a decision by the Administrator to waive the proposed rule's requirements for that study makes sense only if (a) EPA does not believe that public disclosure of underlying data and models is relevant to a study's reliability, or (b) EPA is willing to exempt a study from the rule's requirements despite the lack of mechanisms to ensure the study's reliability. Either way, the exemption provisions demonstrate the arbitrariness of the proposed rule.

D. EPA Should Eliminate the Proposed Exemption for Data and Models Completed or Updated Before the Final Rule's Effective Date and Instead Clarify that the Rule Does Not Apply Retroactively.

EPA's Supplemental Notice includes new language in proposed section 30.9 specifying that one of the bases on which the Administrator could choose to exempt a study from the rule's public availability requirements is that "the development of the data or model was completed or updated before" the effective date of the final rule.[410] EPA "requests comment on this consideration of the age of data and models in determining the feasibility of making underlying data and models publicly available."[411] As explained above, EDF opposes this regulatory language because the rule should not have any retroactive application.[412] EDF opposes the proposed rule in its entirety, but if EPA finalizes it, EPA must strike this exemption and instead confirm in section 30.5 that there will be no retroactive application of the rule.

E. If EPA Persists in Finalizing the Proposed Rule's Mandatory Peer Review Requirements, EPA Must Authorize the Administrator to Waive or Defer Peer Review Requirements When Presented with a Compelling Rationale.

In its comments on the original proposal, EDF raised numerous significant concerns regarding the proposed rule's new peer review requirements.[413] The Supplemental Notice does

[409] *See, e.g.*, *State Farm*, 463 U.S. at 43 ("Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem.").

[410] 85 Fed. Reg. at 15,406.

[411] *Id.* at 15,403.

[412] *See* Section I.E, *supra*.

[413] EDF 2018 Comments at 94-96.

nothing whatsoever to address those concerns. To the contrary, the Supplemental Notice creates more problems by proposing to delete the originally proposed language authorizing an exemption where EPA determines that peer review is "infeasible."[414] According to EPA, this exemption is unnecessary because EPA "does not believe that peer review of pivotal regulatory science or pivotal science would be infeasible."[415]

EPA's claim that there are no circumstances under which peer review would be infeasible is inconsistent with OMB's Peer Review Bulletin.[416] Specifically, Section VIII of the Bulletin provides that an agency may defer or waive peer review requirements based on a "compelling rationale."[417] Certainly, it is possible that costs, expediency or some other unforeseen circumstance may necessitate that EPA consider a study that has not been peer reviewed. As the OMB explained when issuing the Peer Review Bulletin, this general authority to waive or defer peer review requirements "ensure[s] needed flexibility in unusual and compelling situations not otherwise covered by the exemptions in the Bulletin before information is disseminated."[418] While proposed section 30.7 continues to provide that the rule's peer review requirements must be applied in a manner that is "consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review and the Exemptions described therein,"[419] EPA's declaration that there will not be circumstances where peer review would be infeasible, combined with EPA's express decision to eliminate the peer review exemption from proposed section 30.9, could be interpreted as overriding the general waiver and deferral authority provided by Section VIII the OMB Peer Review Bulletin. Eliminating—or even casting doubt upon—the Administrator's flexibility to waive or defer peer review requirements when confronted with unforeseen circumstances and a "compelling rationale" is unwarranted and risky. If EPA moves forward with finalizing its proposed peer review requirements—which, for the reasons set forth in EDF's 2018 comments, it should not—EPA must add language to proposed section 30.9 clarifying that the Administrator possesses authority to defer or waive peer review requirements based on a compelling rationale.

[414] 85 Fed. Reg. at 15,403.

[415] *Id.* In its 2018 comments, EDF argued that the peer review exemption language was flawed in that it was more restrictive than the authority provided by OMB's Peer Review Bulletin. *See* EDF 2018 Comments at 95-96.

[416] Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2677 (Jan. 14, 2005).

[417] *Id.*

[418] *Id.* at 2673.

[419] 85 Fed. Reg. at 15,406.

