

Comments of the Environmental Protection Network on EPA's Proposal entitled "Strengthening Transparency in Regulatory Science"
83 Fed. Reg. 18768 (April 30, 2018)
EPA-HQ-OA-2018-0259
FRL-9977-40-ORD

I. Introduction and Summary

A. Introduction

On April 30, 2018, Administrator Pruitt proposed a rule for setting regulations that would generally require the Environmental Protection Agency (EPA) to ignore any scientific studies for which the underlying data has not been made publicly available. 83 Fed. Reg. 18768 (April 30, 2018). This document sets out the comments on this proposal of the Environmental Protection Network (EPN), a bi-partisan organization of former EPA employees and others who have come together to provide an informed and rigorous defense against efforts to undermine the protection of public health and the environment. Our analysis of this proposal leads us to urge strongly that Acting Administrator Wheeler withdraw this proposal in view of its many legal, policy and logical defects.

B. Summary

1. General Overview

EPN urges Acting Administrator Wheeler to withdraw this extremely defective proposal which announces a rule ostensibly to support "transparency" in science in a document that is anything but transparent, using evasive language and misdirection to conceal the true effect of the rule: to censor available, useful, and reliable science by prohibiting EPA from using it to inform decisions to protect public health from environmental harm. The preamble buries this prohibition under a host of repetitive and unsupported platitudes about increasing "transparency"

without addressing either the legal basis for the rule or its effect on EPA decision-making. In addition, the proposal is riddled with undefined or ambiguous terms and unclear language making it hard to discern more than a general outline of its likely effects. If “the devil is in the details” the proposal keeps him well hidden.

It is either incoherent or duplicitous in using permissive language in section 30.4 providing that “EPA *should* make all such studies available to the public to the extent practicable” and burying in a footnote the interpretation that the proposal would “preclude” the use of studies where the raw data cannot be made available. Indeed, it doesn’t even name certain key studies it would prevent EPA from using, burying that information in the same footnote hidden behind citations to two court decisions and leaving it to the reader to sift through the cases to find the names of the studies. The proposal is vague and evasive about what programs it will affect, its legal basis or how it will be implemented. Instead of explaining how to implement the rule, it asks commenters for guidance about the legal basis for the rule and how to implement it.

In sum, the proposal is so unclear it fails “to disclose to the public the bases for agency rules” or “adequately explain agency actions” as required by the Administrative Procedure Act, and for that reason alone the agency cannot go final based on its current language and record. The agency’s best course of action would be to withdraw this proposal.

Even so, its most severe flaw is substantive: there is neither a legal basis nor a need for this rule; it would require that EPA violate explicit statutory provisions; and it would undermine environmental protection. It unlawfully shifts the basis for deciding what science to use in rulemaking away from the statutory goals of scientific reliability and environmental protection to

“transparency,” but points to no authority under any EPA statute authorizing EPA to reject science on that basis. The proposal is also unlawful because EPA has not demonstrated a need for any rule at all, much less one that would sweep across at least eight different statutes. It is too full of undefined or ambiguous terms to create a workable legal framework.

In sum, it is unlawful for both substantive and procedural reasons: because it misuses science, fails to show a lawful basis for its proposed approach, likely will lead to rulemaking that violates EPA statutes that govern use of science in rulemaking, and will reduce environmental protection. Its substantive defects are even greater than its procedural errors.

2. Outline of Argument

These comments proceed as follows to develop the points summarized above.

a. Description of the proposal

We begin with a description of EPA’s proposal, showing that: (1) It neither cites nor discusses **any** of the statutory provisions whose implementation the proposal would affect; (2) It fails, in similar fashion, to either identify or discuss any of the policy issues raised by the radical step it proposes; and (3) Though EPA lists a number of documents as relevant to its position, the agency does not claim that they actually support that position. On closer examination, they do not. Indeed, several of the authors of those documents have repudiated EPA’s interpretation.

b. Analysis of general deficiencies

The comments then set out a deeper analysis of the proposal’s deficiencies. (1) We begin by explaining the irrelevance of the statutory provisions that the proposal cites and setting out some of the provisions it should have cited -- provisions whose requirements the proposal does not address, and (2) the comments then turn to the proposal’s general lack of any of the policy

justifications that the law requires, beginning with an overview of those requirements. Based on that, they explain:

- That the relevant but uncited governing legal provisions make protection of public health based on the best available science their touchstone - a topic the proposal does not analyze at all. Although the proposal makes “transparency” the deciding factor as to whether information can be used, most of the governing statutes do not even contain this term.
- That there is no evidence of a problem with the quality of the science underlying EPA decisions. On the contrary, the original studies of air pollution most clearly and directly targeted by the proposal have long-since been reproduced through an independent reanalysis. More importantly, they have been repeatedly updated and replicated by other researchers using different data in a process that must be regarded as a model of regulatory science. No regulatory or scientific research body that we know of requires automatic data disclosure before a study can be considered reliable. The proposal in no way explains why EPA should be different.
- That contrary to the proposal’s suggestions, making the raw data underlying a study available will often be impossible or impractical, and unnecessary to ensure the study’s reliability. For many older studies, either the data no longer exist or are subject to promises of confidentiality that were made long ago and cannot be retracted. Designing even current studies so that data can be made available to qualified researchers for reanalysis can significantly increase the

difficulty and cost of protecting confidential personal information. Requiring data used in new studies to be fully available to the public can lead to a loss in study quality by omitting important data such as location, or making by it more difficult to recruit participants concerned about protection of their confidential personal information.

- The proposal does not even mention the impact that a bar on the use of such studies would have on regulations designed to protect public health, even though EPA exists for the central purpose of protecting public health. But there is every reason to expect it would be massive.
- Similarly, the proposal mentions the fiscal costs of implementation only in passing, and those passing comments severely understate them.

c. Analysis of statute-specific defects

For all the reasons just given, the policy justification for the proposal is inadequate. The proposal would apparently change the workings of **all** of the EPA's cited regulatory statutes, making key parts of regulatory decisions under each of them in advance. Accordingly, it must be justified as an exercise of regulatory authority under each such statute.

It is the agency's job, not EPN or any other commenter's, to provide that justification. However, to show how far short the proposal falls, the next section of EPN's comments explores in detail the deficiencies in the justification of this proposal under the cited statutes, and then examines in more detail three of the agency's most important regulatory mandates - the ambient air quality standards provisions of the Clean Air Act (CAA), the drinking water standards

provisions of the Safe Drinking Water Act (SDWA), and the general chemical regulatory provisions of the Toxic Substances Control Act (TSCA).

d. Why the proposed waiver provision cannot save the proposal

EPA proposes to give the Administrator power to waive the per se rule that it proposes. We demonstrate that this waiver provision makes no legal difference, and would not make one even if the waiver provisions were far better designed than the tissue of generalities that EPA has presented.

e. The proposal's misuse of the authorities it cites

Next, the comments explore in more detail --and amplify in Appendix D-- the authorities that EPA refers to in its proposal. We show that in no case do the authorities actually support the proposed position. Indeed, the more thoroughly they are examined, the less support they provide. And in some cases they point away from the proposal. Moreover, the authors of several of the cited studies have expressly repudiated EPA's attempted use of their work. For example, though the proposal cites the "replication crisis" in science as support, Dr. John Ioannidis, the author of the seminal article calling attention to this problem, specifically repudiates the adoption of a per se rule.

f. Broader substantive defects

Our comments then address broader defects in the proposal. We explore the ideological and partisan origins of the proposal - origins that have nothing to do with its ostensible purpose. We explain that this proposal, in defiance of logical consistency, would apply its new requirements **only** to one type of agency action, major rulemakings, and not to any other actions such as enforcement, permitting, and pesticide registration that may have substantial effects on

public health. The proposal fails to face up to the fact that it will result in two different definitions of science applicable to EPA actions, much less explain how this would work in practice. It is jarring to understand it will be applied to reject use of scientific studies in a host of broadly applicable regulatory decisions to protect public health, many of which impose costs on industry, private persons and governments, but allow them to be used in individual regulatory decisions of the kind that typically benefit industry, such as issuing permits or approving chemicals for use. Finally, we explore the implications of this approach - implications that EPA does not even mention - for other agencies of the government and for state and tribal governments.

g. Why EPA's document is not even a valid proposal

We conclude by demonstrating that in addition to its substantive defects, this proposal totally fails to meet the legal standards for a valid proposal on which a final rule could be based, because of the myriad ways it fails to provide adequate notice as to its substance and basis. Consequently, we request that it be withdrawn.

II. Summary of the Proposal

A. What the Proposal Provides

This proposal would establish a per se rule to require the agency to disregard, in setting regulations, any scientific studies for which the underlying data has not been made publicly available.

This is not apparent on the face of the proposal, much of which consists of bland generalizations about the importance of “transparency” and vague statements about increasing

access to relevant data “over time,” and releasing certain information “where available and appropriate.” 83 Fed. Reg. 18770.

But language buried in footnote 3 to the proposal makes clear its true intentions. That footnote reads:

EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA’s use of non-public data in support of its regulatory actions.¹

EPA is proposing to exercise its discretionary authority to establish a policy that would *preclude it from using such data in future regulatory actions*. 83 Fed. Reg. 18769 n.3 (emphasis added).

None of the statutes cited in the proposal provide EPA with the discretionary authority to disregard such data. The cases cited in the footnote involved two of the most consequential EPA regulations, namely the national ambient air quality standards for lead and for fine particles. The studies at issue were the Lanphear study for lead and the Harvard Six-City and American Cancer Society studies for fine particles. EPA is surely aware of the extensive history involving industry challenges to those studies. In the two cited cases, industry had challenged EPA’s reliance on those particular studies, arguing in each case that the underlying data should have been disclosed. In each case, EPA addressed the comments on their merits, finding, with support in the record, that the studies were reliable as they stood despite the criticisms. *Both courts agreed* that there was no need for disclosure. The current proposal claims discretionary authority--for which it identifies no basis--to ignore those considered responses in favor of categorically disregarding such repeatedly examined studies.

¹ See *Coalition of Battery Recyclers Ass’n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass’ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002).

This illustrates the revolutionary scope of this initiative. Perhaps to obscure that point, aside from those studies, the proposal does not identify any of the numerous other studies it would exclude, leaving the public in the dark about how much science the proposal will censor.

EPA also proposes problematic and ill-conceived new requirements that would invalidate EPA's existing guidance regarding dose-response models used in risk assessments that support regulations. This confusing language may also require that the agency undertake costly and unnecessary re-analyses of all key studies at issue in regulatory decision-making. It would, by regulation, establish ambiguous criteria for evaluating, analyzing, evaluating dose-response relationships, and peer reviewing such studies that would supersede long-established EPA guidelines and practice, and would be inconsistent with the recommendations of the National Academy of Sciences (NAS) and other external science advisors. We discuss that part of the proposal in Appendix A.

B. EPA's Support for its Radical Changes

Since, as EPA admits, these changes are not legally required, the agency must justify its proposal as a proper exercise of discretion under some statutory authority. The proposal attempts to do this by (1) citing legal authority; (2) briefly discussing the policy reasons that it claims justify the proposal; and (3) outlining, at somewhat more length, largely in a list of footnotes containing little or no explanatory information, the supporting positions allegedly taken by other organizations and experts.

1. *Legal Authority*

EPA lists 14 statutory provisions as support for its proposal.² On examination, these are all³ either general rulemaking authorities or general research authorities; none of them has anything to do with how to use science in decision-making. Moreover, the proposal does not expressly say--as a well-drafted and genuinely transparent proposal should-- that it will only apply to the programs under the cited statutes (although that may be implicit), much less discuss in any way the policies those programs embody or why the proposed per se rule would be a proper exercise of discretion under each statute. Indeed, the cited provisions, virtually the only statutory authority the proposal cites as support, are irrelevant to the per se issue.

2. *Policy Discussion*

EPA's policy discussion in support of its proposal is short, rambling and hard to follow, but one long quotation will give an adequate idea of its flavor:

The best available science must serve as the foundation of EPA's regulatory actions. Enhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions. By better informing the public, the Agency in [sic] enhancing the public's ability to understand and meaningfully participate in the regulatory process. In applying the best available science to its regulatory decision-making, EPA must comply with federal transparency and data integrity laws, and must also ensure that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility. [footnotes omitted]
(83 Fed. Reg. 18769)

² They are: Clean Air Act sections 103,301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C.1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C.300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1),6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660;Emergency Planning and Community Right-To-Know Act section 328, 42U.S.C. 11048; Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w;and the Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609. 83 Fed. Reg. 18769

³ One apparent exception appears to be RCRA 7009, which addresses labor standards and not science and which is incorrectly included on the list; a more carefully drafted proposal would have used the correct citation to research authority, RCRA 8001.

This string of platitudes says nothing about the real issues. It simply assumes that there is a pressing need to “enhance the transparency and validity” of science supporting EPA regulatory actions, that the proposed per se rule would provide that enhancement, that a per se rule will not affect the ability to achieve other statutory goals, that there are no other approaches to increasing transparency that would avoid those drawbacks, and that it will be easy and uncomplicated to provide for universal data disclosure at no real cost. But it offers no substantial support for either of its two bedrock assumptions, that “transparency” and “validity” are inseparable and that excluding use of reliable science will somehow ensure, rather than prevent, use of “best available science.”

Later in these comments we will show how far short the proposal has fallen of providing a valid policy discussion in support of this rule - a shortfall that makes its proposal indefensible both procedurally and in substance.

3. Claimed Sources of Supporting Authority

The agency references a list of authorities that it claims support the proposal. Many of these are identified only in footnotes without explanation of their relevance, which provides no more illumination than is found in its “discussion” of legal or policy matters. It focuses on two areas: the proposal itself, and the procedures and policies that are available for making the data underlying studies available. We will address each in turn summarily here, and provide much more detail in Appendix D.

a. Authorities said to support the proposal

EPA cites more than twenty separate authorities to buttress its proposal. But interestingly, it never says that any of these authorities actually **support** the proposal. Broadly speaking, it

claims that support of three types is available: federal executive orders and policies and the practices of other federal agencies, third party endorsements of “open science,” and practices followed by science journals. Here is a list of some of the references, and how EPA characterizes them:

- The proposed rule is said to be “consistent with” “the principles underlying the Administrative Procedure Act”, and those of two Executive Orders that “ focus on transparency.”
- The proposed rule is said to “build upon” prior EPA actions and the actions of other federal agencies, citing four EPA documents and making general references to the experiences of four other agencies.
- The proposal ostensibly “takes into consideration” “the policies or recommendations of third party organizations who advocated for open science”, referring to--without discussing -- a variety of particular policies and recommendations.
- Finally, EPA says the proposal is “informed by” policies recently adopted by major scientific journals, spurred in part by the “replication crisis,”
 - b. Sources cited to show that disclosing underlying data will not raise hard issues

The proposal begins its discussion of this issue by stating that “concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government.” And it glibly refers to a statement of the National Academies that “[n]othing in the past suggests

that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach.”

It then suggests that owing to the variety of different circumstances that will arise, different approaches to data disclosure may be appropriate, citing policies of NIH and a number of scientific publishers. It provides little or no discussion of those circumstances, and glides over the fact that in some cases disclosure may be legally or practically impossible.

The whole discussion proceeds as though this were a discussion of rules of scientific management to be applied prospectively and that nothing in the proposal could be objectionable or will diminish the use of “best available science” in decision-making. The proposal states that it is “intended to apply prospectively,” and never addresses the question of how a regulatory proceeding should treat past or ongoing studies that provide support for a rulemaking or where for one reason or another the underlying data cannot feasibly be made available.

The conclusory nature of this summary demonstrates just how shallow is the proposal’s discussion of the relationship of the various cited authorities to what the proposal intends to achieve. It is impossible to learn from this discussion the real relationship between the various authorities cited---in every case with little or no specific explanation of how they support the proposal--and what EPA actually plans to do. In fact, whenever EPN examined any document cited in greater detail, it found that it does not support the proposal at all, and in some cases does the reverse. In addition, after reviewing the proposal, several of the individuals and organizations EPA cites have opposed EPA’s proposal and expressly repudiated its use of their research and analysis.

III. Discussion of the Flaws in the Proposal

This section examines in more detail the manifold defects of this proposal. We will discuss statutory authority first, and then the need for a detailed policy justification for this radical initiative. In the following two sections, we will demonstrate that EPA's provision of waiver authority cannot save its proposal and will examine EPA's use of the authorities it cites and relies on.

A. The Actually Relevant Statutory Authorities

Any rule must have a lawful basis. The proposal does not even attempt to show that it does. It claims "discretionary authority" for its proposed approach, but identifies no source for such authority. It evades that question by purporting to list "statutes and provisions *specifically* addressing the agency's conducting of and reliance on scientific activity to inform those functions" FR 18769 (emphasis added). It does not explain how those provisions authorize the wholesale redefinition of science. **All** the provisions cited either authorize research, or general rulemaking not tied to any specific purpose.

EPA's proposal would, by operation of law, change the standards for using science in issuing covered rules under *all* of the listed substantive regulatory authorities. It would thereby make in advance a critical part of the regulatory decision in any covered proceeding, namely the decision how to weigh available studies to best evaluate scientific evidence. This is a decision that has previously been made by detailed case-by-case review in the rulemaking itself. Until today, such decisions have been made after considering the substantive goals of the particular

statutory provision involved, guided by the attitude toward scientific evidence embodied in that provision, and striving for conformity with any applicable procedural requirement. The affected provisions are the relevant statutory authorities that EPA's proposal should have cited and discussed, in order to show its consistency with their mandates. EPA's citations to general provisions are insufficient because it is axiomatic that a "general grant of authority cannot trump specific statutory provisions". *NRDC v. EPA*, 749 F. 3d 1055, 1064 (D.C. Cir. 2014); *API v. EPA*, 52 F. 3d 1113, 1119 (D.C. Cir. 1995) (same).

The agency's failure to do this is by itself a fatal flaw in this proposal. It is EPA's duty, not EPN's, to identify and discuss these provisions. However, it is clear from even a brief look that these provisions require EPA to consider **all** the best available science, without authorizing, or even mentioning any of the per se restrictions based on "transparency" that EPA has proposed to use as a universal overriding rule. For these reasons, EPA must justify its proposal as a proper exercise of its authority under **each** of the statutory provisions whose operation it would affect - provisions that the agency does not even cite. It is the job of the proposer, not the commenters, to survey these provisions and provide the needed justification.

In several of the listed statutes Congress has explicitly told EPA how to use science in decision-making.

- SDWA 1412(b)(3)(A) addresses EPA's "use of science in decision-making" by providing that risk assessments "shall" use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."

- EPCRA, 42 USC 11023(d)(2)(C) mandates that a determination whether to add a substance to list of “extremely hazardous substances” “*shall* be based on generally accepted scientific principles or laboratory tests or appropriately designed and conducted epidemiological or population studies available to the Administrator.”
- CWA, 33 USC 1314(a)(1) mandates that the Administrator “*shall* develop and publish ... criteria for water quality accurately reflecting the latest scientific knowledge” “on the kind and extent of all identifiable effects on health or welfare” in setting water quality standards;
- CAA 108(a)(2) specifies that “air quality criteria for an air pollutant *shall* accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air.”
- TSCA 15 USC Section 2605 (h) provides that “the Administrator *shall* use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science.”

These provisions all use mandatory language directing EPA to use reliable and relevant scientific information -- and further specify how to do so. They all direct that decisions regarding protection of public health be based on the full range of relevant scientific information, in some cases specifying how to identify what information to use. None of them give EPA discretion to ignore such information for any of the reasons set forth in the proposal.

Other provisions prescribe factors EPA must use in making decisions. FIFRA, 7 USC 136a-1(g)(1) requires that EPA “*shall* conduct a thorough examination of all data submitted under this section concerning an active ingredient ... and of all other available data found by the Administrator to be relevant.” The Comprehensive Environmental Response Compensation and Liability Act (Superfund) requires that EPA rules setting cleanup priorities “shall be based upon relative risk or danger to public health or welfare or the environment... taking into account to the extent possible” seven enumerated factors related to risk.

Like the express science provisions discussed above, both of these provisions are mandatory and prescribe specific factors EPA must assess. Neither offers any basis for failing to consider such factors or evidence regarding such factors because it is supported by science that is not “transparent.” When Congress wished to limit available science to information that is publicly available, it has done so. See CWA Section 311(a)(27), 33 USC 1321(a)(27) (for purposes of addressing oil and hazardous substance liability, “best available science” is defined as evidence that “uses peer reviewed and publicly available data”). Its failure to impose such limits on the use of data or science in the provisions discussed above is thus purposeful. As noted, the proposal does not even mention any of these relevant statutory requirements governing the use of science or data or information, much less explain how any of them could authorize EPA to make a decision without using information that is relevant to decision-making, solely for lack of transparency and regardless of reliability or relevance. None of these statutes provide EPA with any authority to pick and choose what reliable and useful science to use or ignore specific studies based on transparency. While the proposal misleadingly pays lip service to using the best available science, it would expressly “preclude” the use of reliable and available science

that is not, in its characterization, “transparent,” regardless of whether it is the best available science. The proposal does not even mention the governing statutory requirements, much less explain how its approach is consistent with them.

