August 14, 2018

Submitted via regulations.gov

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460
Attn: Docket No. EPA-HQ-OA-2018-0259

Re: *Comment on Proposed Rule—Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768 (Apr. 30, 2018) ("Proposed Rule")

Dear Acting Administrator Andrew Wheeler:

This comment letter is submitted on behalf of a group of 68 professors of law whose names appear below. We are affiliated with 47 universities around the United States, and all have substantial professional experience in the areas of administrative and environmental law. We write to express our serious concerns with the above-referenced Proposed Rule.

In our view, the Proposed Rule represents a significant overstep of EPA's authority and a troubling effort to limit the use of valid, relevant, and rigorously reviewed science in EPA's future decision-making processes. EPA frames this rule as a win for the public through increased access to scientific data. In reality, the regulations that implement some of our nation's marquee environmental laws—like safe drinking water standards and pesticide rules—rely on the very science this rule would bar from EPA's consideration. The minor gains, if any, from making some scientific data publicly available would be more than outweighed by the staggering costs to the public if EPA could not fulfill its core mission to protect our citizens' health and safety because this rule deprived it of the ability to consider the best science.

We object to the Proposed Rule for the following reasons, which are more fully set forth below: (1) the Proposed Rule falls outside the scope of EPA's rulemaking authority and conflicts with existing federal statutes and Executive Orders; (2) the Proposed Rule is at

odds with the goal of increasing transparency in the regulatory rulemaking process; (3) the Proposed Rule suffers from procedural deficiencies that must be corrected; and (4) the Proposed Rule is ill-considered public policy.

In less than two pages of regulatory text, based on little thought and analysis, the Proposed Rule would make sweeping changes to EPA's science-based rulemaking process, paralyzing EPA's ability to fulfill its statutory responsibilities rather than increasing "transparency." To make these changes without consulting expert scientists is ill-advised at best. For example, the rule was not vetted by EPA's internal Science Advisory Board, or by the National Academies of Science, both of which could offer relevant and non-partisan scientific perspectives on this significant action.

While we support efforts by the scientific community to address data accessibility, this rule ignores the complexities of that issue and scientists' ongoing work to tackle it, and hamstrings the agency by limiting regulatory activity before any consensus has been reached among scientists on approaches to data availability. Particularly glaring is the Proposed Rule's misuse of scientists' efforts to create a meaningful approach to data accessibility, highlighted by the fact that scientific bodies have asked EPA to remove or modify the Proposed Rule's inaccurate citations to scientific work on this issue.[1]

The Proposed Rule is rife with legal deficiencies, satisfying neither EPA's obligation to put the public on proper notice of the rule's scope and reach nor EPA's statutory mandates under the numerous federal environmental laws it is charged with administering. The enormous leeway provided to the Administrator to make case-by-case determinations on the rule's applicability opens the door for arbitrary enforcement. Beyond that, the Proposed Rule would be costly to the public and ignore key patient privacy protections.

We believe that the Proposed Rule is not only unnecessary and antithetical to the goal of achieving regulatory transparency, but would also severely constrain EPA's ability to use the best quality science to make critical decisions. Eliminating the consideration of relevant science from the decision-making process based solely on the availability of underlying data

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[1] *See, e.g.,* Bipartisan Policy Center, *Bipartisan Policy Center comments on "Strengthening Transparency in Regulatory Science," Docket ID No. EPA-HQ-OA-2018-0259* (May 22, 2018) ("…we want to be clear that *the proposed rule is not consistent with the BPC report in substance or intent*.) (emphasis in original)); Society of Toxicology, *Re: Docket ID No. EPA-HQ-OA-2018-0259* (May 25, 2018) ("[I]t is not appropriate to infer…an endorsement from either the Specialty Section or the SOT as a whole. We respectfully request that any and all references to 'members of the Risk Assessment Specialty Section of the Society of Toxicology' be removed from the Final Rule.").

would compromise EPA's ability to effectively carry out its mission to protect public health and the environment. We strongly urge that the Proposed Rule be withdrawn.

I. The Proposed Rule Falls Outside The Scope Of EPA's Rulemaking Authority And Conflicts With Existing Federal Statutes and Executive Orders

The Proposed Rule contradicts and conflicts with existing law in three significant ways: (1) EPA lacks regulatory authority to promulgate the Proposed Rule in the first instance, (2) the Proposed Rule directly conflicts with existing federal environmental and privacy laws, and (3) the Proposed Rule fails to comport with the requirements of multiple Executive Orders.

A. EPA Lacks Regulatory Authority To Promulgate The Proposed Rule

EPA cites numerous statutory provisions to support this rulemaking,[2] but none provides authority for the agency to promulgate the Proposed Rule.

Generally, the statutory provisions EPA invokes fall into one of two categories: (1) provisions authorizing EPA to conduct research in furtherance of statutory objectives and (2) general provisions authorizing the EPA Administrator to promulgate regulations as necessary to achieve the purposes of a given statute. None of these statutory references provides the requisite authority for adoption and implementation of the Proposed Rule.