IX. EPA'S SUPPLEMENTAL NOTICE VIOLATES THE PROCEDURAL REQUIREMENTS OF THE APA, CAA, AND VARIOUS OTHER STATUTES

A. EPA HAS PROVIDED INSUFFICIENT TIME FOR MEANINGFUL PUBLIC COMMENT AND UNLAWFULLY FAILED TO HOLD A PUBLIC HEARING.

The Administrative Procedure Act "requires that the public have a meaningful opportunity to submit data and written analysis regarding a proposed rulemaking."[420] The purposes of the APA's notice and comment requirements are "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review."[421]

The Clean Air Act likewise requires that the public be permitted to meaningfully comment on EPA's proposed rulemakings.[422]

Given the complexity of this Supplemental Notice and the immediate public harms that could result from this rule, the 61-day comment period for this Supplemental Notice clearly fails to satisfy EPA's obligation to provide a meaningful opportunity for public comment. The Supplemental Notice builds on the highly controversial 2018 proposal to sharply restrict EPA's consideration of pivotal public health science when making decisions on vital health, safety, and environmental protections issued under a broad range of federal statutes. Responding to public outcry over the inadequacy of the length of the original comment period, and recognizing the complexity, breadth, and significance of that proposal, EPA ultimately afforded a full 108 days for

[420] *Prometheus Radio Project v. FCC*, 652 F.3d 431, 453 (3d Cir. 2011) (citing 5 U.S.C. § 553(c)); *see also Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009) ("The opportunity for comment must be a meaningful opportunity.").

[421] *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005); *United States v. Reynolds*, 710 F.3d 498, 519–20 (3d Cir. 2013) ("[T]he essential purpose of according § 553 notice and comment opportunities is to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies." (alteration in original) (quoting *Dia Nav. Co., Ltd. v. Pomeroy*, 34 F.3d 1255, 1265 (3d Cir. 1994)); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1404 (9th Cir. 1995) ("The purpose of the notice and comment requirement is to provide for meaningful public participation in the rule-making process."). "[T]hese policy goals of maximum participation and full information" are "obvious[ly] importan[t]." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044 (D.C. Cir. 1987).

[422] 42 U.S.C. § 7607(d); *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 518-19, 550 ("[T]he additional notice requirements in § 307(d)(3) suggest that Congress intended agency notice under the Clean Air Act to be more, not less, extensive than under the APA."); *see Sierra Club v. Costle*, 657 F.2d 298, 398 (D.C. Cir. 1981) (public must be able to meaningfully comment on proposed Clean Air Act rule).

comment.[423] Not surprisingly, the 2018 proposal was the subject of intense public interest, ultimately drawing over 600,000 comments—including numerous substantial submissions by practicing scientific researchers, research universities, health and medical associations, state and local governments, industry associations, and environmental and health organizations. The 2018 proposal also drew highly unusual public criticism and statements of concern from the nation's leading scientific institutions, including an open letter by the editors of the nation's top scientific journals and a letter to the Administrator from the president of the National Academies of Science, Engineering and Medicine. And EPA's own Science Advisory Board, which was not even informed in advance of the 2018 proposal, found the proposal significant enough that it took the extraordinary step of conducting its own review.

The Supplemental Notice is every bit as consequential and complex as the original proposal, and warrants a comment period at least as long. For example, the Supplemental Notice radically expands the scope of the original proposal to encompass *all* data and models underpinning studies used by EPA, not just dose-response data and models. Similarly, the Supplemental Notice broadens the proposal to encompass the vast body of "influential scientific information" developed by the agency, raising an array of distinct, major concerns.[424] In addition, the Supplemental Notice presents two complex and vaguely-articulated approaches to implementing the proposed restrictions on science, each of which carries distinct practical impacts and cost implications. What is more, the Supplemental Notice introduces a suite of new regulatory definitions as well as novel claims of legal authority for this sweeping rule, including EPA's newfound theory that the Housekeeping Act permits it to adopt binding and substantive restrictions on science affecting EPA actions under a broad range of environmental laws. And the Supplemental Notice further clarifies that the proposal is intended to affect the handling of some of the most sensitive data used in health research, stating that "[p]ersonnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study" are "intended to be subject to this rulemaking."[425] There is every reason to believe that public interest in the Supplemental Notice will be just as strong as for the original proposal.

Although a 61-day comment period would have been inadequate even in ordinary times, EPA's truncated comment period is especially egregious given that the Supplemental Notice was published on March 18, 2020, amid a national crisis that particularly affects the public health experts whose input is essential to this rulemaking and who filed comments on the original proposal. Since President Trump declared a national emergency on March 13, 2020, over 1.5

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

[424] 85 Fed. Reg. at 15,399.