Moreover, numerous courts have indicated that a plaintiff or petitioner can establish a violation of the “best available science” requirement by “point[ing] to any scientific evidence that the agency failed to consider.” *Safari Club Int’l v. Salazar (In re Polar Bear Endangered Species Act Listing & Section 4(d) Rule Litig. - MDL No. 1993)*, 709 F.3d 1, 9 (D.C. Cir. 2013). “The best available data requirement ... prohibits [an agency] from disregarding available scientific evidence that is in some way better than the evidence [it] relies on.” *Kern Cnty. Farm Bureau v. Allen*, 450 F.3d 1072, 1080 (9th Cir. 2006) (quoting *Sw. Ctr. for Biological Diversity v. Babbitt*, 215 F.3d 58, 60 (D.C. Cir. 2000)). “Essentially, [the agency] ‘cannot ignore available ... information.’” *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 602 (9th Cir. 2014) (quoting *Kern Cnty.*, 450 F.3d at 1080-81 (quoting *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988)).“

B. EPA’s Missing Policy Discussion-General Overview

1. *Introduction*

Since no reasonable argument can be made that the proposal is legally required, the only possible theory upon which the rule itself and its categorical nature might be justified is as an exercise of the agency’s discretionary authority to implement particular statutory provisions.

This section of our comments will explore the defects of EPA’s proposal that are probably common to **all** the statutory provisions it would affect. We do this with the significant handicap of being forced to comment on a very spare, uninformative proposal rather than the

more detailed proposal that the law requires, particularly when a proposal would make such far-reaching changes as this one envisions.

We begin by addressing the relevant legal principles.

2. *The Governing Requirements*

EPA has completely failed to follow well-established principles establishing the legal need for reasoned agency decision-making generally, and in particular for any change to a prior position.

To comply with these requirements, an agency must, among other things:

- Explain why the agency is rejecting policy judgments or factual determinations underlying the prior rule or position.⁴
- Provide a “reasoned explanation” for changing course;⁵
- Demonstrate that the new policy is itself consistent with the governing statute;⁶
- Ensure that the new policy is itself supported by the record, “based on consideration of the relevant factors,” and supported with “rational connection[s] between the facts found and the choice made”;⁷ and

⁴ *State Farm*, 463 U.S. at 51 (finding that NHTSA had arbitrarily failed to explain its rejection of option of requiring airbags despite its prior finding “that airbags are an effective and cost-beneficial life-saving technology”); *Pub. Citizen v. Steed*, 733 F.2d 93, 100 (D.C. Cir. 1984) (setting aside suspension of rule because NHTSA “failed to explain why alternatives, which the rulemaking record indicates were available to the agency, could not correct” the problem the agency relied on as a basis for suspending rule); *Int’l Ladies’ Garment Workers’ Union v. Donovan*, 722 F.2d 795, 816 (D.C. Cir. 1983) (agency impermissibly failed to consider alternatives to repeal “raised in [the] original notice and the comments”).

⁵ *State Farm*, 463 U.S. at 42. See also *AMB Onsite Services-West v. NLRB*, 849 F.3d 1137, 1146 (D.C. Cir. 2017) (“It is well-settled that NRLB. . . cannot ‘turn[] its back on its own precedent and policy without reasoned explanation.’”) (quoting *Dupuy v. NLRB*, 806 F.3d 556, 563 (D.C. Cir. 2015)); see *Public Citizen v. Steed*, 733 F.2d 93, 100 (D.C. Cir. 1984).

⁶ See *FCC*, 556 U.S. at 514-15 (new policy must be “permissible under the statute”); see also *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005); *Chevron USA v. NRDC*, 467 U.S. 837, 865-66 (1984); see *Public Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004).

⁷ See *State Farm*, 463 U.S. at 43 (agency decision must be “based on a consideration of the relevant factors” and agency cannot have “relied on factors which Congress has not intended it to consider”) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)); *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004); 42 U.S.C. 7607(d)(9).

- Consider relevant alternatives reflected in the prior rule’s record, in particular, alternatives most consistent with statutory goals and purposes, and explain why the agency is not adopting them in the new rule⁸

The proposal does not comply with any of these requirements. To show that, we will demonstrate below

- That EPA has not demonstrated -or even asserted - that there is any problem with EPA’s approach to science under the relevant (though uncited) statutory provisions.
- That EPA has in no way addressed the difficulties of requiring universal data disclosure; and
- That EPA has massively and systematically underestimated the cost of its proposal both to the environment and public health, and in purely fiscal terms.

3. *EPA’s Proposal Fails to Identify a Problem That Needs Fixing*

- a. EPA’s proposal fails to identify a problem with quality control procedures

For almost fifty years, EPA’s unbroken practice has been to consider and evaluate on their individual merits **all** scientific studies relevant to a regulatory decision, and to give them the weight in that decision that their merits deserve. That approach fits the language of the various regulatory statutes much more naturally than the per se approach of this proposal. Yet this proposal makes no effort to show - or even to claim - that the long-standing approach has proven flawed.

⁸ State Farm, 463 U.S. at 51 (finding that NHTSA had arbitrarily failed to explain its rejection of option of requiring airbags despite its prior finding “that airbags are an effective and cost-beneficial life-saving technology”); Pub.Citizen v. Steed, 733 F.2d 93, 100 (D.C. Cir. 1984) (setting aside suspension of rule because NHTSA “failed to explain why alternatives, which the rulemaking record indicates were available to the agency, could not correct” the problem the agency relied on as a basis for suspending rule); Int’l Ladies’ Garment Workers’ Union v. Donovan, 722 F.2d 795, 816 (D.C. Cir. 1983) (agency impermissibly failed to consider alternatives to repeal “raised in [the] original notice and the comments”).

Similarly, the various statutory authorities list a number of different methods that can be used to assure the validity of the studies they address. The per se bar on use of studies for which data was not disclosed is not among them. Yet the proposal does not address this unfavorable background or explain why those methods are not adequate with enough clarity to justify the need for the proposed approach.

On this point as well, EPA's past practice reflects the governing authorities far better than the current proposal. Before 2017, EPA over the years had developed and refined its approach to these-case-by case assessments, using a variety of methods that include examination of the data underlying studies where it is available, but without exclusive reliance on that examination, much less making it the foundation of a per se rule. Such examinations typically begin with EPA expert staff identifying and assessing peer reviewed studies and studies published in reputable scientific journals.⁹ This includes examining the strengths and weaknesses of individual studies, including factors such as design, the reputation and past work of the researchers, and quality assurance methods and analyses. This is followed by a broader look at the consistency and coherence of the study at issue with similar study types across multiple studies, as well as a more integrated assessment of the weight-of-evidence that considers multiple lines of scientific evidence. The assessments are in turn peer reviewed by panels of EPA's Science Advisory Board (SAB) as well as the public.

In conducting such assessments, greater weight is given to the results of studies that have been replicated by other investigators using different data sets than to individual studies with limited or no replication. Replication refers to additional studies testing the same hypotheses as

⁹ For example, see EPA's process for reviewing the science and policy for criteria air pollutants. <https://www.epa.gov/criteria-air-pollutants/process-reviewing-national-ambient-air-quality-standards>

the original study, typically conducted by other investigators using different study designs and data sets, to see if the same conclusions are reached.¹⁰ As one of the authors EPA cited in the proposal recognized, replication is “the cornerstone of the scientific method.”¹¹ See also Appendix D below. “Designing and conducting a replication study does not require access to raw data from the original study; this would abrogate the concept of independence.”¹² In reviewing the epidemiology studies supporting air quality standards, EPA has placed greater weight on studies that have been replicated. In cases where one or two new studies appear to break new ground, reanalysis by EPA or competent third party investigators can provide some additional credibility, but not as great as that provided by replication.

The proposal completely fails to acknowledge, much less evaluate this past practice. It makes no effort even to argue, much less to demonstrate, that this historical approach does not reflect established scientific practice, or that it has led to bad decisions. In the absence of such an argument, the proposal has not shown that it is necessary to take the extreme step of discarding reliable and relevant science rather than addressing the issue in some other, less drastic way.

Finally, it is not even clear how broadly any prohibition would extend under the proposal. The proposed regulatory text requires that information be “publicly available in a manner sufficient for independent validation,” e.g. 30.1, 30.5, and that information meets that requirement, and thus can be used “when it includes the information necessary for the public to

¹⁰ As discussed in Appendix B, since the court decision noted in proposal footnote.3 that agreed with EPA’s considered use of the two fine particle epidemiology studies despite not having access to protected health data, EPA and others in the scientific community conducted dozens of new studies, that replicating the core finding a significant association between fine particles and long-term mortality (reference Burnett, 2018 and our list of 31). By 2009, EPA and CASAC concluded these replications, together with evidence from other studies, was sufficient to conclude this is a causal relationship. (PM ISA 2009).

¹¹ R. Lutter et al, 2013. Access to Chemical Data: Lutter et al. Respond. Environ Health Perspect A 112 <http://dx.doi.org/10.1289/ehp.1206438R>.

¹² Goldman LR, Silbergeld E. 2013. Access to Chemical Data Used in Regulatory Decision Making. Environ Health Perspect 121(4):a11-a112. DOI: [10.1289/ehp.1206438](https://doi.org/10.1289/ehp.1206438)

understand, assess, and replicate findings.” 30.5. Nothing in the preamble or elsewhere in the regulatory text sheds light on the term “replicate” and section 30.2, addressing definitions, unhelpfully provides that all undefined terms “shall have the meaning given them in the Act or in subpart A,” without identifying either the Act or subpart A. (This is yet another example of failure to notify the public of the substance and basis of the rule). As just explained, under standard usage, a study can be replicated -as the two “precluded” studies have been--without access to the underlying data. Thus it appears that the *text* of the regulation would allow use of information that can be replicated, notwithstanding advisory language in footnote 3 that the regulation would “preclude” such information.

b. EPA’s proposal fails to identify a problem with the quality of regulations

The ultimate goal of EPA’s evaluation of science is not any particular standard of scientific procedure for its own sake, but rather to support well-grounded decisions that protect human health and the environment. Here again, the proposal fails to demonstrate - or even to claim - that the current approach has led to agency use of unreliable information and to decisions that are unreasonable or that fail to protect human health or the environment.

No such case can be made. Quite clearly, the Harvard School of Public Health’s Six Cities and follow-up American Cancer Society studies of the health effects of airborne fine particles lie at the very center of this effort to censor the regulatory science EPA can consider. We discuss these studies, their use, and subsequent developments in Appendix B, and demonstrate that far from being flawed, the original conclusions have been repeatedly re-confirmed by several different methods of reanalysis and replication through a process that stands as a model of responsible agency consideration of a fundamental scientific issue.

If the conclusions of studies at the center of the proposal's target have stood the test of time so well, the logical conclusion would be that the proposal is not concerned with the quality of the information it is proposing to exclude.

4. EPA Fails to Show That Alternatives to Its Per Se Rule Are Not Available

Since EPA has not identified any problems with EPA's current approach to regulatory science, it cannot argue that its per se rule is a solution to those problems. Indeed, given the variety of different possible approaches to quality assurance in scientific studies, even if there were a problem EPA would have to show that it fully considered available alternatives and that the proposed approach was so much superior to other possible approaches that it could justify a per se exclusionary rule. To do this, EPA would have to evaluate the strengths and weaknesses of the different possible approaches, which it has completely failed to do. On the contrary, EPA has confined its analysis to suggesting that it will be easy and uncomplicated to make data publicly available with a few redactions here and there to preserve confidentiality and privacy. 83 FR 18772/1 (although, as with so much of the proposal, the agency's thinking on this issue is shrouded in vagueness).

In their examination of the proposal, an EPA SAB work group stated: "The proposed rule oversimplifies the argument that 'concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government'."¹³ In fact, there are enormous difficulties involved, many of which are emphasized by the very journal articles and agency policies the agency misleadingly and selectively cites in support of its proposal. We will summarize the most salient

¹³ Cullen, A. Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science, Memorandum to Members of Chartered SAB and SAB Liaisons, May 12, 2018.

points here, and return to the topic when we discuss those articles and policies EPA cites in Appendix D.

In many studies of human health effects, ethical and legal and practical considerations have long restricted, and continue to restrict, the ability of investigators to release for general use personal data such as dates of birth and death, personal health and lifestyle information, and location. In many cases, restrictions on data disclosure are found in federal rules or policies or non-disclosure agreements.

The level of detail in the data supporting many of these studies precludes simply redacting portions of the information to protect privacy as glibly suggested in the proposal. For example, Sweeny found that about 87% of the population can be uniquely identified from U.S. Census data using only three pieces of data: zip code, gender, and date of birth.¹⁴ As Herring notes, the better-characterized the cohort in such studies (e.g., personal information on potentially confounding contexts and behaviors, well-characterized exposures, clinically-confirmed outcomes), the more limitations on data sharing due to federally-mandated personal privacy protections (Common Rule, HIPAA Privacy Rule, informed consent restrictions).¹⁵ Redacting information such as location and date of birth or death might make it possible to release remaining data publicly, but this can reduce the power of epidemiology studies to detect potential health effects of environmental exposures.^{16,17} At a 2014 NAS

¹⁴ L. Sweeney, Simple Demographics Often Identify People Uniquely. Carnegie Mellon University, Data Privacy Working Paper 3. Pittsburgh 2000.

¹⁵ A.H.Herring, 2018. Study Design, Data Analysis, Reporting, and Interpretation: Choices and Consequences. Presentation to Health Effects Institute 2018 Annual Conference, Chicago, IL. April 30, 2018). <https://www.healtheffects.org/sites/default/files/herring-reproducibility-hei-2018.pdf>

¹⁶ S. Herring, op cit.

¹⁷ R.T.Burnett. 2018; *Particulate Matter Reproducibility and Air Pollution Epidemiology*. Presentation to Health Effects Institute 2018 Annual Conference, Chicago, IL. April 30, 2018). <https://www.healtheffects.org/sites/default/files/burnett-reproducibility-hei-2018.pdf>

workshop on data sharing, Greenbaum of HEI noted that sharing *deidentified data files* would not be useful for air pollution cohort studies “because a deidentified one would not allow you to have location and a variety of other things that are absolutely essential.”¹⁸ Ohm also notes how attempts to anonymize data generally reduce the value of the information, but also notes the advances in computer science that have led to what he terms “easy reidentification” technologies.¹⁹

A related issue in the design of human studies arises from the need for informed consent in conducting human health related studies. This has been a major issue for the Harvard Six City study, which began recruiting subjects in the mid 1970s. The investigators assured the subjects that their data would remain private and remain in the control of Harvard University. In a workshop presentation, Casey of Harvard expressed his concern that informing prospective survey participants that data that could be used to identify them might be made publicly available could make it more difficult to enroll subjects in future studies.²⁰

The trade-off between steps needed to make data public and enabling the best results applies both to completed and to ongoing studies that examine the relationship between pollution exposures and human health effects. The policies of other federal research agencies, for example NIH, regarding data sharing, generally recognize the need for restricting access to protect

¹⁸ D. Greenbaum., in National Academies of Sciences, Engineering, and Medicine. 2016. Principles and obstacles for sharing data from environmental health research: Workshop summary. Washington, DC: The National Academies Press. doi: 10.17226/21703

¹⁹ Paul Ohm. 2010. Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization. 57 UCLA L. Rev. 1701, 1724 (2010)

²⁰ K. Casey, in National Academies of Sciences, Engineering, and Medicine. 2016. Principles and obstacles for sharing data from environmental health research: Workshop summary. Washington, DC: The National Academies Press. doi: 10.17226/21703. The summary of his presentation on this point notes his concern that people are likely to respond much differently if they are told that their data will be kept private than if they are told that their data might be provided to members of Congress and other people who will use it as they like. The summary of the workshop noted other discussants who agreed with this concern and others who did not believe it would be a serious deterrent to participation.

privacy or confidential business information, and note that in some cases access may need to be restricted to data enclaves or other limited sharing agreements available only to qualified investigators. Recognizing the effect of privacy concerns in recruiting subjects noted above, NIH also will allow investigators to promise subjects that their data will not be shared with other researchers, but only if the grant application provides an adequate justification.²¹

NIH requires a data sharing plan for extramural research projects requesting \$500,000 or more in a single year, but this requirement is not absolute since NIH will also accept an explanation for why data sharing is not possible. Under the proposal, EPA would not accept such an explanation as anything but a basis for a waiver request either for its own science or for NIH's or both. For research with such plans, NIH funds the costs of necessary data and methodology sharing arrangements as part of the project. EPA's proposal provides no such funding, and does not even acknowledge that it may be needed.

Against this background, it is clear that EPA has completely failed to address some key questions:

- What is the justification for applying this per se rule to past studies? In some cases, the data may simply no longer be available to anyone. In others, it may have been gathered subject to confidentiality conditions that cannot be undone. Yet the study may be informative and reliable. Why should its use be barred?
- Providing for data availability comes with cost and difficulty even for current studies. Since the amount of money for these studies is limited, that can force a trade-off between a powerful study with some restrictions on data availability and

²¹ See NIH Data Sharing Policy and Implementation Guidance.
https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

a less powerful study with fewer restrictions. Indeed, we are aware of no U.S. government agency that funds health-related scientific research that imposes an automatic public data disclosure rule even on prospective studies.

- What justification, therefore, is there to impose such an absolute ban on EPA studies? Would the ban extend to using research developed and relied on by other agencies?

5. *Questions Related to the Regulatory and Financial Costs*

a. Regulatory costs

Given the basic purpose of EPA's statute -- to authorize regulations to protect the public health and the environment -- one would expect EPA to consider those impacts before adopting a per se rule that could affect such decisions. At a minimum, EPA should identify the key studies that its proposal would bar that had been used to support regulations in the past, and evaluate the impact of their loss on those regulations and thereby on human health and the environment.

Indeed, reasoned decision making requires an agency to identify and address the impact of its proposed actions on its ability to perform its Congressionally mandated functions, *State Farm*, 463 U.S. at 43, because the likely impacts of the proposal are a critical issue in deciding whether to proceed with the rule. Nevertheless, the proposal outright fails to consider any impacts at all — literally none at all! Failure to consider potential environmental impacts in a proposal that fundamentally affects each of EPA's core statutory responsibilities is fatally arbitrary. See *Sierra Club v. Costle*, 657 F.2d 298, 326 (D.C. Cir. 1981) (“[W]e can think of no sensible interpretation of the statutory words ‘best technological system’ which would not incorporate the amount of air pollution as a relevant factor.”) See also *N.L.R.B. v. Creative Food*

Design Ltd., 852 F.2d 1295, 1306 (D.C. Cir. 1988) (noting that agencies “may not ignore relevant factors” in making decisions); *Small Refiner Lead Phase-Down Task Force v. U.S.E.P.A.*, 705 F.2d 506, 521 (DC. Cir. 1983) (“Arbitrary and capricious” review generally refers to the requirement that an agency “must consider all the relevant factors” and reach a “reasonable” conclusion; *Sierra Club v. Costle*, 657 F.2d at 323.”); *Environmental Defense Fund, Inc. v. Costle*, 657 F.2d 275, 283 (DC Cir. 1981) (“Thus, we must be assured that the agency action was “based on a consideration of the relevant factors,” *Citizens to Preserve Overton Park, Inc. v. Volpe*, supra, 401 U.S. at 416, 91 S.Ct. at 823; and that “the agency has exercised a reasoned discretion, with reasons that do not deviate from or ignore the ascertainable legislative intent,” *Ethyl Corp. v. EPA*, supra, 541 F.2d at 35-36, quoting *Greater Boston Television Corp. v. F.C.C.*, 444 F.2d 841, 850 (1970), cert. denied, 403 U.S. 923, 91 S.Ct. 2229, 29 L.Ed.2d 701 (1971).)”

Moreover, as in *CMA v. EPA*, 217 F. 3d 861, 865-66 (D.C. Cir 2000), EPA’s assertion of potential benefits without demonstrating their existence or providing any quantitative comparison of their value as compared to costs and disbenefits to public health is yet another clear indicator of arbitrariness and lack of support in the evidence before the agency. *Id.* (citing *State Farm*, 463 U.S. at 43).

The proposal provides no supporting analysis for the following implausible assertion:

EPA believes the benefits of this proposed rule justify the costs. The benefits of EPA ensuring that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation are *that it will improve the data and scientific quality of the Agency’s actions and facilitate expanded data sharing and exploration of key data sets*; this is consistent with the conclusions of the National Academies. 83 FR 18772. (emphasis added)

Not only is there no support provided for the assertion that the proposal will “*improve* the data and scientific quality of the agency’s actions,” but for all the reasons discussed above, it is simply not true, or perhaps more aptly, transparently false. The remaining section of the regulatory “analysis” is a particularly egregious sleight of hand:

The proposed rule directs EPA to make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making dose response models and data underlying pivotal regulatory science used in significant regulatory decisions available to the public in a manner sufficient for independent validation, consistent with law and protection of privacy, confidentiality, and national and homeland security. However, it *does not compel the Agency to make that information available where it concludes after all such reasonable efforts that doing so in way that complies with the law and appropriate protections is not possible.* (emphasis added) Id.

While it is not flatly untrue that the proposal “does not compel” EPA to make the information available, it is worse than disingenuous not to mention also that unless the information is publicly available it cannot be used as a basis for the rulemaking decision unless EPA grants an exemption. See at 18770 n. 7.

EPA regulations have relied on assessing many thousands of health-related studies of pollutants done in the last five decades, including epidemiological, human clinical, and animal toxicology studies. The proposal would exclude many such studies solely because the underlying data are not available, often because of legal or ethical reasons. Even for controlled human and animal studies, where subject data might ethically be released, the underlying data may no longer be accessible years after publication. Without the information provided in excluded research studies it would no longer be possible to assess the full weight of the available scientific evidence – a key guiding principle for judging the scientific integrity of the decision-making process. Some of the most useful information regarding health effects comes from real world

(epidemiological) and laboratory (clinical) studies of human subjects,²² in which detailed information regarding health, lifestyle, medical status, location, and more about participants can be collected.

In fact, as far as we can judge given the ambiguity of EPA's proposal, the per se rule could call into question and potentially invalidate a vast range of currently existing EPA regulations. The proposal says nothing about what studies it will exclude, aside from those identified but not mentioned by name in footnote 3. Appendix C provides some examples that we were able to pull together in the time available.