As a basis for authority to promulgate the Proposed Rule, EPA points to provisions authorizing the establishment of research and development programs pursuant to each of the federal environmental laws EPA administers. But these statutory references are unavailing. Each statute directs EPA to set up research programs and to undertake specific activities attendant to the administration of those programs, but none governs—or even references—the extent to which research should be used in regulatory decision-making by EPA. Further, any regulatory authority EPA may have under the referenced provisions is limited to the individual research and development programs in question, and does not extend to unrelated research by outside parties. In other words, the cited provisions allow EPA to set up its own research programs, but do not create authority to place limitations on how research, whether conducted or financed by EPA or produced by an outside party, is used to set regulatory standards.

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[2] EPA cites the following provisions as authority for the rulemaking: 42 U.S.C. § 7403, 42 U.S.C. § 7601(a), 33 U.S.C. § 1254, 33 U.S.C. § 1361, 42 U.S.C. § 300j-1, 42 U.S.C. § 300j-9(a)(1), 42 U.S.C. § 6912(a)(1), 42 U.S.C. § 6979, 42 U.S.C. § 9616, 42 U.S.C. § 9660, 42 U.S.C. § 11048, 7 U.S.C. § 136r(a), 7 U.S.C. § 136w, and 15 U.S.C. § 2609.

For example, EPA purports to derive authority for the Proposed Rule from Clean Air Act § 103. That provision simply authorizes EPA to establish a national research and development program for the prevention and control of air pollution and, as part of that program, to conduct and promote the coordination of research and studies relating to the causes, effects, extent, prevention, and control of air pollution. 42 U.S.C. § 7403(a)(1). The section authorizes specific activities of the Administrator in establishing such a program, none of which includes limiting the scope of reviewable data, research, or studies when undertaking regulatory action. The section has no bearing on how or to what extent EPA utilizes research in regulatory decision-making processes.

The rulemaking authority provided by provisions authorizing the EPA Administrator to promulgate regulations "as necessary to carry out his functions" under various environmental statutes does not extend to actions that would undermine, rather than further, the relevant acts' directives. *See* 42 U.S.C. § 7601(a) (Clean Air Act); 33 U.S.C. § 1361 (Clean Water Act); 42 U.S.C. § 300j-9(a)(1) (Safe Drinking Water Act); 42 U.S.C. § 6912(a)(1) (Resource Conservation and Recovery Act); 42 U.S.C. § 9615[3] (Comprehensive Environmental Response, Compensation, and Liability Act); 42 U.S.C. 11048 (Emergency Planning and Community Right-To-Know Act); 7 U.S.C. § 136w (Federal Insecticide, Fungicide, and Rodenticide Act). As discussed in greater detail below, both the intent and the language of the Proposed Rule are in direct opposition to the statutory requirements of these environmental statutes, which seek to protect public health and the environment.

The Proposed Rule, apparently mistakenly, also cites as authority 42 U.S.C. § 6979, a labor standards provision within the Resource Conservation and Recovery Act requiring certain prevailing wage standards to be met on construction projects receiving EPA grants, and 42 U.S.C. § 9616, a section of the Comprehensive Environmental Recovery, Compensation, and Liability Act requiring listing and evaluation of facilities and commencement of remedial activities for listed facilities. Neither one of these sections is relevant to the Proposed Rule or to research activities more generally. Inclusion of these mistaken cites in the Proposed Rule's laundry list of "authorizing" provisions highlights the absence from that list of any statutory language that provides clear authority for a rule of this unprecedented breadth and import and the hasty nature of this rulemaking process.

In sum, EPA offers no legal authority upon which to base a rulemaking of this significance.

[3] The Proposed Rule appears to have mistakenly referenced 42 U.S.C. § 9616.

B. The Proposed Rule Conflicts With Existing Federal Law

Not only do the environmental statutes cited as authority to implement the Proposed Rule fail to grant such power, but many of those same statutes contain provisions that contradict the spirit and letter of the Proposed Rule. The Proposed Rule is also at odds with federal data privacy laws.

1. The Proposed Rule Ignores Statutory Text Dealing Directly With Data Disclosure

Multiple environmental statutes cited as authority for the Proposed Rule contain other sections that expressly discuss requirements for EPA's disclosure of data. However, the rule's text fails to mention these provisions and EPA does not reconcile them with the Proposed Rule's requirement of other data disclosure in other circumstances.

For example, although the Clean Air Act contains a provision, Section 307, directly relevant to the issue of data disclosure, *see* 42 U.S.C. § 7607(d)(3) (requiring notices of proposed rulemaking to contain a statement of basis and purpose which includes the factual data upon which the rule is based and the methodology used to obtain and analyze the data), that section is not referenced anywhere in the Proposed Rule. Courts have expressly held that Section 307 does *not* require EPA to publicize all data underlying the studies upon which it bases regulatory actions. *See Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass'ns, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). It is telling that EPA has chosen not to rely upon the provision of the Clean Air Act dealing most directly with this subject and EPA has not explained how other provisions of the Clean Air Act unrelated to data disclosure support a rule imposing requirements beyond those of section 307.

Similarly, the Toxic Substances Control Act already expressly dictates the information that EPA must make publicly available, including a list of the studies EPA considers in carrying out risk evaluations and the results of those studies. 15 U.S.C. § 2625(j). Nowhere does the statute require that the data underlying those studies be made publicly available, or limit the use of data or studies in making evaluations or regulatory decisions. Once again, EPA has declined to cite the provision within the Toxic Substances Control Act that deals most directly with data disclosure and has not explained how other provisions of the Toxic Substances Control Act unrelated to data disclosure support a rule imposing additional data disclosure requirements.