[425] *Id.* at 15,401 (alteration in original).

million Americans have been infected, over 90,000 have died, and over 30 million workers have lost their jobs. Public health and scientific experts are courageously attempting to prevent the pandemic from claiming more American lives. Amidst these trying and uncertain circumstances, EPA initially provided a mere 30 days for public comment, which it only extended after EDF and other stakeholders (including twenty state and city attorneys general) immediately requested that EPA suspend or substantially enlarge the comment period and hold a legally-required public hearing opportunity.[426]

EPA has declined to grant these requests without providing any persuasive justification. Importantly, EPA has identified no concrete health, environmental, or other public benefit that would require urgent action on this proposal. To the contrary, EDF and other commenters have documented extensive harms to health and environmental protections that would result from this latest attack on science. And EPA has given no other reason for why, having taken no action on its original proposal for nearly two years, public health experts, the scientific community, and the broader public should—or even could—now abruptly divert their attention from our national crisis in order to meet the agency's ill-timed and arbitrary deadline. At the same time, EPA has initiated a public comment period on its proposal to retain inadequate levels of protection from particulate matter nationwide, a process that requires full engagement from these stakeholders and only adds to the burden the agency is placing on them during the crisis.[427]

By contrast, the agency appears to believe that the national public health emergency justifies non-compliance with regulations to protect human health and welfare. A memorandum from EPA's head of enforcement, Susan Bodine, explains that the agency is "cognizant of potential worker shortages due to the COVID-19 pandemic as well as the travel and social distancing restrictions imposed by both governments and corporations or recommended by the Centers for Disease Control and Prevention to limit the spread of COVID-19," and on that basis will allow significant non-compliance with the agency's regulations.[428] Apparently, EPA believes that while the national emergency affects polluters' ability to limit pollution, it does not affect the ability of the public health organizations, doctors, and scientists who are on the front lines of responding to the national pandemic to comment on EPA's controversial Supplemental Notice.

EPA's bare 61-day comment period—on a highly complex proposal that poses grave harms to health and the environment, released in the midst of a public health emergency that has grown more dire throughout the comment period—undermines the fundamental purposes of notice and comment. EPA's Supplemental Notice will not be "tested via exposure to diverse public

[426] *See* EDF, *Request to Immediately Halt and Withdraw EPA's Censored Science Rulemaking Action*, *supra* note 6.

[427] *See* 85 Fed. Reg. 24,094, 24,094 (Apr. 30, 2020).

[428] Memorandum from Susan Parker Bodine to All Governmental and Private Sector Partners, Re: COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program, at 1-2 (Mar. 26, 2020).

comment," does not "ensure fairness to affected parties," and does not "give affected parties an opportunity to develop evidence in the record to support their objections to the rule."[429] Before finalizing any rule, EPA must extend the comment period to allow sufficient time for the entire public—including public health officials, doctors, and scientists—to comment on this dangerous Supplemental Notice.

Finally, we reiterate that section 307(d) of the Clean Air Act requires EPA to hold a public hearing on this Supplemental Notice, and to hold the record open for at least 30 days after the hearing.[430] Because the Supplemental Notice—like the original proposal—would "pertain[] to" many EPA rulemakings enumerated in section 307(d)(1), this proposal is clearly subject to the procedural requirements of section 307(d).[431] That EPA relied on the Clean Air Act as a source of authority for the original proposal, and indicates in the Supplemental Notice that it is still considering that possibility, only reinforces EPA's obligation to comply with the public hearing requirements of section 307(d).[432] EPA's failure to do so thus far is unlawful, and wrongly denies the public an important and legally-required opportunity to weigh in on this sweeping and harmful proposal.

B. EPA Continues to Violate FIFRA, Which Requires the Agency to Consult with the Department of Agriculture.

As with the original proposal,[433] the Supplemental Notice fails to comply with the pre-proposal review requirements set forth in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA continues to cite section 25 of FIFRA as a source of authority for this proposed action.[434] Section 25, however, requires the agency to seek comments from the Secretary of Agriculture on all draft proposed regulations 60 days prior to signing a proposed rule.[435] EPA is to publish this solicitation in the Federal Register,[436] and respond to any written comments from the Secretary as part of the Federal Register proposal.[437] FIFRA also requires that *any time* the EPA is required to consult with the Secretary of Agriculture, the agency must also submit a copy of the proposed rule for comment to the Agriculture Committees in the House and Senate at least 60 days

[429] *Int'l Union, United Mine Workers of Am.*, 407 F.3d at 1259.