Even though limited by time and resources, our assessment shows the magnitude of the issue and the absolute need for EPA to address the potential damages to public health and the environment before any final action. To issue a valid rule, EPA would have to analyze this issue on its own, including what studies the proposal will exclude, present the results for public comment, and explain why the benefits of the per se rule justified the public health sacrifice and regulatory confusion that it would cause.

²² The primary ozone NAAQS provides further examples of the pernicious effects the proposal could have. Among the key controlled human exposure studies demonstrating that exposure to ozone causes adverse health effects in even healthy subjects at levels below the level of the then-current NAAQS are Adams (2006) and Schelegle (2009). See *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards* (EPA-452/R-14-006 (August 2014)) at pp. 3-27 and 4-10. These studies were sponsored by the American Petroleum Institute, which controls access to the underlying data. The American Petroleum Institute refused an EPA researcher access to the data of a related Adams study it sponsored (Adams (1998))#. See "First External Review Draft Integrated Science Assessment for Ozone and Related Photochemical Oxidants" (EPA/600/R-10/076A) at p. 6-7 n. 1. So not only would these evidently "useful" (CAA section 108 (a)(1)) studies be barred from consideration under the proposal, but the proposal creates a perverse incentive for industry to refuse access to study data.

b. Fiscal costs

EPA's proposal also ignores the costs to the agency and to affected researchers incurred as result of implementing the proposed rule. OMB's Information Quality Guidelines, 67 FR at 8452-53, recognize that

information quality comes at a cost. Accordingly, the 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) and the benefits of higher information quality in the development of information, and the level of quality to which the information disseminated will be held.²³

The proposal contains no evidence EPA has conducted such an assessment. Instead the proposal simply states the belief that the benefits of the rule will be greater than the monetary costs (and potential disbenefits), without providing any quantitative evidence to support that belief. We are left to examine other sources of information to examine potential costs and other adverse impacts.

As we discuss later, in a section focusing on the political motives for this proposal, this initiative is clearly based on the so-called HONEST Act, legislation introduced in each of the last two Congresses to restrict EPA's ability to rely on scientific information, but never enacted into law (H.R. 1030²⁴ in 2015 and H.R. 1430²⁵ in 2017). The Congressional Budget Office (CBO) in consultation with EPA analyzed the costs that would be imposed by these legislative proposals. The 2015 analysis assumed that EPA would reduce the number of studies it relied on by half, but would still need to expend \$250 million/year initially in an effort to determine data availability,

²³ <https://obamawhitehouse.archives.gov/omb/fedreg.-final-information-quality-guidelines> (October 1, 2001) at p. 2 of 10.

²⁴ Congressional Budget Office, H.R. 1030, Secret Science Reform Act of 2015, <https://www.cbo.gov/publication/50025>

²⁵ Congressional Budget Office, H.R. 1430, Honest and Open New EPA Science Treatment Act of 2017. <https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf>

and where necessary pay for obtaining and disseminating it. Given EPA's intention to "minimize" such costs in its proposed rule, this estimate may be considered an upper bound of the direct costs.

The CBO analysis does not tell the whole story, however, because it did not assess the disbenefits to the regulatory process and to public health of being unable to base regulations on numerous influential studies for which data could not be made available. Considering only the science policy value of the information in multiple original studies that are likely to be lost (e.g. the cohort epidemiology studies noted above, which must limit access to protect privacy) it is reasonable to conclude that their loss would almost certainly outweigh the value of any information gained by subsequent re-analyses of a more limited set of studies, which rely on publicly available databases that are often inferior to those that contain more relevant information.

In the 2017 legislative analysis, CBO estimated a cost ranging from 1 million to 100 million dollars per year, depending on the approach taken by EPA in assessing studies. They determined that meeting H.R. 1430 requirements would cost EPA an average of \$10,000 per study. EPA officials told CBO that the agency would likely greatly reduce the number of studies it relied on and would not take on the cost of disseminating the underlying data.^{26, 27} The proposal reiterates EPA's plan to focus on a more limited number of studies. Under these

²⁶ Id.

²⁷ This CBO estimate is "based on information from the EPA's Office of Research and Development and other federal agencies, as well as feedback from organizations and researchers in the scientific community that publish in peer-reviewed journals." EPA should give greater weight to its own experts as well as the other Federal Agencies than to the lower estimate provided by a Lutter and Zorn working paper EPA cites in footnote 24. They relied more on costs to industry for providing data from confidential business information, EPA paperwork, and base costs of storing data. Their lower estimate did not recognize the challenges and additional costs involved in providing data and methodology for studies that need to consider protection of privacy. These may require special archiving and access arrangements to limit data sharing, such as those noted in NIH data sharing plans, which are required only for studies that receive and spend more \$500,000 per year.

assumptions, CBO suggested costs could be as low as \$1 million/year, but again did not assess the potential implications for existing or future regulations. An unofficial draft response to CBO questions from unidentified EPA staff strongly disagreed with the lower cost estimates, and expressed concern that the legislation would prevent EPA from using the best available science; this response was never forwarded to CBO.²⁸

c. The relation between fiscal costs and regulatory costs

The proposal also fails to acknowledge or explore the close relationship between regulatory costs and financial costs. A good faith proposal would have grappled with the reality that additional funding toward researchers might mitigate the drastic effect that EPA's proposal would have on the agency's ability to set regulations. NIH, for example, compensates researchers for the effort it takes to make data available either publicly or through data enclaves, for new studies where this is called for and possible.

However, the proposal makes no suggestion that EPA would compensate researchers who have already published peer reviewed studies to cover the costs of setting up a process either for public or limited sharing of data in a manner that would protect confidentiality, as is the norm at, e.g., NIH under similar circumstances. The proposal also provides no indication of how it would fund agency staff, researchers, or consultants to address the proposal's post hoc methodology analysis and other requirements listed in section 30.6 of the rule. The proposal mentions

²⁸ CBO Questions for EPA regarding H.R. xxx, the HONEST Act of 2017. <https://www.scribd.com/document/344731162/EPA-analysis-of-Honest-Act-to-CBO> Uploaded by Marketplace (see <https://www.marketplace.org/2017/04/10/sustainability/honest-act-seen-critics-undercutting-epa-s-use-science> April 10, 2017) who verified its origin with two current EPA staff. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1257652/> <https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.86.10.1416>

“cost-effective” strategies for providing public or restricted access to shared data and methods in repositories that might involve collaboration with other federal agencies, but never commits to any particular path, nor indicates that the agency would bear the cost in time and effort for researchers who would be willing to use them. Instead, EPA claims disingenuously that the proposal “does not contain any information collection activities.” FR at 18772.²⁹

EPA cannot have it both ways. Either researchers are compelled by a new requirement to expend significant resources on arrangements to ensure the implications of their research for policy are considered (including in many cases studies that have already have been used to support regulations) or they have no burden because EPA will pay for it. By not offering any support for the process, the proposal betrays its real motive, namely to reduce the availability of scientific information that the agency now sees as inconvenient in view of its policy goal to retreat from environmental rules that have provided significant public health benefits.

The proposal’s unsecured promissory note that it will “make all reasonable efforts to explore methodologies, technologies, and institutional arrangements” for making data available and preserving privacy both fails to say how, and fails to acknowledge the extreme difficulties in doing so. 83 FR 18772. By ignoring all the issues raised (including in the very sources it cites), the agency arbitrarily ignores key issues and record evidence. *State Farm*, 463 U.S. 43.

²⁹ Several of the conclusions in Part IV are unsupported and seem facially implausible.

C. EPA Fails to Comply with the Specific Substantive Requirements of the Statutory Provisions its Per Se Rule Would Affect

For all the reasons just summarized, EPA's proposal fails to present a reasoned basis for its rule, or give fair notice to the public of the "subjects and issues" it raises, and thus fails to comply with the public notice requirements of the Administrative Procedure Act (APA). The rule should not go forward for that reason alone. But these APA standards are not the only standards that apply in this instance.

EPA's proposal would, in a single rulemaking, change the standards for using science in issuing covered rules under *all eight* of the EPA substantive regulatory authorities identified in the proposal. This is a change that can only legally be made through individual program-specific rulemaking. Moreover, it would effectively make in advance a critical part of the regulatory decision in any covered proceeding under any one of those eight statutes, namely the decision which scientific evidence to give weight to, and how much. This is a decision that has previously been made by detailed case-by-case review in the rulemaking itself. Until today, such decisions are made after considering the substantive goals of the particular statutory provision involved, are guided by the attitude toward scientific evidence embodied in that provision, and strive for conformity with any applicable procedural requirement. Accordingly, any attempt to make a part of this decision in advance must meet these same standards. For these reasons, EPA must justify its proposal as a proper exercise of its authority under **each** of the statutory provisions whose operation it would affect - provisions that the agency does not even cite.

To show how far short this proposal falls from acceptable legal standards, we will discuss in more detail three statutory provisions that the proposal would clearly affect. These are (1) the

authority to set national ambient air quality standards (NAAQS) under the Clean Air Act (CAA); (2) the authority to set drinking water standards under the SDWA; and (3) general chemical regulatory authority under the Toxic Substances Control Act (TSCA). The facts will show that all three provisions:

- place a high priority on using reliable science to protect public health, even in the presence of scientific uncertainty, by statutorily spelling out procedures that EPA must follow when it uses science,
- expect that EPA will consider *all* the relevant scientific information,
- articulate methods or standards for assuring the validity of that information, and that EPA's per se rule is not among those methods or standards.

We then further show that decision-making under the proposal cannot possibly comply with these requirements.

1. NAAQS Under the Clean Air Act

a. The substantive regulatory authority

Congress first established the legal standards that NAAQS must meet in the 1970 Clean Air Act. EPA must establish primary and secondary NAAQS for air pollutants, “emission of which ... cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare”. CAA section 108 (a)(1)(A). For each such pollutant, the law requires NAAQS not just to “protect the public health” but to do so “with an adequate *margin of safety*.” CAA § 109(b)(1) (emphasis added). In setting these standards, EPA cannot consider the costs of meeting them, see *Whitman v. American Trucking*, 531 U.S. 457, 464-71 (2001) (Scalia, J.) but must instead comprehensively consider the state of scientific knowledge. To make sure this happens, Congress required NAAQS to be based on “air quality criteria,” CAA § 109 (b), which must “*accurately reflect* the latest scientific knowledge *useful in indicating* the kind and extent of

all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air.” CAA §108(a)(2) (emphasis added). The Supreme Court agrees that NAAQS must be based on “published air quality criteria that reflect the latest scientific knowledge.” *Whitman*, *supra*, at 457. Accord, *State of Mississippi v. EPA*, 744 F. 3d. 1344, 1346 (D.C. Cir. 2013).

Air quality criteria must include information on “variable factors... which of themselves or in combination with other factors *may* alter the effects on public health or welfare of such air pollutant”; the types of air pollutants which ... *may* interact with such pollutant to prove an adverse effect”; and “any known *or anticipated* adverse effects on welfare.” CAA section 108 (a)(2) (A)-(C). To make sure that EPA based its decisions on this latest useful science, in 1997 Congress also required EPA to appoint a scientific review committee -- the Clean Air Scientific Advisory Committee (CASAC) -- to review the scientific information to be embodied in the air quality criteria and used to determine NAAQS. CAA § 109(d).

These statutory provisions originated in the 1970 Senate version of the Clean Air Act. The Senate Report on them stated that: “Margins of safety are essential to any health-related environmental standards if a reasonable degree of protection is to be provided against *hazards which research has not yet identified*” Library of Congress. Environmental Policy Division, (197480). A legislative history of the Clean Air Amendments of 1970, together with a section-by-section index. Washington: U.S. Govt. Print. Off. at p. 410 (emphasis added). The courts agree. See, e.g. *American Trucking Association v. EPA (ATA III)*, 283 F.3d. at 369 (D.C. Cir. 2002).

EPA could not obey these statutory commands unless it considered (1) all knowledge that met the standards of quality observed by the scientific community to establish health effects of pollution; (2) knowledge that, though it might not meet these standards, was nevertheless “useful in indicating” these effects or pointing to “hazards which research has not yet identified;” and (3) all the knowledge regarding the factors which may result in these pollutants’ synergistic effects on public health and welfare.

Since the NAAQS provisions were enacted in 1970, EPA has conducted many NAAQS rulemakings. The agency does not establish per se, a priori rules regarding study inclusion or exclusion, but rather evaluates each of the individual studies — and there are thousands typically evaluated for each NAAQS review — on its merits based on reasoned criteria. While details of the development and review of the criteria and standards have evolved, in practice, over the last four decades, EPA has endeavored to include all relevant peer reviewed scientific studies in the process, even searching out relevant newer literature to be sure that what is considered in a regulatory context is comprehensive.³⁰ During this period, EPA has included tens of thousands of peer reviewed studies of health effects, exposure, and atmospheric interactions, and monitoring in reviews of criteria and standards.

³⁰See, e.g. 28 EPA (2012). Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposures. EPA/600R-12/056F. National Center for Environmental Assessment RTP Division. Office of Research and Development. Research Triangle Park, NC. December 2012.
<https://www3.epa.gov/ttn/naqs/standards/pm/data/20121213psa.pdf>

A requirement that any study must be excluded from consideration unless the raw data and full methodologies are made available for each of them is both impractical and inconsistent with the legislative mandate and EPA's practice over the last 40 years. Reasoned criteria that EPA has typically applied include:

- Are the study populations, subjects, or animal models adequately selected, and are they sufficiently well defined to allow for meaningful comparisons between study or exposure groups?
- Are the statistical analyses appropriate, properly performed, and properly interpreted?
- Are likely covariates adequately controlled or taken into account in the study design and statistical analysis?
- Are the air quality data, exposure, or dose metrics of adequate quality and sufficiently representative of information regarding ambient conditions?
- Are the health, ecological or welfare effect measurements meaningful, valid and reliable?
- Do the analytical methods provide adequate sensitivity and precision to support conclusions?³¹

³¹ Figure II, Illustration of processes for literature search and study selection used for development of ISAs, Integrated Science Assessment for Ozone, EPA 600/R-10/076F (February 2013) at page Iiii. The ISA explains in detail "the initial step in this process is publication of a call for information in the Federal Register that invites the public to provide information relevant to the assessment, such as new or recent publications on health or welfare effects of the pollutant, or from atmospheric and exposure sciences fields. EPA maintains an ongoing literature search process for identification of relevant scientific studies published since the last review of the NAAQS. Search strategies are designed for pollutants and scientific disciplines and iteratively modified to optimize identification of pertinent publications. Papers are identified for inclusion in several additional ways: specialized searches on specific topics; independent review of tables of contents for journals in which relevant papers may be published; independent identification of relevant literature by expert scientists; review of citations in previous assessments and identification by the public and the Clean Air Scientific Advisory Committee (CASAC) during the external review process. Studies that have undergone scientific peer review and have been published or accepted for publication and reports that have undergone review are considered for inclusion in the ISA. Analyses conducted by EPA using publicly available data are also considered for inclusion in the ISA. All relevant epidemiologic, controlled human exposure, toxicological, and ecological and welfare effects studies published since the last review are considered, including those related to exposure-response relationships, mode(s) of action (MOA), and potentially at-risk populations and life stages. Studies on atmospheric chemistry, environmental fate and transport, dosimetry, toxicokinetics and exposure are also considered for inclusion in the document, as well as analyses of air quality and emissions data. References that were considered for inclusion in a specific ISA can be found using the HERO website (<http://hero.epa.gov>)." Id. at I-11.

Thus a science regulation that applies to the NAAQS is unlawful unless EPA can show that the new standard can be established and implemented consistent with the applicable statutory requirements, including those requiring the use of “scientific knowledge” and specifying how to use it. This proposal has neither acknowledged that such requirements exist nor explained how it can, under the regulation, produce scientific information and rulemaking records meeting them, and there is nothing in the record to demonstrate that it can. Thus, contrary to the implicit suggestion in the proposal that EPA is working with a blank slate when it puts a unique spin on science under the Clean Air Act, it is entering a field where Congress has provided expansive directives. Moreover, the agency and the congressionally mandated CASAC have long followed an inclusive approach to selecting and evaluating the relevant scientific literature, consistent with these directives.

Automatic disclosure of data underlying scientific studies, regardless of the obstacles, has never been a precondition to EPA consideration of those studies in setting NAAQS. In two cases cited in the proposal, plaintiffs challenged rules on the basis that there was no public access to underlying data. In each case, EPA declined to provide the data, and in each case, the court affirmed that denial, and endorsed EPA’s reasoning in doing so.³²

³² Specifically, in *American Trucking Ass’n v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002) the court said: This brings us finally to Petitioners' argument that EPA "denied the public essential procedural rights" by failing to obtain and make public the data underlying certain "key studies" relating to the "confounder" issue. Claiming neither that they were unable to obtain the studies, nor that the studies were improperly published or peer reviewed, Petitioners instead urge us to impose a general requirement that EPA obtain and publicize the data underlying published studies on which the Agency relies. The Clean Air Act imposes no such obligation; it merely directs EPA to include in any notice of proposed rulemaking "data, information, and documents ... on which the proposed rule relies." 42 U.S.C. § 7607(d)(3) (emphasis added). Here, EPA explained that it "relied on the scientific studies cited in the rulemaking record, rather than on the raw data underlying" those studies. Particulate Matter NAAQS, 62 Fed. Reg. at 38,689. In addition, Agency counsel advised us at oral argument that on those few occasions when EPA requested underlying data from an

2. *The Safe Drinking Water Act*

The SDWA mandates national drinking water regulations setting required purity levels for water from public water supply systems. 42 U.S.C. §300g-1. Before regulating, the Administrator must conclude that the contaminant at issue “may have” an adverse effect on the health of persons. *Id.* at (b)(1)(A)(i). In regulating, the Administrator must consider “the best available public health information.” *id.* at (b)(1)(B)(ii)(II). The section adds that in setting regulations, the Administrator “shall use ...the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices” and in addition, “data collected by accepted methods or best available methods.” 42 USC section 300g-1 (3)(A). See *City of Waukesha v. EPA*, 320 F. 3d at 247 (D.C. Cir 2003) (agency peer

investigator, the Agency included those data in the record, Tr. of Oral Arg. at 74-75. More generally, we agree with EPA that requiring agencies to obtain and publicize the data underlying all studies on which they rely “would be impractical and unnecessary.” Particulate Matter NAAQS, 62 Fed. Reg. at 38,689.
ATA III at 372

Similarly, in *Battery Recyclers Assn v. EPA*, 604 F. 3d 613, 623 (D.C. Cir. 2010), the court stated:

The Lanphear study investigated the concentration-response relationship between blood lead levels and IQ changes, and provided what EPA described as “the most compelling evidence” for effects of lead on IQ at blood lead levels below 10 µg/dL and for the nonlinearity of these effects. Final Rule, 73 Fed.Reg. at 66,977. Petitioners contend the Lanphear study contained such errors that EPA acted arbitrarily and capriciously in relying on results from the study without first obtaining and making public the underlying data for the study. However, in *American Trucking*, 283 F.3d 355, this court rejected the notion that EPA had improperly failed to obtain and make public data underlying studies on which it had relied during a NAAQS rulemaking, holding that “[t]he Clean Air Act imposes no such obligation” and that “requiring agencies to obtain and publicize the data underlying all studies on which they rely would be impractical and unnecessary.” *Id.* at 372 (quotation marks omitted). Petitioners attempt to distinguish their request on the ground that in *American Trucking* the court was addressing requests for data underlying several studies, while they request only that EPA obtain and make public the data underlying the Lanphear study. This distinction finds no support in the reasoning of *American Trucking*. Rather than distinguishing between an agency's burden in obtaining data from one versus many studies, the court distinguished EPA's reliance on a study's results from its reliance on the raw data underlying such results, noting that raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants. See *id.* Petitioners do not contend EPA possessed the underlying data but failed to include it in the rulemaking record.”

review satisfies requirement to use best, peer-reviewed science and supporting studies); *City of Portland v. EPA*, 507 F 3d 706, 716 (D.C. Cir 2002) (same).

Finally, to ensure that these requirements are met and science is fully integrated into the regulatory decision, Congress specifically directed EPA to solicit the views of the SAB before proposing any drinking water regulations. 300-g (1) (e). Here again, EPA’s opaque “transparency” rule includes no showing that the proposal is consistent with or authorized by the language of the SDWA.

This proposal appears to be in conflict with the directions Congress gave for the use of and communication about scientific information in enacting P.L. 104-182, the 1996 Amendments to the SDWA. The previous law had mandated expedited schedules for EPA to promulgate regulatory standards for literally dozens of drinking water contaminants, notwithstanding “significant gaps in the scientific information available for many of these contaminants.” (Sen. Rpt. 104-169, at 28). “[T]o assure that future standards are based on better science,” the 1996 Amendments “add[ed] to the scientific foundation of future standards by imposing [new] requirements on EPA.” *Id.* The Report of the Senate Committee on Environment and Public Works is authoritative on these provisions, as the language adopted in the Committee bill (S.1316) on the use of science was adopted verbatim in P.L. 104-182. The most fundamental of these added requirements – unacknowledged in the proposal – addresses the use of science in decision-making under SDWA’s standard-setting section, §1412 (42 U.S.C. § 300g–1):

§1412(b)(3)(A) Use of science in decision-making.— In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use—

- (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and
- (ii) 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).

In imposing these requirements, Congress did not give the Administrator the discretion claimed in this proposal to invent novel, EPA-specific definitions of “sound and objective scientific practices,” or to ignore the “best available, peer-reviewed science and supporting studies” based on any factor relating to the public availability or unavailability of data. The report further emphasizes that these *are* requirements by specifying that the “Administrator has a duty to seek and rely upon the best available science and information to support. . . . [m]any of the most important activities including selecting contaminants for regulation, setting standards, designing analytical methods and structuring waivers, variances and exemptions.” (S. Rep. 104-169, at 28) (emphasis added).