While not an environmental statute, the Information Quality Act ("IQA") also contains requirements for data disclosure that are already applicable to EPA and other federal

agencies. *See* 44 U.S.C. §§ 3504(d)(1), 3516. Covered agencies are required to issue their own guidelines for disseminating information, establish administrative mechanisms allowing affected individuals to seek correction of information they believe does not comply with IQA guidelines, and report to OMB on the number of such complaints received. *See* 67 Fed. Reg. 8452. OMB guidelines for implementation of the IQA recommend that "agencies should weigh the costs (for example, including costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality)" when considering the development of information and the level of quality to which agency-disseminated information will be held. 67 Fed. Reg. 8453. EPA's own internal IQA guidance explains that EPA will ensure objectivity in dissemination of influential scientific information "to the extent practicable," and explains that the practicability limitation "is appropriate in many circumstances to conserve Agency resources and those of the regulated community who otherwise might have to generate significant additional data."[4] The Proposed Rule's requirements are at odds with this approach, and entirely fail to consider the rule's costs and burdens on the scientific community.

2. The Proposed Rule Contradicts The Requirements Of Federal Environmental Law, Including Cited Authority For The Rulemaking

The Proposed Rule's requirements are at odds with statutory mandates contained in the very same environmental laws it points to as providing a basis for the rule. They also directly controvert authority it cites as support for the rulemaking.

The requirements of the Proposed Rule conflict with EPA's statutory obligations under federal environmental laws. Clean Air Act § 109 mandates that EPA set air quality standards based on "air quality criteria," which must "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. §§ 7409, 7408(a)(2). The Toxic Substances Control Act requires EPA to use the "best available science" when evaluating the testing and regulation of chemicals. 15 U.S.C. § 2625(h). Decisions are to be made using the "weight of the scientific evidence," and EPA is required to consider all information related to a chemical substance, including hazard and exposure information, "that is reasonably available to the Administrator." 15 U.S.C. §§ 2625(i), (k). Similarly, the Safe Drinking Water Act mandates use of the "best available public health information" when EPA determines whether to regulate a

[4] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA*, EPA-260R-02-008 (Oct. 2002) at p. 23.

contaminant, and reliance on the "best available, peer-reviewed science and supporting studies" when making regulatory decisions. 42 U.S.C. §§ 300g-1(b)(1)(B)(ii), 300g-1(b)(3).

Exclusion of relevant studies from consideration based *not* on the quality of the science but on the public availability of underlying data directly contradicts these mandates.[5] EPA itself has defined "best available science" without reference to the public availability of data:

> Use of best available science involves the use of supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).[6]

Simply put, the "best available science" is science that follows standards accepted by the scientific community, not science that EPA arbitrarily selects based upon the public availability of data—a criterion irrelevant to scientists' standards for determining whether research represents the best science.

Specifically, scientists have observed that the best quality science oftentimes relies upon data that is not publicly available due to significant privacy considerations.[7] It is for that very reason that courts have recognized EPA's need to rely upon studies based on publicly undisclosed underlying data when considering the best science. *American Trucking Ass'ns*, 283 F.3d at 372 (explaining that curtailing EPA's ability to rely on published studies would exclude "plainly relevant scientific information" from regulatory decision-making processes); *see also Coalition of Battery Recyclers Ass'n*, 604 F.3d at 623 (finding that EPA is entitled to rely on published study results as "raw data is often unavailable due to

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[5] Even EPA's current mission statement explains that EPA works to ensure "[n]ational efforts to reduce environmental risks are based on the best available scientific information." *See* EPA, *About EPA*, available at https://www.epa.gov/aboutepa/our-mission-and-what-we-do.

[6] Environmental Protection Agency Office of Chemical Safety and Pollution Prevention, *Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act*, EPA 740-R17-001 (June 2017).

[7] *See, e.g.,* International Society for Environmental Epidemiology, *Comments of the International Society for Environmental Epidemiology on EPA's proposed rule on Strengthening Transparency in Regulatory Science (EPA-HQ-OA-2018-0259-0001)* (citing to multiple robust environmental studies based upon data that could not be disclosed because of federal and foreign laws and access agreements with Medicare).

proprietary interests of a study's scientific investigators or confidentiality agreements with study participants"). Forcing EPA to ignore high quality science controverts EPA's statutory obligations and will impair EPA's ability to protect public health and the environment.

The Proposed Rule also conflicts with provisions of federal environmental laws that EPA specifically cites as its authority for promulgating the rule. For example, the Proposed Rule cites Clean Water Act § 104, which authorizes EPA to establish national programs for the prevention, reduction, and elimination of pollution and to conduct and promote the coordination and acceleration of research and studies in connection with establishing those programs. 33 U.S.C. § 1254(a)(1). The activities authorized by this section do not include placing limitations on the use of scientific research for regulatory decision-making. Instead, this section requires EPA to undertake continuing comprehensive studies of the effects of pollution on estuaries and estuarine zones, considering "all pertinent information"—a mandate at odds with the Proposed Rule's push to exclude relevant peer-reviewed research from the regulatory process.