[430] 42 U.S.C. § 7607(d)(5).

[431] *See, e.g., id.* § 7607(d)(1)(E), (R).

[432] *See* 85 Fed. Reg. at 15,397.

[433] *See* EDF 2018 Comments at 133-34.

[434] 85 Fed. Reg. at 15,397; 83 Fed. Reg. at 18,769.

[435] 7 U.S.C. § 136w(a)(2)(A).

[436] *Id.* § 136w(a)(2)(D).

[437] *Id.* § 136w(a)(2)(A).

prior to publication,[438] and provide the Scientific Advisory Panel with an opportunity to provide comment on the health and environmental impacts of the proposed action.[439]

There is no indication that EPA has satisfied any of these statutory obligations. Pre-proposal review by the Secretary, however, would at least have raised the question of what potential impacts the proposal might have on FIFRA programs—an issue on which the Supplemental Notice is mute. Congress, by requiring these consultation steps, evidently viewed them as necessary and important. EPA's disregard of these requirements is thus consequential, arbitrary, and unlawful.

C. EPA Was Required to Consult Its Scientific Advisory Committees Before Issuing the Supplemental Notice.

As with the original proposal,[440] EPA failed to submit the Supplemental Notice to the Scientific Advisory Board. This failure is particularly troubling given that the SAB requested review of the original proposal,[441] noting that "the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community."[442]

The failure to timely consult with the SAB is contrary to statute. EPA must submit its Proposal to the SAB pursuant to the requirements of the Environmental Research, Development, and Demonstration Authorization Act ("ERDDAA").[443] ERDDAA requires the Administrator to submit to the SAB any "proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the [EPA] on which the proposed action is based" at the time it provides that proposal to another agency of the government for formal review.[444]

Not only does EPA's repeated disregard of ERDDAA requirements evince troubling contempt for congressionally mandated procedures; it is also consequential. Although the Final SAB Report mentions the Supplemental Notice, it does so only fleetingly. Moreover, there was no

[438] *Id.* § 136w(a)(3).

[439] *Id.* § 136w(d)(1).

[440] *See* EDF 2018 Comments at 132-33.

[441] Memorandum from Alison Cullen, Chair of the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, to Members of the Chartered SAB and SAB Liaisons, at 2 (May 12, 2018) https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf ("This action merits further review by the SAB.").

[442] *Id.* at 3.

[443] 42 U.S.C. § 4365.

[444] *Id.* § 4365(c)(1).

opportunity for actual SAB discussion of the Supplemental Notice, and there was consequently no public input into the SAB process, since there was no process—be it a public meeting or any other type of face-to-face deliberation of the SAB. The SAB pre-proposal review requirement in fact exists to forestall proposals as deficient as the Supplemental Notice. EPA's arbitrary failure to adhere to its legal obligation under ERDDAA renders the Supplemental Notice unlawful.

It was also arbitrary under the CAA not to consult with the Clean Air Scientific Advisory Committee (CASAC). CASAC is charged with reviewing national ambient air quality standards (NAAQS) and recommending any new standards.[445] In turn, the NAAQS are to be based on criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare."[446] CASAC's task of reviewing the NAAQS would be complicated and perhaps rendered impossible by the Supplemental Notice. CASAC could be required to recommend a change to the NAAQS based on their evaluation of valid research that EPA now seems to find objectionable,[447] which suggests that this enterprise is not what Congress intended. Further, because the Supplemental Notice would apply to influential scientific information, such as integrated science assessments prepared by agency staff,[448] EPA might itself deprive CASAC of the information it needs to fulfill its statutory duty. EPA should have considered these complexities in its rulemaking and consulted with CASAC on its implications for CASAC's duties. For these reasons as well, finalizing the proposed rule would be arbitrary and unlawful under the CAA.

[445] 42 U.S.C. § 7409(d)(2)(B).

[446] *Id.* §§ 7408(a)(2), 7409(b).

[447] See EDF 2018 Comments at 22-25.

[448] *See* Section IV.A.2, *supra*.