Particularly in light of this history, the requirements in this provision must be considered definitive as to the agency’s permitted approach to the use of science in covered decision-making. Thus, the declaration in the preamble to the proposal that “[w]here available and appropriate, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments” but is “precluded” from using such information where it is not feasible to make it available (83 FR at 18770 and n.3), cannot be reconciled with the scope of the permissible use of science under SDWA §1412(b)(3)(A) (i).

First, under SDWA, the peer-reviewed science used must qualitatively be the “best available”; no discretion is given to the Administrator to further limit the science used on the ambiguous grounds of “appropriate[ness],” much less the non-statutory basis of “transparency” put forward in the proposal. Most important, the core objective of the proposal – “to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for

independent validation” (proposed § 30.1 “What is the purpose of this subpart?”) is one that the Administrator does not have authority to pursue under this SDWA provision.

Tellingly, the authority under SDWA cited for the proposal, SDWA §1442, simply authorizes research, technical assistance, information and research facilities, and training. That section cannot be read to authorize in any way the changes in the use of “regulatory science underlying [agency] actions” in this proposal, especially in the face of the terms and stated intentions of §1412(b)(3)(A) (i). (The other SDWA provision cited in the proposal as “authority”, §1450(a)(1), is simply a general rulemaking authority and cannot be used to bootstrap the lack of direct authority in SDWA for this proposal).

The principal cases interpreting this provision have defined and maintained the strict requirements of this authority. EPA observes the “best available science” requirement where it uses newer, peer-reviewed data rather than older data developed by an EPA scientist for the regulatory determination (re filtration avoidance, *City of Portland v. EPA*, 507 F.3d 706, 716 (D.C. Cir. 2007)), and where the agency explained and provided “substantial scientific support” for the model and data it used (*City of Waukesha v. EPA*, 320 F.3d 228, 250-51, 256-57 (D.C. Cir. 2003)), but not where it rejected the evidence that was the “best available” at the time of the rulemaking (*Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290-91 (D.C. Cir. 2000)). *City of Waukesha v. EPA* furthermore indicates that agency peer review satisfies the requirement to use best, peer-reviewed science and supporting studies, as noted above. 320 F. 3d at 247.

3. *The Toxic Substances Control Act*

TSCA, in section 26(h), provides that in regulating “[t]he Administrator shall make decisions...based on the weight of the scientific evidence” and shall “take into consideration

information...that is reasonably available to the Administrator.” id at (j). The law grants EPA broad authority to act against any “unreasonable risk of injury to health or the environment” created by the use of a chemical substance or mixture. Congress directed EPA to make this unreasonable risk determination without considering costs, though costs become relevant later at the stage of regulation. This directive to consider health impacts alone makes science of even more relevance to an unreasonable risk determination than it might be under a different statutory approach, such as cost benefit balancing.

Congress addressed in detail the types of science that EPA should use. Specifically, Congress directed that to the extent the Administrator based a regulatory decision on science, the agency use information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and [to] consider as applicable—

- (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
- (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
- (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
- (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
- (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models. 15 U.S.C. §2025 (h)

As noted above, Congress added that “[t]he Administrator shall make [regulatory] decisions...based on the weight of the scientific evidence,” id at (i), and shall “take into consideration information...that is reasonably available to the Administrator.” id at (j).

Nowhere is the Administrator barred from considering studies for which underlying data may be unavailable. Quite the contrary. The Administrator is to evaluate studies based on a range of factors — including peer review, internal consistency of study methodology and how well uncertainties are characterized.

The proposed rule is inconsistent with and would lead to decisions that violate these provisions, since it substitutes an *a priori* requirement of data availability to the public in place of the statutory factors. The availability of sufficient underlying data for the public to ‘validate’ or ‘reproduce’ study results is not even among the factors the agency is to consider, much less a determinative factor nullifying all those enumerated. The proposal is likewise at odds with the requirement that decisions be based on the “weight of the scientific evidence” since it bars evidence from the weighting process. In sum, EPA has not identified a lawful basis for applying this rule to regulatory decisions under TSCA. The general regulatory and research authorities cited in the proposal do not provide such a basis.

Small wonder, then, that the proposal, having failed to identify any substantial legal basis for limiting science under the various affected programs “solicits public comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.” 83 FR at 18771. But it is not the job of commenters to identify the legal sources of authority for the proposal, and the proposal fails to do so. That failure alone precludes adopting a final rule based on the proposal.

IV. EPA’s Reservation of Authority to Waive its Per Se Rule Cannot Provide Legal Justification for that Rule

Given the total lack of justification for EPA’s affirmative proposal, it is of no legal significance that EPA proposes to grant itself the power to waive its per se bar. What EPA needs to justify are the cases in which the policy applies, not those cases where the exemption will be used to avoid it. Otherwise, studies might be subject to an illegal bar on use unless EPA saw fit to grant them an exemption that rested in its discretion.

It is well established that existence of a waiver or exemption mechanism cannot be used to justify a provision otherwise beyond an agency’s legal authority. *Dimension Financial Corp. v. Board of Governors of Federal Reserve System*, 744 F.2d 1402, 1410 (10th Cir. 1984) (“The possible exception to the initial impact of Regulation Y (Part 225.21(B)(4)) contains requirements with no objective standard and thus unbounded agency discretion. This is a device to meet objections to the new regulation and cannot cure the exercise of powers denied by Congress or not provided for by Congress. *Public Utilities Comm. of Calif. v. United States*, 355 U.S. 534; 78 S.Ct. 446, 2 L.Ed.2d 470; *In re Surface Mining Regulation Litigation*, 627 F.2d 1346 (D.C.Cir.)”)

EPA moreover has failed to explain or seek comment on how it will administer the exemption provision. The provision itself gives EPA discretion by providing that it “may” allow exemptions in any case where “it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security,” or where peer review

is not feasible. Proposed section 30.9, 83 FR at 18774. Of course, if it were feasible in either case, there would be no need for an exemption. The proposal provides no standards or criteria for picking and choosing among exemption requests. That lack of standards or criteria is particularly troubling because it could lead to arbitrary decision-making in a politically charged climate.

EPA has asked for comments on the general subject of when exemptions should be available, but has provided no suggestions of its own on that subject. With no standards or criteria in the exemption discussion, there is evidently nothing to prevent the exemptions from being granted and withheld arbitrarily. Highly relevant and reliable studies for which data cannot be shared could still be excluded, no matter how authoritative the science might be, and even if it has been subject to peer review, multiple replications, a third party reanalysis, and been approved for use in regulatory decisions and analyses by EPA's external science advisors.³³

³³ Note this is exactly the status of the Harvard Six City and American Cancer Society epidemiology studies noted above and discussed in Appendix B.

V. EPA's Misuse of the Authorities it Cites

EPA's discussion of authorities set out in its proposal would not support the agency's proposed actions even if we took it at face value. That discussion is too generic, too summary, and too disconnected from the real issues to provide the necessary support.

But if we actually examine these authorities, together with the reactions of their authors to the conclusions EPA attempts to draw from their work, we find that they provide little or no support for, and in some cases actually undermine, EPA's position. We provide fuller details in Appendix D. We summarize a few illustrative examples here.

OMB's Data Quality Act Guidelines, which EPA repeatedly cites in support of its proposal, do not in fact provide support for the proposal's call for the automatic release of underlying data, and the exclusion of information that cannot lawfully be released, but makes this a judgment depending on cost and feasibility. The proposal claims that the referenced OMB Guidelines are "consistent with" the proposal, but they are not. The overarching requirement in the Guidelines is that information be "accurate, reliable, and unbiased." OMB IQA Guidelines section V.3. b. The Guidelines state that with "regard to original and supporting data related thereto, agency guidelines *shall not require that all disseminated data be subjected to a reproducibility requirement,*" and that a study remains objective even when underlying data cannot be reproduced in view of "ethical, feasibility, or confidentiality constraints." *Id* at V.3.b.ii. A (67 FR at 8460) (emphasis added). Critically, the explanatory preamble to the Guidelines identifies the Harvard 6-City Study as one that is reproducible and thus satisfies OMB's transparency criteria and expressly endorse the means used to reanalyze the raw data in that these seminal studies. 67 FR at 8456, EPA's proposal, while purporting to be "consistent"

with the Guidelines would “preclude” the use of the same study.³⁴ Thus, far from supporting the proposal, the Guidelines expressly disagree with both the reproducibility requirement and the preclusion of those specific studies.

Upon examination, the other Executive Branch and EPA documents cited by EPA’s proposal likewise provide little support for its conclusions. Many of them expressly recognize that disclosure may not be possible, and *no* agency of the federal government that funds scientific research involving confidential health information provides for the automatic unfettered disclosure of data even when funding new studies. Instead, they make this a balancing judgment with the balancing factors being the added cost of disclosure, the feasibility of providing for disclosure, and the marginal gain in accuracy from disclosure. For example, the NIH policy noted above will allow investigators to promise subjects that their data will not be shared with other researchers, but only if the application provides an adequate justification.

A host of authors and organizations cited by the proposal have expressly rejected the use that EPA attempts to make of their work. These include Dr. John P.A. Ioannidis, author of the seminal article on the “replication crisis,” Professor Wendy Wagner, the author of a study for the Administrative Conference of the United States much relied on by the proposal, the Bipartisan Policy Center, and the editors of the scientific journals *Science*, *Nature Proceedings of the National Academy of Sciences*, and *more*. For example, the Bipartisan Policy Center, which

³⁴ Footnote 3 of the proposal, FR 18769 provides as follows:

EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA’s use non-public data in support of its regulatory actions. See *Coalition of Battery Recyclers Ass’n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass’ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

assembled a thoroughly bipartisan roster of experts to research, consider and then issue a 2009 report of recommendations for both the Executive Branch and the Congress on how to improve the way science is used in making regulatory policy across the government's areas of responsibility, notably concluded in its comments on this proposal that the proposal misrepresented its conclusions:

While the Science for Policy Project panel encouraged greater transparency and access to data:

The report never suggested excluding studies from consideration in developing regulation if data from those studies were not publicly available. Indeed, the panel's overarching recommendation for assembling the "best available science" reads: "Agencies and their scientific advisory committees should cast a wide net (emphasis added) in reviewing studies relevant to regulatory policy, and should make their methods for filtering and evaluating those studies more transparent." (Comment letter, emphasis added).

VI. Other Substantive Defects in the Proposal

A. Clear Evidence of Improper Political Motivation

The substantive concerns about inadequate justification set out above can only be magnified by the process EPA followed in developing the proposed rule, which was anything but transparent and indicates that the proposal was not the result of reasoned consideration. Even our imperfect knowledge of the speed with which this proposal was put together, and the specific steps taken to develop it, indicates a complete departure from approaches that have been used by all past EPA Administrations for developing rules, policies, and procedures that involve the assessment and use of scientific information.

Typically, these actions rely heavily on work done by the career staff in ORD and/or program offices and consultation with the SAB, the FIFRA Science Advisory Panel (SAP), and/or the NAS and others before proposing a regulation. None of this was done here.

Multiple reports based on emails and other documents obtained by the Union of Concerned Scientists (UCS) indicate that the idea of developing a policy memorandum or a rule based on legislation developed by Congressman Lamar Smith of the House Science, Space, and Technology Committee began in January 2018.³⁵ Serious work on drafts took place during February under some deadline pressure, as evidenced by email traffic mainly involving EPA political staff. The Administrator's first public mention of the effort appeared in a March 19 story in the Daily Caller,³⁶ which was linked in an official EPA news release. The story reported it as a "science transparency policy" mirroring Lamar Smith's legislation. Five weeks later, on April 24th, one day before OMB first reported clearing the draft, the Administrator signed the proposed regulation.

The agency was in such a rush to judgment that it did not provide a role for its own career scientific and science/policy experts in crafting the policy/regulation or assessing potential unanticipated impacts, never included the rule in its regulatory agenda, did not follow its guidance for how to develop agency rules,³⁷ did not notify or consult with or request a review of the proposal by its SAB, SAP, or the Department of Agriculture (USDA) as required by law, did not solicit the advice of the NAS on provisions that would change dose-response models used in

³⁵ Y. Kothari. UCS Blog. . Here are the "Transparency Documents the EPA Does Not Want You to See." April 21, 2018. <https://blog.ucsusa.org/yogin-kothari/here-are-the-transparency-policy-documents-the-epa-does-not-want-you-to-see> The blog contains links the documents as well as to five press accounts based on their contents.

³⁶ Daily Caller. Scott Pruitt Will End EPA's Use of 'Secret Science' to Justify Regulations. March 19, 2018. <https://www.epa.gov/newsreleases/daily-caller-scott-pruitt-will-end-epas-use-secret-science-justify-regulations>

³⁷ EPA's Action Development Process, EPA Office of Policy, March 2011 [https://yosemite.epa.gov/sab/sabproduct.nsf/5088B3878A90053E8525788E005EC8D8/\\$File/adp03-00-11.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/5088B3878A90053E8525788E005EC8D8/$File/adp03-00-11.pdf)

risk assessment from those previously recommended by the NAS, and did not conduct an interagency review to consult other Agencies that conduct research and/or use health effects science in developing policies and regulations.³⁸

As a final example of how little it really wanted input from the scientific community and other members of the public, EPA initially allowed only a 30 day comment period, which would close one day before a long-scheduled meeting of the full SAB. Indeed, this rushed and largely secret process, antithetical to any standard of reasoned consideration or transparency, shows that EPA is not really concerned about transparency in public policy, much less in science.³⁹

B. Failure to Apply the New Policy Consistently as its Logic Requires

EPA programs do not differ among each other in how they treat the desirability of making raw data available in the consideration of relevant science and research. If some EPA programs need the changes that EPA has proposed, then they all do. Indeed, much of the justification in EPA's preamble reads as though the proposal would in fact apply to all EPA regulatory decisions.

³⁸ According to the revised dates on OMB's Reginfo.gov site, OMB received the draft proposal on Thursday April 19th and cleared it just four days later on Monday April 23rd. Given the intervening weekend, there was no time for interagency discussion.

³⁹ It is useful to contrast this process with the one EPA followed for a less far-reaching change in science/policy assessment that took place largely in 2006. The deputy Administrator requested a top to bottom review of the process of reviewing scientific criteria supporting the review and setting NAAQS and to make recommendations that would strengthen the process. It began with a workgroup that included experienced staff from both the research and air offices. They first consulted with CASAC and some other stakeholders and within three months wrote a report with conclusions and recommendations and an analysis of how the process could be completed in the mandated five years. This was followed by a public workshop involving stakeholders and public comments. EPA management made final decisions based on staff recommendations and CASAC and public comment and announced a revised process in December 2006. Some smaller changes were made based on EPA and CASAC experience with executing the process in later years. EPA, Historical Information on the NAAQS Review Process <https://www.epa.gov/naaqs/historical-information-naaqs-review-process>

The specific discussion from the proposal begins:

The best available science must serve as the foundation of EPA's regulatory actions. Enhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions. By better informing the public, the Agency in (sic) enhancing the public's ability to understand and meaningfully participate in the regulatory process. In applying the best available science to its regulatory decision-making, EPA must comply with federal transparency and data integrity laws, and must also ensure that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility. 83 Fed. Reg. at 18769 [footnotes omitted]

One would think from this language that the proposal applies to **all** EPA regulatory activities under all of the statutes listed in the proposal. And indeed, to the extent that EPA's purported concerns have validity, the proposal should so apply. But it does not. In fact, EPA states that it applies only to "major rules" and, by a serendipitous and unexplained coincidence, does not apply to many types of decisions where industry is seeking a benefit from the government. Specifically, it does not apply to air or water permits for major industrial facilities, to standards for hazardous waste cleanups, to registration or reregistration of pesticides, or the setting of tolerances for pesticide residues on food, or to the approval for market of new chemicals. Such differential application is itself arbitrary. See *American Trucking Ass'ns v. EPA*, 175 F. 3d 1027, 1052-53 (agency arbitrarily applied different criteria for considering certain studies). Any defensible EPA proposal would have to explain why the need for transparency is so compelling that it could support a drastic change in the decision-making standards for, "major regulatory actions," and yet so weak that it does not apply at all to a host of other EPA decisions, many of which benefit industry directly and that collectively are probably far more important for protection of human health and the environment.

However, instead of acknowledging and discussing the implications of having two definitions of science, one of them applicable only to major rulemaking, the proposal simply takes the major rule limitation as a given, offering no explanation to support it and then asks the public to comment on the scope of the rule, giving no indication of what approach EPA plans to take [or of whether the new definition of science should be applied more universally]. The rule effectively proposes two different definitions of science for purposes of agency decision-making, one for major rules and the other for everything else; in other words there would be two different EPA definitions of science for actions addressing the same subject, the risk from the conduct, under the same statute. This is the very definition of arbitrary.

How would EPA address such a situation? The proposal says nothing about this, despite the obvious potential for confusion. For example, would a decision whether to enforce a regulation based on the constricted new rule on science be based on all relevant science, including data not considered in developing the rule in the first place? What about permitting, licensing and registration decisions? What about evaluating a grant proposal under traditional science, for activities governed by a regulation using censored science? None of these serious concerns are addressed in the proposal.

Rather, EPA's motivation for the distinction seems obvious. Emails released pursuant to FOIA requests reveal that senior political officials at EPA did not know that pesticide registrations depend on information which is protected from disclosure to the public. When this was pointed out to them by Nancy Beck, Deputy Assistant Administrator for Chemical Safety and Pollution Prevention, the draft proposal was revised so that it would not cover licensing

actions like pesticide registrations and other activities providing a benefit to industry.⁴⁰ This distinction between using studies when they confer a benefit on industry, but disallowing them when used to influence public health protection is not only arbitrary but invidious. The proposal is irremediably tainted at its inception as a result.

Indeed, EPA has not even applied the principles of its proposal to **rulemaking** when that would get in the way of its central agenda of providing relief to industry. Most tellingly, EPA's commitment to "transparency" seems to be a recent invention that it has not followed in recent rulemaking proposals. Just a few months before issuing this proposal, when EPA proposed to rescind the rule restricting glider trucks (trucks with old diesel engines placed in new truck chassis), the agency uncritically summarized purported emission test results of glider trucks. The study it used was not peer reviewed; did not disclose its methodology (it turned out the critical observation was done by 'visual observation', i.e. eyeballing!), and EPA did not examine it for any indication of reliability. See 82 FR 53444 (Nov. 16, 2017). In contrast, EPA's National Vehicle and Fuel Emissions Laboratory (NVFEL) laboratory conducted its own study using, "standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments."⁴¹ 83 FR 18770. EPA did not even consider the NVFEL study in its proposal.

⁴⁰ Here is one of the relevant e mails, where Ms. Beck explains that the proposal will have to be amended so as not to affect industry submissions under FIFRA and TSCA:

So for pesticide registrations, the regulation ... requires a huge amount of data to be submitted to the agency-- it costs companies millions of dollars...My understanding is that these studies come in as CBI but for a large majority of these, the CBI can be waived and the data made available (on request). Making data available is very different from a publication requirement....There will also be a problem for TSCA where for many existing chemicals ... companies conduct OECD guidelines studies ... The directive needs to be revised. Without change it will jeopardize our entire pesticide registration/re-registration process and likely all TSCA risk evaluations.

⁴¹ U.S. Environmental Protection Agency, Chassis Dynamometer Testing of Two Recent Model Year Heavy-Duty On-Highway Diesel Glider Vehicles, Nov. 20, 2017, Docket No. EPA-HQ-OAR-2014-0827-2417, <https://www.regulations.gov/document?D=EPA-HQ-OAR-2014-0827-2417>

Consequently, we would submit that, if the agency insists on attempting to promulgate this flawed rule, there should be no distinction made between application of its provisions to major rules and to all other regulatory actions with regard to the consideration of the science in the development of such decisions. If it is appropriate for one category of rules, then it is appropriate for all of them.

VII. Rule's Implications Beyond EPA

The proposal on its face does not apply to other federal agencies or to states and tribes, (or for that matter, even to EPA outside of major rulemaking). But it does not acknowledge that this would mean two different federal definitions of science, or address the potential confusion this would create.

In some cases, sister federal agencies have a formal role in EPA decision-making. Several provisions of the Clean Water Act require that EPA act “after consultation with appropriate Federal and State agencies and other interested persons.” E.g. CWA 304(a), 33 USC 1314(a) . See also CWA 104 (c) (providing for cooperation with Department of Health and Human Services on research on the harmful effects of pollutants on health or welfare); SDWA 1412(d) (in proposing and promulgating regulations, EPA “shall consult with the Secretary”); CERCLA 104(i)(1),(2),(3),(10) (creating Agency for Toxic Substances and Disease Registry with representatives from many federal agencies, including EPA reporting to the Surgeon General, to examine, summarize, and interpret “available toxicological information and epidemiologic evaluations” of “hazardous substances”). Because the proposal does not acknowledge the existence of any such provisions, it does not explain how any such consultation will be affected. If EPA receives comments from agencies during rulemaking based on the best

available science, would EPA examine the data underlying the comments to decide whether to disregard those comments? Would disregarding them result in a decision that is arbitrary for disregarding relevant information in the record? Or will it consider them, effectively overriding the terms of this proposal when it comes to science from other agencies? EPA has not attempted to explain how the different federal definitions of science would work, or even identified it as a source of potential problems for EPA or other agencies. This is another instance of inadequate notice under the APA.