Likewise, Comprehensive Environmental Response, Compensation, and Liability Act § 311 requires EPA to carry out a research program to develop and demonstrate "alternative or innovative treatment technologies" for potential use in response actions. 42 U.S.C. § 9660(b). Information gathered as part of that research program is already required to be made publicly available, with the express exception of trade secrets or personal proprietary information, two categories of data that the Proposed Rule does not protect on its face. Indeed, in requiring that all studies' supporting data be made publicly available, the Proposed Rule's language contradicts this statutory mandate. In sum, the authority EPA has cited for the rulemaking not only fails to confer upon EPA the power to promulgate the rule, but also is inconsistent with the rule's requirements.

3. The Proposed Rule Is At Odds With Federal And Other Privacy Protections

In addition, federal data privacy laws protect sensitive personal information, including the very types of data gathered in studies that research the health effects of environmental exposures in humans.[8] For example, under the Health Insurance Portability and Accountability Act's ("HIPAA") Privacy Rule, individually identifiable health information

[8] As the National Academy of Sciences explained, these protections are well-founded. National Academy of Sciences, *Improving Access to and Confidentiality of Research Data: Report of a Workshop* ("unrestricted access can cause harm to individuals and also conflicts directly with respect for individual autonomy").

is protected and "de-identification" standards must be met when disclosing protected health information. *See* 45 CFR § 164.514. As explained by the International Society for Environmental Epidemiology's comments on the Proposed Rule:

> Research on the health effects of environmental exposures in people, by its very nature, includes sensitive information on the medical, physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. As such, requirements under [HIPAA] and the National Death Index place restrictions on sharing these data. Similarly, Institutional Review Boards that must review all proposed research by universities and other government funded research organizations require the protection of data from study participants. Even investigators who have obtained death or birth certificate information from state departments of health, or hospital admissions data from Medicare, all sign Data Use Agreements prohibiting them from making public anything other than aggregate data summarizing statistics from large numbers of people.[9]

The Proposed Rule would require EPA to ensure that data relied upon in scientific studies be made "publicly available in a manner sufficient for independent validation," a mandate that would necessitate the sharing of data protected under HIPAA and otherwise barred from disclosure. 83 Fed. Reg. 18773.

The Proposed Rule does not address these inconsistencies with existing federal law. Nowhere does the rule explain how the EPA will be able to fulfill its statutory duties without the ability to consider the best available science, which includes robust, peer-reviewed, and cutting-edge studies that rely upon protected data that cannot legally be made publicly available.[10] The rule's scant text entirely omits a discussion of privacy protections or how EPA would navigate those protections to adequately shield the identities

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[9] International Society for Environmental Epidemiology, *Comments of the International Society for Environmental Epidemiology on EPA's proposed rule on Strengthening Transparency in Regulatory Science (EPA-HQ-OA-2018-0259-0001)*.

[10] For example, the ESCAPE study relied upon data protected by European privacy laws to combine multiple cohorts across Europe and examine the association of air pollution with mortality in study participants. *See id*. (*citing* Beelen R, et al. Effects of long-term exposure to air pollution on natural-cause mortality: an analysis of 22 European cohorts within the multicenter ESCAPE project. *Lancet*. 2014; 383:785-95.) The findings of that study are consistent with multiple other studies that examine the effects of particulate matter exposure using different methodologies.

of study participants while still providing "the information necessary for the public to understand, assess, and replicate findings."[11] 83 Fed. Reg. 18774. As such, the Proposed Rule amounts to a proposal to shirk EPA's statutory obligations and ignore patient privacy laws administered by other agencies.

C. The Proposed Rule Is Out Of Step With Multiple Executive Orders

In addition to conflicting with multiple federal statutes, the Proposed Rule contradicts the spirit and letter of Executive Orders 12886, 12898, 13045, and 13563. These Executive Orders require EPA to analyze and provide an assessment of the Proposed Rule's cost impacts, its implications for environmental health risks to sensitive populations, and potential alternatives to the Proposed Rule. EPA has entirely failed to meet these requirements.

- Executive Order 12886: This Order instructs federal agencies to "assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating….agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)…" EO 12886, § 1(a). When, as here, a proposed rule constitutes a "significant regulatory action," the agency is required to provide an analysis of the benefits and costs anticipated from the proposed rule, as well as any costs and benefits of reasonably feasible alternatives to the rule. EO 12886, § 6(a)(3)(C). No such analysis has been provided with respect to the Proposed Rule.

- Executive Order 12898: Pursuant to this Order, environmental human health research must "include diverse segments of the population in epidemiological and clinical studies, including segments at high risk from environmental hazards, such as minority populations, low-income populations and workers who may be exposed to substantial environmental hazards." EO 12898, § 3-301(a). Minority populations and low-income populations are also guaranteed an opportunity to comment on the development and design of research strategies undertaken per the Order's direction. EO 12898, § 3-301(c). In failing to assess the ramifications of the Proposed Rule on

[11] On this point, the Proposed Rule only says that data will be made publicly available "in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." It is entirely unclear how EPA means to satisfy this direction, which is diametrically opposed to the Proposed Rule's requirement that EPA make an unprecedented amount of protected scientific data publicly available.

this Order's mandates, the Proposed Rule offers only a conclusory determination that "this action does not concern an environmental health risk or safety risk." 83 Fed. Reg. 18773. But the Proposed Rule would directly impact the nature of human health studies upon which decisions to regulate environmental hazards are based, implicating Executive Order 12898's mandates. EPA should provide an analysis of the Proposed Rule's impact on inclusion of diverse communities in studies relied upon for rulemaking purposes.