It is also silent on how this proposal will be implemented in regard to states and tribes, who may comment or have consultation roles in developing major regulations, raising some of the same issues raised by the consultation of federal agencies. Moreover, federal standards may govern the level of environmental protection within states and on tribal lands. Those levels of protection would be reduced under a new regulation that ignores evidence because of the new rule. Would states or tribes have any recourse when this happened, or could they keep the old standards? Under what circumstances would or could EPA disapprove a program for failing to adhere to the new federal law requirement? Does EPA believe that a state with an authorized program based on actual science would still meet federal standards after the program becomes regulated under censored science providing for reduced federal standards? Would EPA disapprove a state program if the state failed to relax its standards to reflect new federal requirements? What kind of oversight would there be when states make permitting or enforcement decisions, actions that are not covered by the proposal but possibly implementing

regulations that are covered. Notably, the proposal makes no reference at all to states or tribes, other than perfunctory boilerplate claiming that it imposes no duties on states or tribes.⁴²

Finally, because few federally recognized Indian tribes operate their own regulatory programs, federal requirements and standards apply to most Indian lands. Has EPA considered whether it would be consistent with the federal trust responsibility to tribes to relax requirements or standards, and thus reduce protection for tribal lands solely because of a new regulation based on ignoring reliable and relevant science? Would such a reduction in protection on tribal lands be consistent with principles of environmental justice?

VIII. Fatal Procedural Defects

A. The Proposal Fails to Provide Adequate Notice and Opportunity for Public Comment Under the Administrative Procedure Act

EPA's proposal fails all of the general administrative law requirements to provide adequate notice and opportunity for informed public comment. Indeed, this proposal ostensibly to support "transparency" in science is shrouded in so many vague generalities and so few specifics that any reader going beyond the introductory paragraph will learn next to nothing about the rule. As explained above, the proposal sends contradictory signals even about its substance--whether it is mandatory or hortatory, and whether a study that can be replicated but where the raw data is not available can be used. Compare the preamble summary (EPA "should" ensure that the data underlying its rulemaking is publicly available) and 30.4 (EPA "shall" identify the studies it is relying on and "should" make all such studies available to the public to the extent practicable) with 30.1 (rule "directs" EPA to ensure public availability) and 30.8

⁴² Several of the perfunctory statements concluding that other legal or administrative requirements are not implicated are unpersuasive.

(authorizing exemptions). Compare 30.5 (information in a study is publicly available where it includes enough information to enable the public to “replicate” its findings) with Preamble note 3 (rule would “preclude” use of two studies that have been replicated). Assuming that such an incoherent, ambiguous, and self-contradictory proposal would even be possible to implement, it falls pathetically short of stating with the required detail and specificity the substance and basis of the agency action.

EPA proposes to adopt rules restricting its use of science under at least eight statutes. Yet, the entire support for that radical step is set forth in a proposal of 21 paragraphs (and 24 footnotes), 8 of the paragraphs of which are filled with thirty questions posed to commenters rather than a clear explanation of the purpose, legality or implications of the proposal. The requested comments cover a wide array of topics, including such basic questions as how the proposal “can best be implemented” and the legal bases for EPA’s authority to issue the proposal. Providing answers to these questions is the responsibility of the agency, not the commenting public.

Ordinarily, an agency should fully understand how it proposes to answer those questions in order both to understand its rule, and to meet its legal obligation “to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions.” That explanation should be included in the preamble, which can serve as a guide to interpreting the regulation. The proposal does not do that, and fails also to discuss how it will actually work under each of the eight statutes. It lists research and general rulemaking authorities under eight statutes but does not even identify any statutory requirements for science it might affect, much less the likely effects of those proposed changes to programs under the eight statutes. See

Connecticut Light & Power Co. v. Nuclear Regulatory Commission, 673 F.2d 525, 530 (D.C.Cir.) (notice of a proposed rulemaking should provide an accurate picture of the agency's reasoning so that interested parties may comment meaningfully upon the agency's proposed rule). See *Billington v. Underwood*, 613 F.2d 91, 94 (5th Cir.1980) (“Such a statement must be sufficiently specific for it to enable an applicant to prepare rebuttal evidence to introduce at his hearing appearance.”) In that context, in which the principles are similar to those in rulemaking, the purposes of adequate notice, including having the opportunity to prepare for the hearing and rebut the agency's allegations, require that a statement of reasons include a brief description of the event including when it occurred, who was involved, and what provision was violated. See *id.*, see also *Edgecomb*, 824 F.Supp. at 314; *Driver*, 713 N.W.2d at 673.”); *Owner-Operator Independent Drivers Ass'n, Inc. v. Federal Motor Carrier Safety Admin.*, 494 F.3d 188, 209 (D.C. Cir. 2007). It is certainly true that a notice can be “too general to be adequate.” *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 549.

Because it has not done so, the rule should be withdrawn and the agency should provide adequate information to make notice and opportunity for public comment on these fundamental issues meaningful, if it issues a revision.⁴³

Among the multitudinous issues about which the proposal is mute are:

1. Its impacts on rules across each of EPA's core environmental statutes, both as to how this rule would apply and how it would affect existing regulations. As noted, it does not even identify the relevant statutory provisions, much less potentially affected regulations. If the proposal would leave those rules in place, it would accomplish little. If it would repeal some or all of them, either directly or by requiring them to be redone, EPA should say so and describe the scope of the proposal's impact. Instead, it is completely silent about whether any existing rules would be affected, and does not even identify any such rules, much less describe how this rule would affect them. Thus it provides no basis for informed public comment.

⁴³ Ironically, the proposal cites EO 13563 as support. Here is what that Executive Order recommends as to public participation, virtually every word of which is disregarded here:

“Sec. 2. Public Participation. (a) Regulations shall be adopted through a process that involves public participation. To that end, regulations shall be based, to the extent feasible and consistent with law, on the open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole.

(b) To promote that open exchange, each agency, consistent with Executive Order 12866 and other applicable legal requirements, shall endeavor to provide the public with an opportunity to participate in the regulatory process. To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days. To the extent feasible and permitted by law, each agency shall also provide, for both proposed and final rules, timely online access to the rulemaking docket on regulations.gov, including relevant scientific and technical findings, in an open format that can be easily searched and downloaded. For proposed rules, such access shall include, to the extent feasible and permitted by law, an opportunity for public comment on all pertinent parts of the rulemaking docket, including relevant scientific and technical findings. (c) Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking. 76 FR 3821 (Jan. 21, 2011) (emphasis added).

2. Its cost impacts both on the agency and on reviewers; among other deficiencies, the proposal unhelpfully and tautologically states that costs will be low because EPA will “implement” the rule “in a manner that minimizes costs” (proposed section 30.8). There is no explanation of what specific types of costs may be incurred, much less how they will be minimized. This type of vague and unsupported pronouncement does not provide an adequate basis for public comment; see *Chamber of Commerce v. SEC*, 443 F. 3d 890, 904-05 (D.C. Cir. 2006) (unsupported statement that costs of action are expected to be minimal does not provide adequate notice of agency’s final actions relating to cost estimates).
3. How or whether it can be implemented without simply disqualifying scientific information wholesale considering a) researchers’ needs and funding; b) EPA resources; c) HIPPA requirements to preserve privacy and confidential information; and d) the fact that many studies are conducted by third parties. It fails to explain how it is meant to function for third party-conducted studies (for example, the text of the proposal says, “[w]here data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section” and leaves it at that (proposed 30.5).
4. Its scope (including its potential application to past actions), and why it does not apply to many of the types of agency actions that confer a benefit on regulated industry;

5. The meaning of proposed 30.7, which suggests that EPA will be required to re-peer review every study upon which it relies.⁴⁴ The regulatory text is accompanied by no explanation, leaving commenters to speculate about how it would apply, or what problems its implementation might present. The proposal's complete failure to explain this far-from-self-explanatory provision is yet another instance of failure to give adequate notice of the substance and basis of the rule.
6. The proposed rule cross-references the OMB Information Quality Bulletin for Peer Review. Aside from problems raised by cross-referencing a document that can be amended, that Bulletin recognizes that an agency need not conduct peer review of studies which already have been adequately peer reviewed. 70 FR at 2671. It is not clear if EPA is aware of this, or what, if anything, the proposed rule is intended to add to the Information Quality Bulletin with which EPA already complies or how in fact it would operate. As noted above, proposed section 30.5 is so awkwardly drafted that it is not clear if it is intended as an absolute requirement or is advisory. Language in footnote 3, and in 30.5 suggest that it is a requirement. Other language does not, e.g, 30.5 (information can be used if it provides the information necessary to "replicate" findings).

⁴⁴ The proposal may be trying to revive the argument thoroughly rejected and debunked by the D.C. Circuit in *Coalition for Responsible Regulation v. EPA*, 684 F. 3d 102 (D.C. Cir. 2012) (finding that substantial evidence supported EPA's finding that emissions of enumerated greenhouse gases endanger public health and welfare and that vehicular emissions contribute to that endangerment). There, the court stated that "EPA simply did here what it and other decision-makers often must do to make a science-based judgment: it sought out and reviewed existing scientific evidence to determine whether a particular finding was warranted. It makes no difference that much of the scientific evidence in large part consisted of 'syntheses' of individual studies and research. Even individual studies and research papers often synthesize past work in an area and then build upon it. This is how science works. EPA is not required to re-prove the existence of the atom every time it approaches a scientific question." 684 F. 3d at 120. Proposed section 30.7 shows signs of being designed to 're-prove the existence of the atom' by requiring re-peer review. No need for doing so is apparent, none is provided in the notice, and this proposed provision appears both substantively and procedurally defective as a result.

7. It acknowledges that data may be “controlled by third parties,” but its entire explanation of what this may mean is a vague promise that “EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section.” That language does not begin to address the variety of complexities involved with data controlled by a wide variety of third parties each with different policies of access, making it nearly impossible for commenters to know whether third party studies can ever be used without some type of interactive process between the study authors and EPA. Again, even if EPA does not intend to apply this provision to categorically bar the use of third party studies, its failure to point this out, or otherwise explain this provision makes the rule too vague to implement and is still another instance of failure to provide adequate notice.
8. The relationship between this proposal, subsequent rulemaking proposals and applicable Administrative Procedure Act requirements. 5 U.S.C. 553(c) requires agencies proposing a rule to “give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or argument.”

If commenters on a future proposed rule submit studies barred by this per se rule, will EPA refuse to consider them? Two other questions are noted above: What if the studies are submitted by a federal agency, either consulting or commenting on a rule, or a state, or a tribe? What would be the legal basis, under the relevant statute, for refusing to do so? If EPA will consider them at this stage of rule development, what is the argument for not considering them when framing EPA’s proposal of that same rule? To provide adequate notice, an agency must of course disclose

all underlying supporting data on which it relies. See e.g. *Chamber of Commerce v. SEC*, 443 F.3d at 899; CAA Section 307 (d)(3) (A) and (B).

Here, EPA has included only an undifferentiated data dump of citations without identifying passages of particular relevance (e.g. footnotes. 9-12, see above), or explaining references to policies of other federal agencies (e.g. 83 FR 18770).⁴⁵ As explained above and in Appendix D most of these sources are either mis-characterized or provide no support for the proposal. But in any case, such undifferentiated references do not provide adequate notice of the agency's thinking or intentions. *Jackson v. Des Moines Mun. Housing Agency*, 2008 WL 10707693, at *4 (S.D.Iowa, 2008) states this clearly in the context of the necessity of giving individuals adequate information to prepare rebuttal evidence against the government (“This is incorrect, however, because even a citation that includes a statement of the general language of a regulation is not sufficient to provide adequate notice. ‘Agency notice must describe the range of alternatives being considered with reasonable specificity[;][o]therwise, interested parties will not know what to comment on.’ *Small Refiner Lead Phase–Down Task Force*, 705 F.2d at 549”). The proposal does not identify any alternatives it may be considering, much less discuss them.

Once this rule is in place, what recourse would be available to commenters on future actions that seek to use science that is excluded by the new rule? Would they be barred from challenging this rule in that later proceeding? Finally, EPA's virtually open-ended solicitation of comments on many complex, nuanced issues related to the proposal—such as criteria for possible exceptions to the new science policy, methodologies and technologies to provide access where identifiable and sensitive data are involved -- are questions posed without even

⁴⁵ The regulatory docket is likewise devoid of meaningful information, consisting of a handful of executive orders and copies of the OMB Data Quality Act Guidelines and related Guidance (which, ironically, specifically endorse the Harvard Six Cities study as satisfying all criteria for transparency).

suggestions of how EPA would respond or what it proposes to do. These are clear examples of the agency's failure to give due consideration to the rule and its implications, as well as its failure to notify the public as to the substance of the rule. The public is on its own when it comes to inferring or intuiting what the proposal proposes to do, or whether there are better alternatives or, indeed, how to respond to the posed questions. And the rule gives no guidance as to the substance or basis of the rule the agency will ultimately adopt.

In sum, it is difficult to conceive of a "proposed rule" notice that provides less information about its substance, basis, application, and likely effects than this one. Even its ostensible definitions are unclear: what law or regulation is it referring to when it says, "all terms not defined herein shall have the meaning given in the Act or Subpart A?" Neither the Act nor Subpart A is identified more specifically, making the meaning of this provision, and thus the regulation unclear.

B. The Process Used in Developing the Proposal did not Comply with Applicable Statute-Specific Rulemaking Procedures

1. *FIFRA*

The proposal lists FIFRA sec. 25 as an authority for the rulemaking. 83 FR 18769. The agency, however, has failed to follow required procedures for issuing a valid regulation under FIFRA. FIFRA requires the agency to seek comments from the Secretary of Agriculture on all draft proposed regulations prior to signing the regulation for publication in the Federal Register; and, if USDA provides comments, the agency must respond in writing to the comments as part of the proposed rulemaking package. See FIFRA sec. 25(a)(2); 7 U.S.C. 136w(a)(2). The statute contains a similar provision regarding consultation with the SAP --a body of independent expert

scientific peer reviewers chartered under the Federal Advisory Committee Act (FACA) on all draft proposed regulations. See FIFRA sec. 25(d); 7 U.S.C. 136w(d). FIFRA further requires EPA to publish a notice in the Federal Register simultaneously with the transmission of the proposed rule to USDA. FIFRA sec. 25(a)(2)(C); 7 U.S.C. 136w(a)(2)(C). In addition, the statute requires the agency to submit a copy of the proposed rule to the Agriculture Committees in the House and Senate. See FIFRA sec. 25(a)(3); 7 U.S.C. 136w(a)(3). The agency did not comply with any of these requirements. A very serious consequence of these procedural mistakes is to deprive the agency of a full understanding of how the proposed rulemaking might affect the regulation of pesticides and thereby affect agriculture, human health, and the environment. Had this proposal been referred to the SAP, EPN and other interested entities would have had the opportunity, according to SAP practices, for comment, a process which assures that the decision-makers obtain the widest possible input to these critically important decisions.

2. Clean Air Act

Even if the per se rule could satisfy the substantive requirements of the NAAQS — which it cannot — the proposal fails utterly to comply with procedural requirements for establishing NAAQS, and in particular, for amending the air quality criteria on which the NAAQS are based. The law requires EPA to set NAAQS (as well as virtually every other significant Clean Air Act rule) through a structured dialogue with the public. CAA § 307(d)(3). First, EPA must issue a proposal setting out the “factual data” relied on the “methodology used in obtaining the data and in analyzing the data,” and the major legal and policy considerations underlying the proposal. The public can then comment on every aspect of this proposal, and can

submit its own data. When EPA takes final action, it must respond, “to each of the significant comments, criticisms, or new data submitted.” *Ib.*

These provisions largely mirror the requirements of the APA though they are more elaborately stated. Other specific provisions, however, go well beyond APA requirements. Specifically, any change in criteria documents must by law be reviewed by CASAC. CAA §109(d). In addition, criteria documents must also be reviewed by EPA’s SAB under 42 USC 42 USC section §4365 (c)(1) (the Environmental Research Development Demonstration Authorization Act).

EPA’s proposal would specifically and indisputably amend the air quality criteria, adopted pursuant to section 108 (b) of the CAA, for particulate matter (PM) and lead. See proposed rule footnote 3 final sentence which states that the proposed rule would “preclude” using the Lanphear study⁴⁶ which is part of the criteria for the NAAQS for lead, and the Harvard Six Cities and American Cancer Society II studies which are part of the air quality criteria for the PM NAAQS, and presumably a number of informative studies that update and expand these original works by adding more recently collected health and air pollution information. For these reasons the statement at proposal 18773 saying the rule “does not establish an environmental health or safety standard” is false.

The proposal furthermore affects the current review of the PM NAAQS by proposing to regulate -- in fact, dictate -- the type of science that can be used in that review, and removing studies which were part of the air quality criteria in the past reviews, which would again directly alter the air quality criteria. Air quality criteria cannot be amended without review by CASAC.

⁴⁶ Bruce P. Lanphear et. al, *Lead-Contaminated House Dust and Urban Children's Blood Lead Levels*, 86 Am J Public Health 1416 (1996). <https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.86.10.1416>

See CAA §109 (d)(2)(B). EPA consequently must submit its proposal to CASAC for its review, following all procedural requirements for public meeting and deliberations in doing so. CASAC must then submit its recommendations to the Administrator (see §109 (d)(2)(B) final clause), and the Administrator must consider these recommendations and provide a reasonable explanation for any actions that deviate significantly from those recommendations (CAA §307(d)(3)).

EPA cannot proceed with this action until these requirements are satisfied. And EPA cannot short-circuit the role the law assigns CASAC by using this type of broad rulemaking, effectively dictating how science can be used in future rule-makings, to restrict CASAC's authority.

The proposal would amend the substantive standards for decision-making for a host of actions covered by CAA section 307 (d), among them the NAAQS (§307 (d)(1)(A)), residual risk determinations for hazardous air pollutants (§307 (d)(1)(C)), standards for mobile source air toxics (§307 (d)(1)(K)), and residual risk standards for municipal solid waste combustors (§307(d)(1)(D)). Therefore, CAA §307 (d)(5)(ii) and (iv) require the Administrator to hold a public hearing on his proposal and to keep the record open for an additional thirty days, “to provide an opportunity for submission of rebuttal and supplementary information.”

EPA should have submitted its proposal to the SAB pursuant to the requirements of 42 USC§ 4365 (c)(1) (the Environmental Research Development Demonstration Authorization Act), which 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. The SAB is then to review and

comment on the proposal, which the Administrator is to consider, although the Administrator is not required to obtain SAB approval for any final action. See H. Rep. No. 95-722 (95th Cong. 1st Sess. (1977) (Conference Report).

EPA and the SAB have adopted procedures to implement this statutory requirement, whereby EPA provides SAB with a description (including a pertinent summary of potential issues of scientific concern) of planned major actions not yet proposed and the SAB determines, in a public forum, which of these actions merits its consideration and comment. See Memorandum of December 27, 2012, “Identifying EPA Planned Actions for Science Advisory Board Consideration of the Underlying Science” from Michael Goo, Assistant Administrator for Policy, Glenn Paulsen, EPA Science Advisor, and Vanessa Vu, Science Advisory Board Office Director, and Memorandum of November 12, 2013 from Science Advisory Board Chair James Mihelic to Members of the Chartered Science Advisory Board and Liaisons. EPA has failed to comply with its statutory obligations and the requirements of its internal procedures.

In short, in its evident zeal to advance purported “transparency,” EPA has thus ignored a variety of statutory and regulatory requirements which provide actual transparency to agency rulemakings, including most notably both the FIFRA and the Clean Air Act’s scientific review process.

IX. Conclusion

There are so many things wrong with this proposal that it is easy to lose track of the most important one: the harm it will do to the health of the American public and to our environment. The proposal hides its impacts in a fog of ambiguous language, meaningless generalities and vague platitudes about the value of “transparency.” It requires EPA to wear a blindfold when it is developing major rules by ignoring what relevant and reliable science tells us about health risks any time the raw supporting data is not publicly available. The laws governing EPA programs require the agency to consider all of the available scientific information in deciding how best to protect health and the environment. Ignoring pertinent and relevant information would be both arbitrary and unlawful.

The proposal would put even the most persuasive and useful science off-limits, and would preclude using even recent studies that are subject to confidentiality agreements or legal restrictions on disclosure. It also will certainly -- deliberately -- exclude older studies where raw data is no longer available, even if their findings are widely accepted as authoritative and formed the basis for EPA regulations that have proven effective for many years. The proposal is evasive about its targets, using footnote language only a legal expert can decipher to identify two seminal air pollution studies, long disliked by the regulated industry, that it would exclude. Otherwise, remarkably for a proposal that creates a per se ban in eight EPA programs against using any science not meeting a self-defined “transparency” requirement, it says nothing, nothing at all, about other important studies it would ban: which ones it will ban, how many studies, the

reliability or utility of the banned studies, or the harm their exclusion will do to informed decision-making, and thus to environmental protection.

In sum, there is neither a legal basis nor a need for this rule. It would require that EPA violate explicit statutory provisions and would undermine environmental protection and critical health protections the public has come to rely on. It unlawfully shifts the basis for deciding what science to use in rulemaking away from the statutory goals of scientific reliability and environmental protection to so-called transparency, a term not used in the relevant EPA statutory provisions. The proposal is brief, evasive, superficial and ambiguous, and provides far too little information to meet the legal requirement that the public must be alerted to its substance and basis in order to understand sufficiently to provide public feedback and ultimately to create a workable legal framework the public must be fully alerted to its substance and basis. In other words, this proposal is unintelligible, unlawful and unworkable. EPN respectfully requests that EPA withdraw it.

Respectfully Submitted,

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Gary Timm. Areas of expertise: chemical testing, Toxic Substances Control Act, Endocrine Disruptor Screening Program. Years at EPA: 1973-2011.

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Appendix A

The Defects in EPA's Proposal Regarding Dose-Response and Statistical Modeling Requirements

The proposed rule includes a brief preamble discussion as well as a proposed rule (section 30.6), with additional criteria and actions that EPA must take regarding “dose-response data” and “dose-response models.” Stating “that there is growing evidence of non-linearity in concentration response for specific pollutants and health effects,” but without citing any evidence or identifying examples of the pollutants, and/or the kinds of effects to be addressed, the proposal asserts a need for EPA to be more transparent regarding the assumptions underlying dose response models. 83 FR 18770/1-2. It is hard to argue for that as a principle and even harder to see how the rule itself addresses that policy objective.

The proposal ignores the existence of “systematic review” methods for review of evidence that are being developed within the agency, most notably within the IRIS program, prompted by criticisms and recommendations from the NAS.⁴⁷ The development of such methods is informed by the National Toxicology Program’s Office of Health Assessment and Translation (NTP/OHAT) guidance⁴⁸ and other similar tools (UCSF’s Navigation Guide).⁴⁹ No authoritative body of experts has ever recommended requiring “raw data” in order to perform or review dose

⁴⁷ National Academies of Sciences, Engineering, and Medicine. 2018. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25086>.

⁴⁸ Rooney AA, Boyles AL, Wolfe MS, Bucher JR, Thayer KA. 2014. Systematic review and evidence integration for literature-based environmental health science assessments. *Environmental Health Perspectives* 122:711-718.

⁴⁹ Woodruff T, Sutton, P. 2014. The Navigation Guide Systematic Review Methodology: A Rigorous and Transparent Method for Translating Environmental Health Science into Better Health Outcomes. *Environmental Health Perspectives* 122(10): 1007-1010. Available at <https://ehp.niehs.nih.gov/>.

response assessments. As a corollary, they have never concluded that scientific findings should be disregarded if “raw data” for dose response assessments are not available.

One part of the preamble discussion appears to establish criteria for identifying high quality studies, listing a set of carelessly chosen statistical attributes, some of which would be mutually exclusive in any single publication, for example “a broad class of parametric concentration response models” and “nonparametric models,” as well as including others that are not in sync with best practices in regulatory science as recommended by authoritative bodies such as the National Academies. Even if these criteria for evaluation were apt and reasonable, the language suddenly departs from them, via statements such as “incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation” using alternative models. This kind of statement would apply to EPA’s use of such data and methods in producing risk assessments and cost-benefit analyses and, in fact, is consistent with current agency policy. It is not relevant to evaluating studies that may underlie such assessments. In short, the proposal’s description of the “fix” is as inadequate and off the mark as its description of the “problem.”

Both the discussion of purportedly desirable attributes in studies to be used for assessment and how the agency should use alternative low dose models are far less detailed and nuanced than either EPA’s voluminous existing guidance on risk assessments or recommendations on these topics contained in several NAS reports relating to risk assessment, including the 2007 “Silver Book.”⁵⁰ It is impossible to tell from reading the proposal what the real problems, if any, might be, nor how commenters should respond to EPA’s proposed fixes.

⁵⁰ National Research Council. 2009. Science and Decisions: Advancing Risk Assessment. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12209>.

Nevertheless, suggesting the use of non-linear, including threshold, assumptions in all dose-response modeling is at variance with the current state of the science, as well as current EPA guidelines for risk assessment and the NAS advice - both of which encourage careful evaluation of all scientific information in determining the possible shape of dose response curves (based on mechanistic considerations) as well as the application of a number of mathematical models to one or more specific sets of dose response data to determine which model provides the best fit and prediction. Raw data is not required for these analyses. Analyses are done on a case-by-case basis, with the results produced depending upon the nature of the data examined. The outcome of this exercise may lead to the conclusion that the dose-response for the observed adverse effect exhibits non-linearity or that it doesn't. Considerable scientific judgment is required not only in interpretation of the results of models but also in placing them in context of other data about the chemical.

For assessing human health risk based on animal toxicology studies, EPA has developed a publically-available, widely-used and accepted tool (the Benchmark Dose software (BMDS)) that can perform these calculations. BMDS currently contains thirty different models that are appropriate for the analysis of dichotomous (quantal) data, continuous data, nested developmental toxicology data, multiple tumor analysis, and concentration-time data. There also are many other open source and proprietary tools available to use as well. The agency has access to most of them.

Because air quality standards have been based in large measure on human clinical and community epidemiology studies, EPA adopted an "acceptable risk" interpretation of the

requirement for “an adequate margin of safety” early in the initial reviews of the NAAQS.^{51,52}

The approach for conducting formal risk assessments for NAAQS criteria and standards reviews evolved over time, but has remained consistent with the principles and practices outlined above, namely that quantitative dose or concentration-response approach should flow from the available scientific data. As the NAS noted in 2009, the more recent human clinical and epidemiologic evidence available for fine particles and ozone risk analyses has involved fairly low-level exposures, and extrapolation below the level of observation to any great degree is less important than for compounds for which evidence is derived from animal bioassays or occupational (high dose) epidemiology.⁵³

The most recent risk assessments for the ozone⁵⁴ and fine particle⁵⁵ NAAQS include examples of a non-linear threshold approach based on human clinical studies, and no-threshold concentration-response models based on short and long-term epidemiology studies of premature mortality. These risk assessments, which are peer reviewed by CASAC, form the primary basis for benefits estimates for the NAAQS as well as for cost-benefit analyses of regulations that reduce NAAQS pollutants. The proposal would force both risk assessment and cost benefit analyses to include thresholds and/or other non-linear concentration-response functions,

⁵¹ Richmond, H.M. A Framework for Assessing Health Risks Associated with National Ambient Air Quality Standards; Environ. Prof. 1981, 3,225-234.

⁵² Bachmann, J.D. 2007. Critical Review: Will the circle be unbroken: A history of the U.S. national ambient air quality standards. J. Air Waste Manag. Assoc. 57(6):652–697. doi:10.3155/1047-3289.57.6.650

⁵³ The NAS Silver book also stated that “Fine PM (PM_{2.5}) belongs to a family of pollutants (including ozone) with noncancer end points for which the evidence points to a linear or other non-threshold population response at low doses.”

⁵⁴ EPA, 2014. Final Report: Health Risk and Exposure Assessment for Ozone, EPA-452/R-14-004a August 2014 <https://www3.epa.gov/ttn/naaqs/standards/ozone/data/20140829healthrea.pdf>

⁵⁵ EPA, 2010. Quantitative Health Risk Assessment for Particulate Matter. EPA-452/R-10-005 June 2010. https://www3.epa.gov/ttn/naaqs/standards/pm/data/PM_RA_FINAL_June_2010.pdf

regardless of what the review of the scientific information concludes. If EPA has issues with its current risk assessment and benefit analysis procedures that currently follow NAS recommendations and its own existing guidelines, a more straightforward and fruitful approach would be to update the guidelines as needed, showing in far more detail than provided here the details of their reasoning, the conditions in which they should be employed, and the scientific bases for requiring consideration of alternative models in all risk assessments. The draft guidelines should then undergo peer review by expert panels of the NAS and/or its own SAB and SAP. While guideline development is arduous and time consuming, it has several advantages over rulemaking, including 1) guidance is developed by experienced risk assessors; 2) it is a science-based process that involves consensus building across the EPA as well as with the broader science community; and, 3) critically, it maintains the separation between risk assessment and risk management so that EPA's decision makers benefit from the availability of science that is produced in an independent and objective fashion. This has been the practice at EPA since 1983 when the NAS published *Risk Assessment in the Federal Government: Managing the Process*.

The most puzzling, and perhaps costly requirement in the rule (S. 30.6) appears only in the wording of a specific requirement in the actual proposed rule regarding use of dose-response data and models from pivotal studies: "EPA shall clearly explain the scientific basis for each model assumption used and *present analyses showing the sensitivity of the modeled results to alternative assumptions*." Proposed section 30.6 (emphasis added). This appears to require the agency not only to explain the basis of each model-related assumption in the original study but also to provide an analysis of the original data using alternative assumptions. EPA provides no

reasons why this should be an automatic and invariable requirement for all studies identified as “pivotal.”

Unless the study already includes such alternatives, this would require the agency to reanalyze the original data on its own. EPN believes that EPA is not staffed to reanalyze the number of pivotal studies that could reasonably arise for all of its significant rules under all statutes, and EPA provides no reason to believe that staffing levels would be adequate.

Therefore, the agency might need to enlist external analysts. This would take substantial time and money. As a point of comparison, the reanalysis of the ACS and six-city studies, which included analysis of alternative model specification, cost HEI approximately one million dollar.⁵⁶ If just half of recent cohort studies were to submit their data through some limited use agreement, it could cost EPA on the order of \$10 million to hire outside analysts to do the work.

If this level of analysis were required for even one or two studies in every major regulation, it would likely impair significantly the agency’s ability to meet regulatory deadlines for the NAAQS or other programs, among other things precluding the agency from meeting its avowed goal of completing NAAQS reviews for PM and Ozone by 2020.⁵⁷

The proposal’s poorly defined requirement that EPA “shall conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions” could pose similar problems. Proposed 30.7, FR at 18774. It also is puzzling that this is included in the proposed rule given that external peer review generally already occurs in the cases of significant regulatory actions. It would appear that the authors of this proposed rule are either not aware of, or have

⁵⁶ This extensive and expensive reanalysis did not result in a different estimate for the health risks of PM pollution.
⁵⁷ Pruitt, E.S. 2018. Memorandum: Back-to-Basics Process for Reviewing National Ambient Air Quality Standards, May 9. Online at <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf> Accessed May 18, 2018.

never bothered to read the Agency's Peer Review Handbook.⁵⁸ If they have read it, they chose not to cite it. The Handbook lays out very clearly the levels of peer review expected to be implemented, depending upon the nature and potential impact of a particular scientific product, including risk assessments. There is no evidence given in the proposed rule to support that EPA is not following these policies and that this rulemaking is necessary.

In short, this is yet another cost and impact which the agency has arbitrarily failed to acknowledge, much less account for. This is not only substantive error, but a failure as well to provide adequate notice and opportunity for comment.

Fundamentally, this proposal for the first time opens the door to EPA's scientific practices being determined by politically-appointed regulators, and not scientists. This is a rush down a slippery slope that would replace a scientific process with a political one and would freeze the science in procedures that may be dubious today but certainly will not be scientifically defensible in the future. By contrast, EPA's current science policy guideline-based approach provides the agency with the flexibility to move forward to incorporate new science information in a timely manner, whether it is developed by industry, the academic community, or the agency itself. The proposed approach is a breach of the fundamental principle of separating risk assessment from risk management, as championed in the 1983 NAS report.

⁵⁸ U.S. EPA. 2015. Peer Review Handbook. 4th Edition. Science and Technology Policy Council. U.S. Environmental Protection Agency. Washington, DC. EPA/100/B15/001.

Appendix B

The Air Pollution Studies Centrally Targeted by the Proposal and EPA's use of them are in Fact Models of Responsible Science Policy

The record of EPA's analysis and reanalysis over many years of the two fine particle epidemiology studies that the proposal would definitively bar from regulatory use shows how scientific researchers and EPA successfully used a number of different approaches to confirm the association between long-term exposures to fine particles and mortality, as well as how EPA's reliance on the growing body of evidence increased over the last two decades. The new evidence of a significant relationship between mortality and long-term exposure to fine particles from "cohorts," which provided detailed health and lifestyle characteristics such as weight, age, smoking status, and income, began with the 1993 Harvard "Six City" study.⁵⁹ The researchers sought to replicate their initial findings using data from the American Cancer Society (ACS) cohort, which had a much larger number of subjects and cities than the six city cohort. The follow-up ACS study did indeed replicate those findings.⁶⁰

Because these were the only two high quality fine particle cohort studies, EPA's 1996 Criteria Document's evaluation of the implications of these new studies was measured,⁶¹ as was EPA's reliance on them in setting the 1997 fine particle standards.⁶² EPA placed greater weight

⁵⁹ Dockery, D.W.; Pope, C.A., III; Xu, X.; Spengler, J.D.; Ware, J.H.; Fay, M.E.; Ferris, B.G.; Speizer, F.E. (1993). An Association between Air Pollution and Mortality in Six U.S. Cities; *N. Engl. J. Med.* 329, 1753- 1759.

⁶⁰ Pope, C.A., III; Thun, M.J.; Namboodiri, M.M.; Dockery, D.W.; Evans, J.S.; Speizer, F.E.; Heath, C.W. (1995). Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults; *Am. J. Respir. Crit. Care Med.* 151, 669-674

⁶¹ In evaluating these and other studies, EPA concluded that "However, the chronic exposure studies, taken together, suggest that there may be increases in mortality in disease categories that are consistent with long-term exposure to airborne particles and that at least some fraction of these deaths reflect cumulative PM impacts above and beyond those exerted by acute exposure events." (EPA, 1996, page 13-33).

⁶² In establishing the level of the annual standard, EPA gave most consideration to the annual concentrations in studies that found significant associations between short-term mortality and other effects, and then concluded that the cohort studies did not provide a basis for a more stringent level.

on evidence from more numerous new “time-series” short-term studies of particle pollution and health, for which health and lifestyle related variables (e.g. smoking) are less important.⁶³ EPA based the levels of both the annual and 24-hour fine particle standards on information from short term studies that measured fine particles, using the cohort studies as supporting evidence of the seriousness of the mortality risk from long-term exposures.⁶⁴

Some groups raised concerns about gaining access to the data in public comments as well as in subsequent lawsuits on the 1997 standards. As discussed above, the court later upheld EPA’s consideration and use of the studies as published in the peer-reviewed literature. Harvard and the ACS had refused to release data collected on the cohorts due to privacy concerns regarding the subjects’ lifestyle, medical data and location, as well as confidentiality commitments made to participants when they enlisted in the cohort. Given the continuing demands to release these data for reanalysis, however, the original investigators solicited the help of the Health Effects Institute (HEI), which is jointly funded by EPA and industry. Harvard and the ACS agreed to make the data and methodology available in a controlled manner to experienced independent third party investigators for reanalysis. These researchers would be chosen and managed by HEI. The reanalysis of both studies was successful and HEI published the results in 2000.⁶⁵ The HEI report conclusion stated: “Overall, the reanalyses assured the

⁶³ As detailed in a case-study of particle standards, EPA supported reanalyses of some of the then newer time-series studies by third party investigators. See, D.S. Greenbaum, Bachmann, J.D., Krewski, D., Samet, J.M., White, R. and R.E. Wyzga, Particulate Air Pollution Standards and Morbidity and Mortality: Case Study. *American Journal of Epidemiology*, Volume 154, Issue 12, 15 December 2001, Pages S78–S90, <https://doi.org/10.1093/aje/154.12.S78>. It is easier to avoid privacy concerns when providing access to aggregate single or multi-city daily mortality and hospital admission data.

⁶⁴ EPA (1997). National Ambient Air Quality Standards for Particulate Matter: Final Rule. *Fed. Regist.* **1997**, 62,38652-38760.

⁶⁵ Krewski, D., Burnett, R.T., Goldberg, M. Hoover, K., Siemiatycki, J., Jerrett, M., Abrahamowicz, M. and White, W. H. 2000. “Investigators’ report”. In *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality. Special report*, 7–244. Cambridge, MA: Health Effects Institute.

quality of the original data, replicated the original results and tested those results against alternative risk models and analytic approaches without substantively altering the original findings of an association between indicators of particulate matter air pollution and mortality.”⁴²

By 2009, however, enough new evidence had accumulated for EPA’s Particulate Matter Integrated Science Assessment (PM ISA)⁶⁶ to conclude that the weight of the evidence from over 15 more recent large U.S. cohort studies;⁶⁷ together with supporting evidence from both older mortality and epidemiology and toxicological studies, was sufficient to infer a causal relationship between long-term fine particle (PM_{2.5}) exposures and mortality and cardiovascular effects. This conclusion regarding causality (the strongest finding possible under the causality classification methodology) based on these studies was endorsed by the external CASAC, which noted:

The five-level classification of strength of evidence for causal inference has been systematically applied; this approach has provided transparency and a clear statement of the level of confidence with regard to causation, and we recommend its continued use in future ISAs.⁶⁸

More importantly, in the intervening years other investigators have published many additional studies⁶⁹ that essentially replicated the earlier long-term fine particle-mortality findings using

<https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air>

⁶⁶ US EPA (2009a). Integrated Science Assessment for Particulate Matter: Final Report. National Center for Environmental Assessment-RTP Division, Office of Research and Development, Research Triangle Park, NC. EPA/600/R-08/139F. December 2009. http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html.

⁶⁷ Several of these newer studies were updates that added more recent mortality and air quality data to the Six City and ACS cohorts, while others used alternative data sets and authors (see Figure 7-7, PM ISA). While most of the effects estimates from the then recent studies were positive, some were not significant. Some studies suggested no excess mortality associations in California and other western areas, while others did. The ISA placed greater weight on larger new studies representative of the entire US as strengthening the already strong evidence assessed in the 2004 Criteria Document.

⁶⁸ J. Samet. Review of Integrated Science Assessment for Particulate Matter (Second External Review Draft, July 2009) November 24, 2009. EPA-CASAC-10-001

⁶⁹ Partial list of air pollution cohort studies published after completion of the 2009 PM ISA, that replicate the findings of earlier PM_{2.5} prospective cohort studies regarding long-term exposure to fine particles and mortality, in many cohorts, and excluding updates based on the six-city or ACS cohorts. Nurses Health Study: Puett et al. EHP, 2009; Health Professionals: Puett et al. EHP, 2011; U.S. Truckers: Hart et al. AJRCCM, 2011

different data sets, bringing the total number of replications and updates of the original two studies to over three dozen.⁷⁰ This type of cumulative weight of evidence is highly probative in

California Teachers: Lipsett et al. AJRCCM, 2011
Vancouver: Gan et al. EHP, 2011
China: Cao et al. J Hazard Mater. 2011
China: Zhang et al. PLoS One, 2012
Canadian: Crouse et al. EHP, 2012
New Zealand: Hales et al. J Epi Com Health, 2012
Rome: Cesaroni et al. EHP, 2013
National English: Carey et al. AJRCCM, 2013
22 European: Beelen et al Lancet, 2014
Ag. Health Study: Weichenthal et al. EHP 2014
Canadian Women : Villeneuve et al. Epi. 2015
CanCHEC (Canadian): Crouse et al. EHP 2015
Nurses Health: Hart et al. Environ Health 2015
Elderly Hong Kong: Wong et al. EHP 2015
Taiwan: Tseng et al. BMC Public Health 2015
Dutch (DUELS): Fischer et al. EHP 2015
France: Bentayeb et al. Environ Int. 2015
Canadian Com. Health: Pinault et al. EH 2016
U.S. Medicare: Kioumourtzoglou et al. EHP , 2016
NIH-AARP Diet and Health: Thurston et al. EHP, 2016
U.S. Medicare: Di et al. NEJM , 2017
Chinese Male: Yin et al. EHP, 2017
U.S. NHIS: Pope et al. AQ&AH 2017
U.S. NHIS: Parker et al. Circulation 2018

⁷⁰ As was the case in 2009, not all of the more recent cohort studies found effects of fine particles on mortality. In particular, Enstrom drew from the ACS cohort used in original 1995 ACS study by Pope et al, and replicated their findings for 50 cities, but found no effect on mortality when using the “best available” PM_{2.5} data. (Enstrom, J.E. Fine particulate matter and total mortality in cancer prevention study cohort reanalysis. Dose-Response. 2017;15(1):1–12. Google Scholar, SAGE Journals, ISI). This paper did not take note of the fact that the independent HEI (2000) reanalysis of the original study also tested the same alternative metric (PM_{2.5} annual mean) from the same monitoring network that Enstrom used with a somewhat larger cohort and found that the choice of air data had little effect on the positive and significant relationship between fine particles and mortality. Pope and ACS responded to the Enstrom article noting some differences and deficiencies; they highlighted the potential for significant exposure misclassification, as well as the consistently positive results from 14 updated ACS cohort studies with larger cohorts, which employed improved exposure data and analyses (Pope CA, III, Krewski D, Gapstur SM, Turner MC, Jerrett M, Burnett RT. Fine particulate air pollution and mortality: response to Enstrom’s re-analysis of the American Cancer Society Cancer Prevention Study II cohort (letter). Dose-Response. 2017;15(4); Gapstur SM, Brawley OW. Re: fine particulate matter and total mortality in cancer prevention study cohort reanalysis (letter). Dose-Response. 2017;15(4)). Enstrom later responded to the critique and provided a written comment to the EPA SAB meeting on the proposed transparency rule, claiming that his results call both the original and reanalysis studies into question, instead of the other way around. He suggests all studies using ACS data should be reassessed. His written comments also misrepresented the findings of a 2016 cohort study by another author, George Thurston, who provided a correction at the SAB meeting, pointing out that the effects estimate for PM_{2.5} in his study for total (and cardiovascular) mortality were in fact, statistically significant.

assessing both causality and in establishing the level of the NAAQS. *State of Mississippi v. EPA*, 744 F. 3d 1334, 1344 (D.C. Cir. 2013) (endorsing EPA’s weight of evidence approach, and stating that “incremental (and arguably duplicative) studies are valuable precisely because they confirm or quality previous findings or otherwise decrease uncertainty.”).⁷¹

One of the most recent fine particle mortality studies created a cohort of 60 million subjects from the Medicare database.⁷² This study found even larger effects of fine particles at levels well below EPA’s current standards. The Medicare database is available to any research group that pays a fee and can guarantee confidentiality of the personal data. Yet, because these data are not fully available to the public, under the proposed rule, the Administrator could choose to bar consideration of even this powerful study. See proposed section 30.5: “where data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section.” The ambiguous wording never specifies what actually might qualify, nor what interactions would be required before third party studies such as the Medicare study might be given an exemption from the requirement of public availability.⁷³

⁷¹ See Comment from Carnegie Mellon University faculty: “For example, meta-analyses such as those used to determine the odds ratios for the effect of maternal smoking on lower respiratory illnesses during infancy can rely on scores of studies that cover decades. Retroactive application of the proposed new language for §30 would be highly problematic for such meta-analyses. The combination of legal requirements under HIPAA to protect patient privacy and a poorly conceived transparency requirement could preclude the use of *any* epidemiological data to support agency decision- making, a result which would be inconsistent with the EPA’s legislated mandate to set pollution requirements which “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare...” 42 USC §7408 (a)(2).”