- Executive Order 13054: Per this Order, federal agencies "shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children…." EO 13054, § 1-101(a). In the case of a "significant regulatory action" such as the Proposed Rule, the promulgating agency must provide an evaluation of health or safety effects of the planned regulation on children and an explanation of why the proposed regulation is preferable to other reasonably feasible alternatives. EO 13054, § 5-501. EPA has not provided any such analysis of the Proposed Rule.

- Executive Order 13563: This Order directs that "[o]ur regulatory system…must be based on the best available science." EO 13563, § 1(a). Consistent with Executive Order 12866, Executive Order 13563 requires a cost-benefit analysis and mandates that federal agencies adopt regulations only upon a determination that the benefits of the regulation outweigh its costs. The Order also requires agencies to "identify and assess available alternatives to direct regulation…." EPA has entirely failed to assess the costs and benefits of the Proposed Rule, or to even make mention of its possible costs and benefits. Nor has EPA analyzed any possible alternatives to the Proposed Rule, instead asking the public to provide suggested alternatives. This directly contradicts the requirements of the Order.

In short, EPA lacks authority to adopt and implement the Proposed Rule; the Proposed Rule conflicts with multiple federal laws, including laws EPA is charged to properly administer; and the Proposed Rule is out of step with several Executive Orders. Accordingly, the Proposed Rule should be withdrawn.

II. The Proposed Rule Paralyzes The Regulatory Process Instead Of Enhancing Transparency

EPA purports to be promulgating the Proposed Rule to enhance transparency in regulatory decision-making processes, but its true effect would be to paralyze those processes while

offering no guidance for scientists working to provide relevant and high caliber information to the Agency. The Proposed Rule disregards settled scientific standards and drums up a transparency problem that does not exist,[12] one based on questions of data availability instead of study reliability. It adds nothing to—and in fact completely ignores—the complex discussions within the scientific community about how best to achieve additional transparency and enhance replicability while maintaining commitments to patient confidentiality and production of high quality science. And its vague language suggests unpredictable implementation that will only further interfere with EPA's mission to protect public health and the environment.

1. **The Proposed Rule Is Unnecessary To Ensure The Best Science Is Used, And Ignores The Scientific Community's Approach To Transparency**

The Proposed Rule's focus is on the public availability of data, distracting from what scientists agree should be the true goal of transparency in science-based decision-making processes: ensuring the integrity of research by subjecting it to established standards for reliability.[13] The rule also ignores the complex and thoughtful discussions about additional transparency within the research process that are ongoing within the scientific community. Instead of consulting scientists and scientific organizations like the National Academies of Science and the EPA Science Advisory Board about legitimate ways to augment transparency, EPA is twisting the concept of transparency to justify a rule that limits the Agency's ability to make important regulatory decisions based on sound science.

As described below, EPA already has in place a robust process for determining studies' reliability; achieving the additional transparency gains sought by the scientific community, while a laudable goal, is not best achieved through this rule.[14] EPA has spent decades

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[12] A group of 985 scientists concur, in a letter reacting to the potential adoption of the Proposed Rule. *See* 985 Scientists, *Don't Restrict EPA's Ability to Rely on Science* (April 23, 2018), *available at* https://s3.amazonaws.com/ucs-documents/science-and-democracy/secret-science-letter-4-23-2018.pdf ("Proponents for these radical restrictions purport to raise two sets of concerns: reproducibility and transparency. In reality, these are phony issues that weaponized 'transparency' to facilitate political interference in science-based decisionmaking, rather than genuinely address either.").

[13] *See, e.g.*, Wagner and Steinzor, *Deconstructing Regulatory Science* (June 19, 2018), *available at* https://www.theregreview.org/2018/06/19/wagner-steinzor-deconstructing-regulatory-science/.

[14] *See* footnote 9, *supra* (explaining that "The EPA proposal is not necessary to assure people that the studies have been reasonably conducted because the study protocols, recruitment

creating and implementing an elaborate system to ensure the best scientific research serves as the basis for its regulatory actions.[15] This system already includes vigorous peer-review requirements, ethical standards, and independent review by scientific professionals.[16, 17] According to EPA's own IQA guidelines, EPA "maintain[s] a robust quality system that addresses [information collected through contracts with EPA; information collected through grants and cooperative agreements with EPA; and information submitted to EPA as part of a requirement under a statute, regulation, permit, order or other mandate] by including regulatory requirements for quality assurance for EPA contracts, grants, and assistance agreements."[18] This includes an Agency-wide Quality System that requires, among other things, a quality assurance manager and Quality Assurance Project Plan for projects and tasks that involve the use of environmental data, and a Peer Review System that requires major scientifically- and technically-based Agency work product to be peer reviewed.

EPA is charged not only with conducting research on pollution's adverse effects and how they can best be controlled, but also with "strengthening environmental protection

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criteria, measurement techniques, and statistical modeling methods including lists of the adjustment variables have all been made publicly available, and peer reviewed.")

[15] Among the many requirements of this system is a mandate that proposed regulations pursuant to the environmental statutes administered by the EPA be submitted to the Science Advisory Board ("SAB") for review and comment, along with supporting scientific and technical information, if they are provided to another federal agency for review. 42 U.S.C. § 4365(c)(1). On June 28, 2018, the SAB recommended that EPA seek the SAB's consideration of the Proposed Rule's scientific and technical basis. We urge EPA to heed the SAB's recommendation and provide the SAB an opportunity to review and provide scientific advice on the Proposed Rule.

[16] *See, e.g.*, EPA, *The NRC Risk Assessment Paradigm*, available at https://www.epa.gov/fera/nrc-risk-assessment-paradigm ("To estimate potential health impacts associated with environmental exposures, EPA scientists and others have spent more than two decades developing an extensive set of risk assessment methods, tools, and data to estimate environmental health risks.") EPA follows the risk assessment and risk management paradigm set forth by the National Academy of Sciences' National Research Council, and its risk assessment methodology "has been extensively peer reviewed." *Id.*

[17] For example, EPA uses the Integrated Risk Information System ("IRIS") to characterize the health hazards of chemicals found in the environment. The IRIS process applies principles of systematic review to identify pertinent studies; review the studies' methods and quality; select studies that will be used to derive toxicity values; and subject those values to internal, interagency, and external peer review before arriving at a final assessment. EPA, *IRIS Assessment Development Process* (2015), *available at* https://www.epa.gov/sites/production/files/2015-09/iris_process_figure_2015.jpg.

[18] See footnote 6, *supra*, at p. 7.

programs and recommending policy changes." President Richard M. Nixon, *Special Message from the President to Congress About Reorganization Plans to Establish the Environmental Protection Agency and the National Oceanic and Atmospheric Administration* (July 9, 1970). EPA cannot properly fulfill this role unless it makes use of the best available scientific information, regardless of data availability to the public. The Proposed Rule would replace EPA's existing successful process, which is in step with established scientific procedures,[19] with one driven by the public availability of data, and unconcerned with well-established hallmarks of reliable scientific research, like peer review requirements. This emphasis is inappropriate, given the courts' agreement that publicizing the data underlying studies upon which EPA relies "would be impractical and unnecessary." *American Trucking Ass'ns*, 283 F.3d at 372; *see also Coalition of Battery Recyclers Ass'n*, 604 F.3d at 623. In short, the Proposed Rule sets out to solve a problem EPA does not have, and does so at great expense to the Agency's mission. By the time EPA relies on studies, they have already been rigorously vetted by other scientists and through internal review processes. The Proposed Rule would reduce, not enhance, the quality of data available to EPA as it considers important regulatory actions.

The result of this process overhaul would be to restrict EPA's use of critical research in key decisions that impact public health and the environment, even when that research is peer-reviewed, because of insurmountable hurdles—among them patient privacy concerns and the practical inability to locate and release data for older peer-reviewed studies—to making underlying data publicly available. Both existing and future agency actions would be affected: the Proposed Rule would impact updates to existing standards that have been supported by important, validated epidemiological studies for which the underlying data cannot be made available, and would undercut EPA's ability to properly assess the benefits of potential future regulatory actions by shrinking the universe of scientific information EPA can rely upon to assess those benefits. None of this will further the scientific community's interest in ensuring the best research is used to support regulation.

2. The Proposed Rule's Poor Drafting Would Lead To Unpredictable Implementation

In addition to the Proposed Rule's procedural deficiencies and conflicts with existing law, the rule's ambiguous language would result in inconsistent and arbitrary implementation.

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[19] *See* footnote 13, *supra*.

Because the Proposed Rule provides the Administrator with broad discretion to waive the rule's requirements, all future decisions about the use of science in regulatory decision-making are left to the Administrator's whims. This dangerously places key decisions about the use of science in the hands of a political appointee, with no requirement to consult scientific experts or meet objective standards in applying exemptions. This creates the potential for significant inconsistency in future regulatory decision-making even when the scientific community has reached consensus on the underlying issue. The Administrator may grant exemptions on a case-by-case basis, and the circumstances under which such a waiver may occur are ill-defined at best.[20] The Administrator need only decide that it is not "feasible" to make data available for a particular regulatory action or to conduct independent peer review on certain "pivotal regulatory science," with no requirement to employ specific scientific standards or make findings in support of an exemption determination. 83 Fed. Reg. 18774. The resulting "black box" exemption process would provide no guidance to the scientific community on how to conduct studies that meet the Proposed Rule's requirements (or qualify for an exemption) and can thus serve as meaningful tools for EPA under the new regulatory regime.

The Proposed Rule also requires the EPA to explicitly consider a long list of risk-assessment models provided by stakeholders "when available." 83 Fed. Reg. 18774. There are no limitations provided on the number of additional studies that must be reviewed, nor any defined timeframe within which studies must be submitted for consideration, meaning that regulatory activities could be significantly delayed as additional models are submitted for EPA review. Nor does the Proposed Rule provide a framework for EPA's consideration of additional studies and incorporation of any review into the rulemaking process. The result is still more ambiguity, decreasing the efficacy of the regulatory process and increasing the potential for legal challenges to define the role of these additional studies.