⁷² Qian Di, Yan Wang, Antonella Zanobetti, Yun Wang, Petros Koutrakis, Christine Choirat, Francesca Dominici, Joel D. Schwartz. Air Pollution and Mortality in the Medicare Population. *New England Journal of Medicine*, 2017; 376(26): 2513 DOI: 10.1056/NEJMoa1702747

⁷³ See also FR 18772/2-3 which states “it does not compel the agency to make that information available where it concludes after all such reasonable efforts that doing so in way [sic] that complies with the law and appropriate protections is (sic) not possible”. Although opaque and ungrammatical, this sentence seems to imply some prior agency determination before a third party study with confidential data is considered to be usable under the proposal.

In particular, because most of the long-term cohort studies of fine particles and premature mortality discussed above rely on information that cannot be fully released directly to EPA or the public, due to the need to protect the privacy of the participants, the EPA proposal would automatically categorize their results as unavailable -- “untrustworthy” -- for consideration in future regulatory decisions, i.e. as discussed above, a per se rule. See 83 FR 18769 n. 3 final sentence; see also former Administrator Pruitt’s testimony that indicates the six-city study, already reanalyzed, would not be accepted unless it provided the data and methodology to EPA, in effect making it public in a way it was not in the HEI reanalysis.⁷⁴ Likewise, the proposal itself mandates that “the Agency shall ensure that dose response data and models ... are publicly available in a manner sufficient for independent validation,” proposed section 30.5.

⁷⁴ <https://docs.house.gov/meetings/IF/IF18/20180426/108218/HHRG-115-IF18-Transcript-20180426.pdf> at 1138-39.

Appendix C

The Potential Devastating Health Impacts of the Proposal

While claiming unspecified benefits of transparency, the proposal has nothing to say about the health and environmental costs associated with the arbitrary removal of studies that have previously been peer reviewed and accepted for use by external science panel for regulations and cost benefit analysis. Under EPA's proposed policy, any regulation that relied on these studies might have to be withdrawn. The proposal clearly would require any study used to support a major regulation, risk or cost-benefit assessment by EPA to provide free access to all requests to underlying data and detailed methodology used in producing a peer reviewed publication. This restriction could eliminate use of some or all the following kinds of studies, depending upon whether an exemption based solely on a case-by-case decision by the Administrator were granted :

- Human studies using data sources that contain protected private medical, lifestyle, location, and other information
- Studies that contain or rely on confidential business information and protected intellectual property of researchers
- Older studies for which the original data records were either not maintained, lost, or stored on media that can no longer be accessed
- Human and animal studies published by independent investigators, who could refuse to incur the time and expense required to reformat their original raw data and produce a step by step guide to their methodology beyond the summary given in their peer reviewed paper

The proposal would also add a second overarching requirement, not based on any identified statutory language, which is that studies EPA uses must be able to replicated by

others. In context, EPA is using replicate not in the sense of conducting a new study to determine if the original conclusions also are supported by analyses of new data, but whether the results are “reproducible” by other analysts using the original data. Neither the proposal, nor the legislation it is based on, define “reproducible,” or “replicable” as used in the rule and are in fact not clear on how broadly this goal might be applied. c.f. section 30.5 (information must be sufficient to “replicate” findings). This is yet another instance of a failure to provide adequate notice. Read literally, requiring studies be reproducible as well as ‘transparent’ would also exclude the use of the following:

- Studies of the effects of natural or human-induced disasters and interventions on health and the environment
- Studies of human exposures to historically high concentrations of environmental pollutants or to occupational exposures that could not ethically be reproduced.

Our preliminary examination of the potential impacts of the proposal reveals many examples of rules and programs that might have been impossible to establish if EPA had adopted a data transparency limitation in past regulations.⁷⁵ Among these are programs to: reduce or eliminate lead exposure to children from paint, gasoline, and drinking water; develop water quality criteria for priority toxic pollutants, including polychlorinated biphenyls (PCBs); approve the registration of pesticides for agricultural and other uses under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetics Act (FFDCA); approve increases in production volume and usage of commercial chemicals under the Toxic Substances Control Act (TSCA); promulgate air quality standards for particulate matter

⁷⁵ See assessment based on legislation by Environmental Data and Governance Initiative (EDGI). Public Protections Under Threat at the EPA. Examining Safeguards and Programs that would have been blocked by H.R. 1430. March 2017. <https://envirodatagov.org/wp-content/uploads/2017/03/Public-Protections-under-Threat-at-the-EPA.pdf>

and possibly other air pollutants; and control certain toxic pollutants in air, drinking water, and solid wastes. If this misguided proposal had been in effect 20 years ago, the nation might have forgone programs that are preventing over 50,000 premature deaths each year.⁷⁶

Older Studies

EPA has not considered or examined the number of potentially significant studies for which, for reasons summarized above, EPA cannot obtain raw data or methodology due to age. We have attached to our comments (Attachment to this Appendix C) a detailed review of EPA's IRIS and pesticide data bases to highlight the age of many of the studies that underlie risk assessments for carcinogens and reference doses and concentrations (Rfd, Rfc) for a number of substances that are regulated under legislation that addresses hazardous wastes, toxic chemicals, clean water, drinking water, clean air and pesticides.⁷⁷

⁷⁶ Based on EPA Regulatory Impact Analyses for eight regulations related to reducing fine particles to help meet the air quality standards and reduce risk. These include:

1) EPA. 2012. Total benefits and costs from EPA analyses of 5 major regulations. See: Benefits and Costs of Five Important Clean Air Rules in 2030.

<http://www.epa.gov/sites/production/files/2015-05/documents/2030annualbenefits.pdf>

2) Regulatory Impact Analysis (RIA) for the final Transport Rule: Regulatory Impact Analysis for the Federal Implementation Plans to Reduce Interstate Transport of Fine Particulate Matter and Ozone in 27 States; U.S. EPA Office of Air and Radiation June 2011. Docket ID No. EPA-HQ-OAR-2009-0491

<https://www.epa.gov/sites/production/files/2017-07/documents/epa-hq-oar-2009-0491-4547.pdf>

3) EPA-452/R-11-011. December 2011. Regulatory Impact Analysis for the Final Mercury and Air Toxics Standards. U.S. Environmental Protection Agency. Office of Air Quality Planning and Standards. Health and Environmental Impacts Division. Research Triangle Park, NC

<https://www.epa.gov/mats/regulatory-actions-final-mercury-and-air-toxics-standards-mats-power-plants>

4) EPA-452/R-12-005 December 2012. Regulatory Impact Analysis for the Final Revisions to the National Ambient Air Quality Standards for Particulate Matter. U.S. Environmental Protection Agency Office of Air Quality Planning and Standards Health and Environmental Impacts Division Research Triangle Park, NC 27711

<https://www3.epa.gov/ttn/ecas/regdata/RIAs/finalria.pdf>

Note that even these benefit estimates, which are based on peer reviewed studies with dozens of replications, might not be permitted by the 'transparency' and dose response modeling requirements under this proposal. If so, the impact analyses for certain regulations, e.g. diesel rules might significantly understate health benefits suggested by the best available science, resulting in misleading the public and decision maker with respect to costs and benefits.

⁷⁷ P.F. Crisp, Potential Impacts of the Loss of EPA's Ability to Use Key Study Data or Risk Assessment and Decision Making, see Attachment to Appendix C.

Perhaps the most revealing and stark finding of this review comes from the examination of the IRIS data base used to determine cancer classifications, RfDs and RfCs for IRIS chemicals. It is clear that most of the entries are over 20 years old, and some over 30 years old. That guarantees that the studies used to develop the findings are at least that old, and, perhaps, decades older still. Without examining the support document for each entry, one cannot rule out that the age of the key studies may far exceed that of the entry. If a regulatory action that relied on one or more of these assessments was challenged due to the lack of the original data, under the requirements of the proposed rule, most of the cancer classifications and reference values could be vacated, aside from those values that are based upon certain NIOSH epidemiology data, NTP bioassay data or pesticide-related CBI data, and then, only if an exemption were made for the latter.

What follows presents two examples of EPA specific regulatory programs that might be adversely affected by the requirements of the proposed rule.

1) Protecting Children's Health: Regulation of Multiple Sources of Lead Exposure

Lead is a heavily-studied pollutant, and a partial regulatory success story. Many federal programs are in place which have drastically decreased the average blood lead levels in children over decades. Nonetheless, the urgent need for updated regulations has been highlighted by EPA's Children's Health Protection Advisory Committee (CHPAC) in March 2017 and by EPA's National Drinking Water Advisory Council (NDWAC) in December 2015. Under court order, EPA must propose an updated rule on lead in soil, dust and paint this year. In addition, EPA will propose an updated lead and copper rule for drinking water by 2020.

Lead exposure comes from industrial sources, drinking water distribution systems, the residential environment, and elsewhere. EPA considers basic health research, epidemiologic studies, and exposure studies including how lead enters the environment and bloodstream, the relative importance of various exposure pathways, and how housing and lifestyle affect the severity of exposure and possible solutions.

Many of the foundational lead studies analyzed children with higher exposure and blood lead levels than are commonly seen today. While lead research continues, many pivotal studies were done in the past and many regulatory decisions have been made on the basis of those older studies. While both past and current research connects elevated blood lead to a host of adverse health effects, the older studies connect past severe lead exposures (to, among others, unregulated industrial emissions, widespread automobile exhaust, plumbing components, pesticides, etc.) to increases in blood lead levels.

It would be unethical to run the same tests today, exposing children to levels of lead that we know are unhealthy. Yet, due to numerous factors related to their age, it may well not be possible to recover the original data. If use of those older studies were successfully challenged because they do not meet the data requirement policy, they could not be used. Their exclusion would weaken the scientific support for EPA regulations that have clearly proved their worth in the dramatic declines in blood lead levels in American children. Moreover, CDC and other Federal Agencies involved in reducing lead risk, would not be subject to the restrictions on use of science imposed by the proposal, and thus would continue to use the older studies as evidence, creating an unwarranted science practice and policy schism in the federal government.

None of this is justified. EPA typically relies on the overall weight of evidence prior to developing regulations, rather than on individual studies. For the 2000 Risk Analysis to support standards for lead in paint, dust, and soil, EPA relied on well over 300 references, including the EPA Air Quality Criteria documents for lead, which itself relied on even more studies. Some researchers already share and re-analyze data from colleagues to explore and confirm results. Some have performed meta-analyses to confirm overall trends and to diminish the influence of outliers. In an ordinary assessment of scientific validity, such multiple routes of confirmation would constitute sufficient quality assurance.

One example of a possible regulatory issue would be the 2006-2008 lead air standards, which were based in part on a pooled analysis, for which two of the seven primary investigators declined to provide the raw data to the public. EPA has not considered the potentially significant implications of this policy for researchers doing meta-analyses, which have been crucially important in understanding lead, and which consider many studies by many researchers, who may have varying views on releasing their individual data for public review.

Because lead exposure comes from a wide range of sources, lead exposure models must account for this range of sources, behaviors, and more. While the proposal suggests that the scope of the new policy could be limited to particularly influential studies, it has failed to consider the effect on such consolidated models. The Integrated Exposure Uptake Biokinetic (IEUBK) model,⁷⁸ a crucial tool to assess lead body burden in regulatory and other settings, is based on many individual studies to support various individual relationships; given the number

⁷⁸ Technical Support document: Parameters and Equations used in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (v 0.99d) (older version), <https://semspub.epa.gov/work/HQ/176287.pdf>

of studies needed to support what is clearly a highly influential tool in regulation, how would EPA determine which supporting studies needed to provide data and which would not? EPA has not fully considered these kinds of multi-study issues, and the potential effect on the model as a whole. In addition, many of these studies that provide critical inputs to the lead model are in fact not even specific to lead - for instance, research on child mobility and hand-to-mouth behaviors independent of the presence of lead. The contributing researchers may have little motivation to prepare and make available data to satisfy this new and unique policy.

As noted above, this proposal's requirement for data transparency and proposed new requirements for risk assessment models would set EPA apart from federal partners who deal with lead issues, making the failure to submit the draft rule for interagency review especially inscrutable. A few examples include:

The Centers for Disease Control and Prevention (CDC) has acknowledged that no safe level of lead in blood has been identified, and has identified a "reference level" to define especially high-risk populations and geographic areas most in need of primary prevention. Even some of the studies that the Federal government's most respected lead advisory group (CDC's Advisory Committee on Childhood Lead Poisoning Prevention, or ACCLPP) used to develop background justification for the reference level could be precluded from EPA use under this policy. If some of those 92 plus references and studies fail to meet this policy, EPA could not rely on them in developing regulations, and thus could issue regulations that fail adequately to address CDC's high-risk exposures. Moreover, EPA cost-benefit analyses could not use the CDC health effects work in calculating regulatory benefits.

Further, the additional requirements in the proposal could require that EPA re-evaluate the appropriateness of the CDC dose-response relationship, and give “explicit consideration” to other dose-response models even if, as in this case, they have been vetted and rejected by CDC and its advisory committee.

Both EPA and the U.S. Department of Housing and Urban Development (HUD) regulate similar residential sources of lead (paint, soil, and dust) - EPA in private housing, and HUD in Federally-supported housing, including Federally-supported units in private buildings. This policy shift increases the potential for disparate treatment and public confusion stemming from those situations. The identical risks addressed by the two programs should be analyzed consistently. HUD has already acted to incorporate CDC’s statement into its programs by making its policy on dust-lead clearance levels more stringent;⁷⁹ EPA is still considering its response. But under this proposal, EPA might not be able to rely on as wide a range of studies as would be available to the rest of the federal family, which could result in different risk assessments and regulatory outcomes for similar, and possibly even adjacent, dwellings.

2) Drinking Water Standards and Health Advisories

Lawsuits filed based on this proposal might force EPA to roll back current drinking water standards and drinking water health advisories for pollutants such as arsenic and nitrate. Under the SDWA, EPA establishes legally enforceable drinking water standards and treatment techniques for most public water systems in the U.S. Over the years, standards have been

⁷⁹ HUD Policy Guidance Number: 2017-01, Revised Dust-Lead Action Levels for Risk Assessment and Clearance; Clearance of Porch Floors, January 31, 2017, <https://www.hud.gov/sites/documents/leaddustclearance.pdf>

promulgated for microorganisms, disinfectants, disinfection byproducts, inorganic and organic chemicals, and radionuclides. EPA also has the authority to recommend non-regulatory drinking water health advisories, which public water systems can voluntarily choose to follow.

EPA has not assessed how the requirements in the new policy might affect drinking water standards and advisories. An assessment of similar legislation (H.R. 1430) by the Environmental Data and Governance Initiative (EDGI) found that the radionuclide standard would have been blocked by multiple requirements, including availability of study data and reproducibility.² Our preliminary look suggests that the standards for arsenic and nitrate standards will most likely be affected.

EPA's drinking water standard for arsenic is based on human health studies, which document skin damage and possible increased risk of cancer.⁸⁰ EPA's drinking water standard for nitrates is based on studies of infants exposed to nitrate in the drinking water used to prepare their formula.⁸¹ The nitrate standard is set at a level to prevent infants below 6 months of age from serious illness and, if untreated, death. Symptoms include shortness of breath and blue baby syndrome. Both drinking water standards rely on epidemiological data including confidential patient information, as well as on older studies. As noted above, data from such studies may have been discarded or lost, or be in an unreadable form. In addition, none of these studies could

⁸⁰ Cites for studies supporting arsenic drinking water standards and health advisories: Tseng, W.P. (1977) "Effects and dose-response relationships of skin cancer and blackfoot disease with arsenic." *Environmental Health Perspectives* 19, 109-119.

Tseng, W.P., Chu, H.M., How, S.W., Fong, J.M., Lin, C.S., and Yeh, S. (1968) "Prevalence of skin cancer in an endemic area of chronic arsenicism in Taiwan." *Journal of National Cancer Institute* 40 (3), 453-463.

⁸¹ Cites for studies supporting nitrate drinking water standards and health advisories:

Bosch, H.M., Rosefield, A.B., Huston, R., Shipman, H.R., and Woodward, F.L. (1950) "Methemoglobinemia and Minnesota well supplies." *Journal of American Water Works Association* 42, 161-170.

Walton, G. (1951) "Survey of literature relating to infant methemoglobinemia due to nitrate-contaminated water." *American Journal of Public Health* 41, 986-996.

realistically or ethically be reproduced since they derive from a unique cohort, and it would be unethical to expose people to ingested pollutants.

Attachment to Appendix C

Potential Impacts of the Loss of EPA's Ability to Use Key Study Data for Risk Assessment and Decision-making for Two Categories of Chemicals

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Background

Risk management decisions, particularly those which incorporate a numerical standard such as a drinking water MCL, a Superfund clean-up goal, a pesticide tolerance or an ambient air standard are informed by a substance-specific hazard and/or risk assessment. As prerequisite to setting a drinking water standard, a health goal is derived, then considered along with cost and treatment technology, to establish the regulatory standard. Superfund clean-up goals for air, soil, surface and groundwater are translated from reference values and/or cancer risk estimates for sentinel site contaminants. While pesticide tolerances are determined primarily by data on the magnitude of the residues remaining on the commodity at levels shown to be effective against the pest, they are compared against the reference values or cancer risk estimates to assure that they meet the regulatory standard of "reasonable certainty of no harm." And, certain hazardous air pollutant standards are based on the "residual risk" following application of best technology. Depending upon the nature of the situation, an assessment may include the calculation of a non-cancer Reference Dose (RfD) and/or Reference Concentration (RfC) and/or a cancer classification which is a qualitative declaration of the substance's human carcinogenic potential. Quantification of an estimated excess cancer risk also may be warranted. This step is nearly always taken for those substances to which the following descriptors apply: "*Carcinogenic to humans*" and "*Likely to be carcinogenic to humans*," and, occasionally, "*Suggestive Evidence of Carcinogenic Potential*," as defined in EPA's 2005 cancer guidelines. The studies used for any of these actions would be considered to be "key studies."

The proposed rule articulates a scenario wherein the key studies could not be used in risk assessment and decision-making unless their raw data were made available for public scrutiny. This analysis is meant to provide an understanding of what might be at stake with regard to the protection of public health if this scenario were to play out with few or no exceptions/exemptions.

The two case examples presented focus on two chemical categories for which a cancer classification has been assigned and/or an RfD and/or RfC has/have been calculated. These two categories are 1) Currently-registered Pesticide Active Ingredients and 2) Chemicals currently on

IRIS. Pre-assembled lists were available to facilitate a timely evaluation. With additional time and effort, other lists could be compiled which would likely identify additional candidates.

At this time, roughly 700-800 conventional chemical pesticides are registered for use in the U.S. and, perhaps, double that number if the antimicrobials (N ~ 400) and biopesticides (N~ 400) are included. No biopesticides have either a cancer call or RfD/RfC, but some antimicrobials do, as their primary uses in commerce are for other purposes and they get captured under other legislative authorities (e.g., TSCA, SDWA, Superfund, FFDCAs as food additives, etc.)

As of mid-May 2018, there were 511 individual records on the Integrated Risk Information System (IRIS) which is a human health assessment program that evaluates information on health effects that may result from exposure to environmental contaminants. IRIS contains substances that: are some but not all of the NAAQS substances, many of the substances for which drinking water standards and human health ambient water quality criteria exist, are listed as Hazardous Air Pollutants (HAPs), are Superfund site or RCRA hazardous waste concerns, or are/were pesticide active ingredients. Most of the IRIS listings are decades out of date, including most of the pesticide active ingredients which have undergone at least two cyclical updates by the Office of Pesticide Programs (OPP) in the intervening years. Another subset of entries is simply names with no reference values or cancer calls. (N ~25).

In Part I of the analysis (Dependence upon human data), the principal criterion for substances to be identified is that any number calculated (*i.e.*, RfD, RfC, Q*, IUR) will have been supported, in whole or part, by human data. In the case of the RfD or RfC, the human dose response data would be used in their calculation. For cancer hazard assessment, the presence and quality of the human data would contribute to classification as a “Known” (“Carcinogenic to humans”) or “Likely/probable” (“Likely to be carcinogenic to humans”) and could be of sufficient quality to use for calculating the Q* or IUR.

Part I: EPA Cancer Classifications and RfDs/RfCs based, in whole or in part, upon Human Data

A. Currently-registered Pesticide Active Ingredients

The Office of Pesticide Programs’ document entitled “Chemicals Evaluated for Carcinogenic Potential,” dated September 30, 2013, was examined for chemicals classified as “Known” or “Likely/probable” (to be carcinogenic to humans) and for which a quantitative estimate of risk was calculated (that is, a Q* or, rarely, an IUR).

1. Known Human Carcinogens [Substance (date of assessment) study/ies] (date(s) of study/ies] (N =4) :

Cacodylic acid (2006) Supported by data on inorganic arsenic (see below on IRIS list)

Dichromic acid (2010) assessed as Chromium VI (see below on IRIS list)

Potassium dichromate (No longer registered) assessed as Chromium VI (see below on IRIS list)

Ethylene oxide (2016) Known-based upon 2003 and 2006 NIOSH occupational epi studies-inhalation route (see below on IRIS list)

2. Likely/Probable Human Carcinogens: [Substance (date of assessment) study/ies] (date(s) of study/ies](N=58):

NONE of the **58** “Likely/probable” substances on the 2013 list of the **498** pesticides are supported by any human data/epidemiology studies. Six are no longer registered.