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[20] A recent Administrative Conference of the United States recommendation outlines several best practices for agencies exercising waiver or exemption authority, including establishing standards and procedures for exercising waivers, making those standards available to the public, providing written and publicly-available waiver determinations, ensuring similarly situated parties are treated similarly, and delineating a duration for waivers. None of these suggested best practices are incorporated as part of the Proposed Rule. *See* Administrative Conference of the United States, *Administrative Conference Recommendation 2017-7 – Regulatory Waivers and Exemptions* (December 15, 2017), *available at* https://www.acus.gov/research-projects/regulatory-waivers-and-exemptions.

III. The Proposed Rule Suffers From Procedural Deficiencies

In addition to the substantive deficiencies discussed above, EPA has failed to satisfy the appropriate procedural requirements for the Proposed Rule's promulgation.

First, the Notice of Proposed Rulemaking does not meet the federal Administrative Procedure Act's ("APA") requirement to cite adequate authority providing a basis for EPA's promulgation of the rule. *See* 5 U.S.C. § 553(b)(2) (requiring that an agency make reference to the authority under which the rule is proposed in a notice of proposed rulemaking). As discussed, none of the statutory authority identified by EPA authorizes it to support the proposed rule, and further, EPA has solicited comment on this basic question, asking the public to supply the basis for EPA's rulemaking authority. This is not permissible under the APA.

The Notice of Proposed Rulemaking, by soliciting comment on the very nature of the rule itself, also suggests that EPA could adopt a Final Rule that deviates significantly from the Proposed Rule, an outcome which would violate the APA's notice provisions were the rule not first subjected to another round of notice and comment. 5 U.S.C. § 553(b)(3); *see National Black Media Coalition v. FCC*, 791 F.2d 1016 (2d Cir. 1986) (final rule that deviated significantly from notice of proposed rulemaking did not provide the public with adequate opportunity to engage in the rulemaking process as required by the APA). Given the Proposed Rule's potential to affect scores of significant regulatory decisions, its brevity and ambiguity are breathtaking. Indeed, the Proposed Rule is more akin to a brainstorming document than a precisely noticed regulatory action. Without a clear statement of the Proposed Rule's reach and implications, members of the public cannot engage as informed participants in the rulemaking process, the very purpose of the APA. As the Third Circuit recognized in *Prometheus Radio Project v. FCC*, 652 F.3d 431, 450 (3d Cir. 2011):

> "…there must be an exchange of views, information, and criticism between interested persons and the agency…Consequently, the notice required by the APA…must disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based…**[A]n agency proposing informal rulemaking has an obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible.**" (*quoting Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977) (internal citations and footnotes omitted))

Here, despite EPA's purported commitment to transparency, the Proposed Rule contains no "concrete and focused" explanation of its impacts upon which the public can rely to formulate opinions regarding the rule's potential adoption. For example, nowhere does the Proposed Rule assess possible impacts on environmental quality and public health from implementation of this rule, including the likelihood that EPA would be unable to consider important scientific research in its rulemakings and other activities; discuss how issues associated with patient privacy and confidential business information will be resolved; or identify any authority or data supporting the rule's promulgation.

Instead, the Proposed Rule creates a confused and muddled picture, soliciting comments on "additional or alternative sources of authority" for the rulemaking and "whether other alternative or additional regulatory or other policy vehicles on a programmatic or statutory level would be appropriate as alternative or additional steps." 83 Fed. Reg. 18769, 18771. Far from satisfying the APA's requirements, the Proposed Rule entirely fails to "describe the range of alternatives being considered with reasonable specificity." *Horsehead Res. Dev. Co. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) (*citing Small Refiner Lead Phase–Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983)). In other words, the Proposed Rule, on its face, provides the public with no opportunity to understand the authority for its implementation or precisely how its mandates would apply to future regulatory decision-making, and leaves the door open to adoption of a Final Rule that looks very different from EPA's proposal. Given the vagueness of the Proposed Rule and the broad request for comments, EPA must engage in another round of notice and comment before finalizing the rule if it intends to follow any substantive suggestions offered by commenters.

Furthermore, the Proposed Rule is arbitrary and capricious, as written and as it would be applied. *See* 5 U.S.C. § 706(2)(A) (an agency's action can be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"). For example, the Proposed Rule applies only to EPA regulatory actions, which often regulate industry to protect human health and the environment, and omits from its ambit Agency adjudications, which often involve private companies seeking regulatory exemptions or permissions from EPA and are more likely to implicate industry-provided studies that are specific to the particular adjudication in question. The Notice of Proposed Rulemaking offers no explanation for this distinction, but documents obtained through the Freedom of Information Act suggest that EPA introduced the distinction mid-way through the rulemaking process, when the Agency realized the implications of its Proposed Rule for pesticide registration proceedings, many of which rely on industry-generated and

proprietary data, which cannot be publicly disclosed.[21] Similarly, while the Proposed Rule suggests that EPA "should be guided by this policy to the maximum extent practicable during ongoing regulatory action," it also provides that the Administrator—and the Administrator alone—would be empowered to offer case-by-case exemptions in myriad instances. *See* 83 Fed. Reg. 18771. As discussed above, this would likely lead to inconsistent application of the Proposed Rule, suggesting its implementation would be arbitrary at best.

Implementation of the Proposed Rule could also impair future Agency rulemaking actions by forcing EPA to ignore key comments and regulatory record evidence in violation of the APA. *See Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983) (an agency must "examine the relevant data" and acts arbitrarily and capriciously when it "entirely fail[s] to consider an important aspect of the problem"). For example, if a commenter were to cite studies that are based upon data that is not entirely publicly available, the Agency would not be able to consider those studies—or fully evaluate the comment—as part of the rulemaking action, regardless of the scientific validity of the comment. In other words, the Proposed Rule would expose the Agency to challenges not only to arbitrary and capricious application of the rule itself, but also to the arbitrariness of future rules.

Simply put, the Proposed Rule fails to satisfy the basic requirements of the APA and denies the public a meaningful opportunity to engage in this rulemaking process and in future rulemaking processes.

IV. The Proposed Rule Is Ill-Conceived Policy

Beyond these legal deficiencies, adoption of the Proposed Rule would be bad public policy: hastily implemented, expensive for taxpayers, and harmful to individual privacy.

First, the Proposed Rule would be effective immediately upon adoption, rather than including any sort of implementation schedule that recognizes the significant practical challenges of applying the rule. Putting the Proposed Rule into practice would mean that EPA would need to gather and make available enormous amounts of data, requiring the Agency not only to acquire that data, but also to devise a system to manage it; secure its

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[21] See Science Magazine, *Trump's EPA wants to stamp out 'secret science.' Internal emails show it is harder than expected* (April 20, 2018), available at http://www.sciencemag.org/news/2018/04/trump-s-epa-wants-stamp-out-secret-science-internal-emails-show-it-harder-expected; The Hill, *Internal emails show EPA working to limit agency's use of science* (April 19, 2018), available at http://thehill.com/policy/energy-environment/384039-internal-emails-show-epa-working-to-limit-agencys-use-of-science

storage; appropriately redact data; ensure data subject to HIPAA and other privacy laws or otherwise considered to be confidential is not disclosed; and implement "feasibility" exemptions to the rule. But the Proposed Rule does not provide for any phase-in time to establish the complicated procedures that will be necessary, meaning that any ongoing or planned rulemaking processes will be stalled or thwarted upon the rule's adoption as EPA struggles to take practical steps towards rule implementation. This would not only stymie necessary regulation, but would also, as discussed above, leave the scientific community in the dark as it attempts to design and carry out studies to provide high quality information EPA can use to make informed decisions.

Second, EPA's proposal ignores the significant costs of the rule. Based on prior estimates of the costs associated with the proposed HONEST Act, the Proposed Rule's costs could tally in the hundreds of millions of dollars, particularly given challenges associated with creating an appropriate infrastructure for the implicated data. These costs are not disclosed to the public anywhere in the Proposed Rule. Also unanalyzed are the public health costs that would inevitably result if EPA is constrained in its ability to use the best research to support its future decision-making.

Finally, the rule's emphasis on publicly available data would have the perverse effect of discouraging individual participation in scientific studies due to personal privacy concerns. Potential study subjects, uncertain about EPA's willingness or ability to protect their identities and sensitive health information, would be more likely to be hesitant about participating in any study that could inform an EPA regulation. As a result, researchers could face increased difficulty in attracting subjects for crucial studies, reducing the availability of scientific information upon which to base EPA's decisions. The studies upon which EPA would be forced to rely could be less rigorous and trustworthy; the fact that a study's underlying data is publicly available has no bearing on the quality of the data or the study,[22] and ground-breaking research on the health and environmental effects of pollution often relies upon the very kinds of highly sensitive data that would be most likely to be excluded from EPA review if the Proposed Rule were to be implemented.

Indeed, notably missing from the Proposed Rule is any explanation of how sensitive personal data of the kind often utilized in scientific studies, particularly public health studies, will be shielded from public disclosure. In addition, as we have discussed above, the rule's language is inconsistent with existing laws protecting patient information. While EPA specifically solicits comment on balancing "increased transparency" with protection for

[22] See footnotes 9 and 10, *supra*.

copyrighted or confidential business information, when it comes to sensitive personal data, EPA has asked for input only on how to "provide protected access," not how to balance that access with appropriate privacy protections, creating the impression that no such balancing calculus is required in the case of individual health data. 83 Fed. Reg. 18774. This focus overlooks the significant personal privacy pitfalls of the Proposed Rule.

The Proposed Rule's legal deficiencies are numerous, but its policy implications are no less troublesome. The rule is unnecessary and antithetical to the use of the best science in EPA's decision-making, and should accordingly be withdrawn.

V. Conclusion

As legal scholars, we find the Proposed Rule deeply concerning. Far from promoting transparent regulatory decision-making, the rule would institute an arbitrary process to stymie EPA's use of the most relevant science in key regulatory decision-making processes, at great cost to the public.

EPA is charged with making critical choices that impact human health and safety and the preservation of our environment. The rule's ill-considered, inadequately noticed, and overwhelmingly vague proposal would make sweeping changes to the way EPA makes those choices with barely any thought given to the incredibly complex regulatory, scientific, and privacy issues implicated.

These decisions are simply too important to be made without the benefit of the best information science has to offer, or to be subjected to an ill-thought-out process that even EPA cannot clearly articulate. We therefore urge EPA to withdraw the Proposed Rule.

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