3. RfD and/or RfC [Substance (date of assessment) study/ies] (date(s) of study/ies]:

Aldicarb (2012) aRfD*-single dose human (1991); No RfC

Chlorpyrifos (proposed 2016) –a combination of animal data and human epi study-CCCEH cohort; current official RfD is based upon animal data

Methomyl (2010) aRfD-human study (2005)

Oxamyl (2010) aRfD- human study (2005)

*aRfD = acute RfD; chronic RfDs are not considered appropriate for these chemicals

B. IRIS Chemicals [Substance (date of assessment) study/ies] (date(s) of study/ies]

1. Known Human Carcinogens (N=16):

Arsenic, inorganic (1991) human chronic studies (1968 and 1977) by oral and inhalation routes

Asbestos (chrysotile) (1988) human occupational epi (1980-1984) by inhalation route

Benzene (2000) human occupational epi(1996)-oral and inhalation

Benzidine (1987) human occupational epi (1973) oral and inhalation

Bis(chloromethyl)ether (BCME) (1988) human occupational epi (1975)and animal data-oral and inhalation

1, 3-Butadiene (2002) via inhalation -human occupational epi (1973) + animal data

Chloromethyl methyl ether (CMME)(1987) respiratory cancer in workers (1970-1977)

(Commercial grade CMME is always contaminated with 1 to 8%

bis(chloromethyl)ether (BCME), a known human carcinogen.

Chromium VI (1988) human occupational epi (1975) via inhalation + sufficient animal data

Coke oven emissions (1989) human occupational epi (1975, 1976)

Ethylene oxide (2016) based upon 2003 and 2006 NIOSH occupational epi studies-inhalation route

Formaldehyde: “Known” was proposed in 2010 based upon several human occupational epi studies (1996, 2004, 2009). (1989 official position is Probable/likely); 2010

proposed RfC based upon three child epi studies examining asthma and other respiratory effects (1990, 1999, 2002)

Libby amphibole asbestos (2014) multiple animal and human occupational epi studies with the 2007 Sullivan et al human study serving as basis for quantification-inhalation route

Nickel refinery dust (1987) multiple nickel refinery worker epi studies (1981, 1982, 1984)

Nickel subsulfide (1994) multiple nickel refinery worker epi studies (1981, 1982, 1984)

Trichloroethylene (2011) Multiple occupational epi studies (1991-2010)

Vinyl chloride (2000) Multiple epi studies (1974-1998)

2. Likely/Probable Human Carcinogen [Substance (date of assessment) study/ies) (date(s) of study/ies] (N=7):

Acrylonitrile (1991) via inhalation route, based only on human data (1980); via oral route, based only on animal data (1987)

Beryllium (1998) inhalation-limited human (1992), sufficient animal data

Cadmium (1987) Limited evidence-occupational epi. (1989) and sufficient animal data

Creosote (1988) Limited human (1924, 1935, 1956) + sufficient animal data

Diesel engine exhaust (2003) Official assessment is "Likely" by inhalation, but I believe data would support "Known." Many epi studies (1988, 1998, 1999) but they are not good enough for quantitative purposes.

Formaldehyde (1989) inhalation route, based on human data, also supported by animal data (proposed upgrade to "Known" in 2010)

Tetrachloroethylene (2012) suggestive evidence in several occupational epidemiologic studies (1993-2009) and conclusive evidence in rats and mice by ingestion and inhalation

3. RfD and/or RfC [Substance (date of assessment) study/ies) (date(s) of study/ies](N=37):

Arsenic, inorganic (1995) RfD-human chronic study-oral (1968 and 1977); no RfC

Ammonia (2016) no RfD; RfC based on occupational epi study (1989)

Baygon (1992) IRIS RfD based on human single dose study (1971), but the official Agency RfD derived by OPP is based upon single dose in rat

Benzene (2003) both RfD and RfC based on human occupational epi(1996)

Benzoic acid (2003) RfD based on human intake data (1973); no RfC

Beryllium (1998) RfC based upon human occupational epi (1949), RfD on dog dietary data

Cadmium (1989) RfD- chronic human exposures (1985)

Calcium cyanide- (2010) RfC-human occupational epi studies (1975)

Carbon disulfide (1995) RfC- human occupational epi studies (1983)

Chromium VI (1998) RfC based upon human subchronic inhalation data (1983) + 90d rat inhalation study
Cyanide, free- (2010) RfC based upon human occupational epi study (1975)
Cyanogen (2010) RfC based upon human occupational epi study (1975)
N, N-Dimethylformamide (1999) RfC based on human occupational epi study (1984)

4, 6-Dinitro-o-cyclohexyl phenol- (1990) RfD based on adult human subchronic oral study (1942)

2, 4-Dinitrophenol (1987) RfD based on adult human subchronic oral study (1942)

Fluorine (soluble fluoride) (1987) RfD based upon data from epi study with children (1950), cited in a 1977 study

Formaldehyde (RfD in 1989; proposed RfC in 2010)(see above)

Libby amphibole asbestos (2014) RfC based upon human occupational epi study (2008)

Malathion (1992) IRIS chronic RfD based upon subchronic human feeding study (1962) but there no longer is an official Agency chronic RfD; OPP has derived only the 2016 updated aRfD and a ssRfD (steady state RfD) based upon acute and repeated dose comparative cholinesterase assay (CCA) studies in rats

Mercury, elemental (1995) RfC-Human occupational inhalation studies (1983 and 1989)

Methylmercury (2001) RfD human epi studies (1997 and 1999)

Molybdenum (1992) RfD 6yr human dietary study (1961)

Nitrate (1991) RfD human infant epi (1950, 1951)

Nitrite (1991) RfD human infant chronic drinking water study (1951)

Perchlorate (2006) RfD-adult human volunteers (2002)

Potassium cyanide (2010) RfC-human epi study (1975)

Potassium silver cyanide (2010) RfC- human epi study (1975)

Selenious acid (1991) RfD-human epi study (1989)

Selenium and compounds (1991) RfD-human epi study (1989)

Silver (1991) RfD based on 2-9 yr human i.v. study (1935)

Styrene (1992) RfC based on human occupational epi study (1984)

2,3,7,8-Tetrachlorodibenzo-p-dioxin (2012) RfD based upon two human epi studies (2008)

Tetrachloroethylene- (2012) RfD and RfC based upon two occupational epi studies (1994 and 1995)

Toluene (2005) RfC based upon multiple occupational epi studies (1990-2001)

Toluene diisocyanate (1995) RfC based on prospective epi study (1982)

1, 1, 2-Trichloro-1,2,2-trifluoroethane (1987) RfD based on human occupational epi (1972)

Zinc compounds (2005) RfD-adult human male and female volunteers (1984=2001)

Part II: EPA Cancer Classifications and RfDs/RfCs based solely on Animal Data

Let's look now at the substances for which the cancer call and/or RfD/RfC are based upon animal data alone.

A. Currently-registered Pesticide Active Ingredients

1. Carcinogens

Those pesticides that depended upon animal data for classification and quantification of human carcinogenic potential also were identified in the document entitled "Chemicals Evaluated for Carcinogenic Potential," dated September 30, 2013. This list includes chemicals classified as "*Known to be carcinogenic*," "*Likely/Probable to be carcinogenic*," "*Suggestive Evidence of Carcinogenic Potential*," "*Inadequate Information to Assess Carcinogenic Potential*," and "*Not Likely to Be Carcinogenic to Humans*," as defined in EPA's 2005 cancer guidelines,

Subtracting **three** of the **four** "Known" carcinogens (Ethylene oxide was not on the 2013 list), leaves **495** of the **498** pesticides on the 2013 list which relied on animal data to inform the cancer classification and, in some cases, the quantification of the estimate of excess cancer risk.

As noted above, there are **58** pesticides in the "Likely/Probable" category that relied on animal data for classification and, perhaps, also for quantification. In addition, **10** of the **96** "Suggestive/Possible" chemicals were quantified. All **10** of these remain registered. None of the "Inadequate" or "Not Likely" chemicals were quantified.

The bottom line: **495** pesticides on the 2013 list depended upon animal data for judging their human cancer potential; up to **68** of them also included quantification (that is, a Q* was calculated).

2. RfDs and/or RfCs based upon animal data

The numbers of RfDs and RfCs that have been calculated for pesticide active ingredients is in the thousands. And, only a very few active ingredients (N=4) are dependent upon human data. Every conventional chemical with approved uses on agricultural commodities ("food use" pesticides) will have at least one RfD calculated, usually chronic, but occasionally acute or short-term, for use in risk assessment. A subset of this category of pesticides may also have an RfC calculated. The same is true for a number of the antimicrobials, but not likely for the biopesticides. Nonetheless, their risk assessments remain dependent upon animal data. The "non-RfD/RfC" chemicals generally are assessed by characterizing margins of exposure which

are derived by comparing known or estimated exposures to No-Observed-Adverse-Effect-Levels (NOAELs) or modeled Points-of-Departure (PODs) from the relevant key toxicity studies. The bulk of the key studies for all three categories of chemicals are CBI because they are financed by the registrant and protected under the exclusive use and data compensations provisions of FIFRA. However, some of those for the antimicrobials are not CBI. Because some antimicrobials may have other commercial uses, registrants can submit publically-available studies funded and conducted by other parties in order to satisfy their data submission requirements. Thus, there is a major problem: OPP cannot share the CBI data and could have great difficulty acquiring and sharing the non-CBI data. Under the conditions of the proposed rule, if CBI data were exempted, OPP might be able to go forward with decision-making for chemicals based upon CBI data alone but would be hard-pressed to conduct scientifically-sound risk assessments for those chemicals for which the registration package is mixed. Even assessments for many conventional chemicals are informed by studies from the open literature that were not funded by registrants and declared CBI.

B. IRIS Chemicals

1. Carcinogens

IRIS lists **151** entries of the **511** total as including an evaluation of human carcinogenic potential. If one subtracts the number of “Known” and “Likely/probable” chemicals based solely or in part upon human data (N = 20), this would result in ~**130** that were classified based upon animal data alone. Quantitative estimates of cancer risk also were calculated for virtually all of the “Likely/probables” and many of the “Suggestives,” thereby, resulting in the cancer endpoint driving the risk assessment.

2. RfDs/RfCs

IRIS lists **485** entries of the **511** total as including an RfD and/or RfC. If one subtracts the number of chemicals for which these reference values were based solely or in part upon human data (N = 37), that results in **448** that were dependent upon animal data alone.

3. Last Significant Revision of IRIS Entries by Date

2017-1
2016-5
2015-0
2014-1
2013-3
2012-3
2011-6
2010-15
2009-14
2008-5
2007-2
2006-1
2005-5
2004-3
2003-11
2002-4
2001-6
2000-5
1999-1
1998-8
1997-3
1996-1
1995-12
1994-20
1993-23
1992-33
1991-64
1990-56
1989-28
1988-63
1987-107

The information above on the **Last Significant Revision of IRIS Entries by Date** is perhaps the most revealing and stark regarding the likelihood that the raw data for the key studies used to determine cancer classifications, RfDs and RfCs for IRIS chemicals would be available to EPA to share. As is made very clear, most of the entries are over 20 years old, some over 30 years old. That guarantees that the studies used to develop the findings are at least that old, and, perhaps, decades older still. Without examining the support document for each entry (which I did not do), one cannot rule out the likelihood that the age of the key studies may far exceed that of the entry. If the proposed rule were to apply retroactively, most of the cancer classifications and reference values would be vacated, aside from those values that are based upon accessible NIOSH epidemiology data, NTP bioassay data or pesticide-related CBI data, if an exemption were made for the latter.

Observations/Conclusions:

1. OPP's "Known" carcinogens all were assessed in collaboration with ORD-NCEA as those substances also have non-pesticidal uses and/or are an issue for other program offices. So access to their raw data would be a problem for OPP as well as everyone else, since they were not generated by registrants in response to FIFRA regulatory requirements.
2. OPP has the raw data for chemicals on the 2013 and the RfD/RfC lists, but, of course, they cannot share them with the public because of [FIFRA section 3\(c\)\(1\)\(F\)](#) which provides for both "exclusive-use" and compensation rights for data submitted to EPA to support registration actions. In other words, they are Confidential Business Information (CBI) and one can be fined and/or jailed for releasing them without approval by their rightful owner.
3. OPP's regulatory decisions rarely rise to the \$100 million cost threshold and most are not considered "rules" in the traditional sense. And, of those that might meet the dollar threshold, most of them are not chemical-specific. Rules such as the Worker Protection Standard or the Container rule may have met that threshold. Actions on individual requests for approval or revocation of uses do not qualify. On rare occasions, the cancellation/revocation of the entire spectrum of uses could meet the threshold if the number of uses was large enough. The 2015 proposed revocation of all of the chlorpyrifos tolerances (~80) might qualify by virtue of numbers of uses although EPA concluded that "revoking all tolerances for chlorpyrifos will not have a significant economic impact on a substantial number of small entities," so maybe it didn't.
4. Under the conditions of a final rule in which CBI data were exempted, OPP might be able to go forward with decision-making for chemicals based upon those data alone but would be hard-pressed to conduct scientifically-sound risk assessments for those chemicals for which the registration package is mixed. Even assessments for many of

the conventional chemicals often are informed by studies from the open literature that were not funded by registrants and declared CBI. Important details in their toxicity or exposure profiles might have to be discarded leading to an underestimation of the actual risk.

5. The IRIS assessments, for the most part, have significant age on them (late 1980's into the 1990's). This indicates that the studies used to generate those assessments are even older than that. Access to their raw data would be very much a challenge, unless the studies were conducted by NIOSH (epidemiology), the National Toxicology Program (animal studies) or the EPA, itself (human volunteer laboratory studies).
6. If the proposed rule were to apply to both human and animal studies, then everything on IRIS could become compromised and many of the pesticides may be at risk, too, depending upon the nature of any exemption for them and the degree to which they depended upon non-CBI data.
7. If a chemical exhibits suggestive to known human carcinogenic potential, and the cancer risk is estimated quantitatively, then this endpoint usually drives the risk assessment and the human data and/or the long-term animal bioassays become the key studies. Data from non-government-conducted epidemiology studies are likely difficult or impossible to acquire and share. Unless the animal data are CBI data from manufacturers or from NTP bioassays, gaining access to them also is likely to be very difficult. Most all of the cancer bioassay data on pesticides are from the manufacturers. Some number of the key studies for the non-pesticide IRIS chemicals are NTP bioassays. In these two cases, EPA will have access to the raw data but will be able to share only the NTP information.
8. For chemicals for which cancer is not the driving endpoint, the RfDs and RfCs become the important factors in quantitative assessments. Again, for conventional pesticides and biopesticides, most of the key data are from the manufacturers. In the case of the antimicrobials, some submitted studies may come from alternative non-CBI sources, presenting a challenge to access the raw data for them. For the IRIS chemicals, a small number are calculated from NTP data. Most key studies are from the peer-reviewed literature, primarily academic research. Given the age of most of the IRIS assessments, these data would be difficult, if not impossible, to acquire.
9. If the rule means to define reproducibility/replication as applying to the data/results of the key studies used rather than EPA's assessment of them, then the pesticide and commodity chemical manufacturers might have to submit TWO of every key study used in developing a regulatory decision, each being conducted in accordance with FIFRA Part 158 data requirements and data call-ins or TSCA Section 4 or 5 test rules.

- 10.** An inability to acquire and share the raw data for the substances in both of these case examples would seriously comprise EPA's risk assessments and thwart its mission to protect public health.

Appendix D

EPA’s Misreading of References and Drawing of Conclusions that the Study Authors Have Repudiated

As the main body of our comments notes, EPA cites a wide variety of documents in support of both its proposal to restrict the use of scientific studies where the underlying data was not publicly disclosed, and its assertion that providing this data will be quick and easy. Most often, EPA does not claim that these documents actually endorse the proposed approach, but only that they are “consistent” with it, or it is consistent with them, or some similar language.

EPN and others have examined all these documents to the extent that time and resources permit. It seems clear that only one of them in fact supports this proposal. Either they simply do not stand for the proposition for which they are cited, or their authors have expressly repudiated EPA’s attempted reliance on them, or the citation is simply too vague and generic to permit any conclusions to be drawn.

To demonstrate this, we will discuss EPA’s use of authorities in roughly the order in which the proposal sets them forth. We will begin with the twenty or so authorities cited (however equivocally) in support of the proposal, and then move on to EPA’s discussion of why it thinks data disclosure will be easy. In all cases where a document is not discussed, either it is too vaguely cited for us to locate an arguably relevant passage, or it is irrelevant on its face.

Authorities Cited in Support of the Proposal

I. Executive Orders

A. Assertion

The proposed rule is said to be “consistent with” Executive Orders 13777 and 13783. The proposal also cites Executive Order 13653 in a footnote.

B. Response

Executive Order 13777 calls on agency regulatory reform efforts to attempt to identify “those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility.” This language calls for individual examination of rules for future unspecified action. It in no way supports EPA’s proposal to impose a blanket bar on all studies relying on undisclosed data.

Executive Order 13653 simply says that EPA shall base its regulations on the best available science. As discussed in detail above, EPA’s proposal would make this impossible by making wide areas of such science unavailable to regulatory decision makers.

II. **OMB Directives**

A. Assertion

The proposed rule is said to reflect “the focus on transparency” in OMB’s *Data Quality Act Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies* and OMB Memorandum 13–13: *Open Data Policy—Managing Information as an Asset*.

B. Response

1. *The Data Quality Act Guidelines*

The referenced OMB Guidelines, cited as “consistent with” the proposal, are not. The overarching requirement in the Guidelines is that information be “accurate, reliable, and unbiased.” V 3 (b). The Guidelines make clear that a study remains objective even when underlying data cannot be reproduced in view of “ethical, feasibility, or confidentiality constraints.” OMB IQA Guidelines section V.3. b. ii. A (67 FR at 8460) .

The Guidelines expressly state that:

Even in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard. For example, a qualified party, operating under the same confidentiality protections as the original analysts, may be asked to use the same data, computer model or statistical methods to replicate the analytic results reported in the original study. See, e.g., “Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality,” A Special Report of the Health Effects Institute's Particle Epidemiology Reanalysis Project, Cambridge, MA, 2000. 67 FR at 8456

Critically, the explanatory preamble to the Guidelines identifies the Harvard Six-City and the American Cancer Society studies as reproducible, thus satisfying OMB’s transparency criteria. EPA’s proposal, while purporting to be “consistent” with the Guidelines would “preclude” the use of the same study.⁸²

Moreover, these same Guidelines recognize that there will be constraints relating to ethics, feasibility, or confidentiality that preclude disclosure or replicability, and that studies should not be invalidated for this reason. Thus, the Guidelines state that, “[w]ith regard to original and supporting data related thereto, agency guidelines *shall not require that all disseminated data be subjected to a reproducibility requirement*. Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicabl[y] be subjected to a reproducibility requirement, given ethical, feasibility, or

⁸² Footnote 3 of the proposal, FR 18769 asserts:

EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA’s use non-public data in support of its regulatory actions. See *Coalition of Battery Recyclers Ass’n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass’ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

Although the footnote does not identify studies it proposes to exclude, a reader who goes to the cited cases will find that those courts do something this proposal does not: identify those studies by name. They are the Harvard 6-City and the American Cancer Society particulate matter studies and the Lanphear lead study. See also Appendix B.

confidentiality constraints.” V.3.b.(A) 67 FR at 8460 (emphasis added). Even more basically, “if data and results have been subject to formal, independent, external peer review, the information can generally be considered of acceptable objectivity”. Id. section V.3.b.1, 67 FR at 8454.

2. *Managing Data as an Asset*

While OMB’s memorandum on managing data as an asset does support downstream dissemination, complete public transparency without regard to privacy or security is the opposite of its goal. Rather, the main aim of this memorandum is to institute a framework of data collection, formatting, and storage that allows for public dissemination if possible. The Memorandum (at p.4) also specifically recognizes the “mosaic effect” (i.e. “when the information in an individual dataset, in isolation, may not pose a risk of identifying an individual --or threatening some other important interest such as security- but when combined with other available information, could pose such risk”) as a limitation on even partial dissemination of data used in some studies, an obstacle that EPA completely fails to consider in the Proposal.

III. EPA Policies

A. Assertion

The proposed rule self-characterizes as “build[ing] upon” prior EPA actions and the actions of other federal agencies. Here, the proposal cites four documents, namely (1) Plan to Increase Access to Results of EPA Funded Scientific Research (which the proposal says it draws on for “concepts and lessons learned”); (2) The EPA Open Government Plan 4.0; (3) Open Data Implementation Plan; and (4) EPA’s Scientific Integrity Policy; Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.

B. Response

1. *Increase Access Plan*

This policy contains language that expressly repudiates the thrust of EPA's proposal. It states:

While the Agency strives to increase access to its research results, it recognizes ...that Federal agencies have a responsibility to protect confidentiality and personal privacy, respect proprietary interests and property rights, and balance between the value of providing long-term access and its associated costs. It is important to recognize that some research data cannot be made fully available to the public but instead may need to be made available in more limited ways, e.g., establishing data use agreements with researchers that respect necessary protections. Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications. p. 4

And

EPA will require research data underlying a publication are posted to publicly accessible data repositories within 30 days of posting the paper in PMC, unless: a) the dataset has already been made available to the public via public release or another sharing mechanism, or b) the research data cannot be released due to one or more of constraints, such as requirements to protect confidentiality, personal privacy, proprietary interest, or property rights. p. 11

2. *The EPA Open Government Plan 4.0*⁸³

This document reaffirms EPA's commitment to an appropriately nuanced culture of transparency, participation and collaboration, consistent with the constraints articulated elsewhere in this appendix.

3. *Open Data Implementation Plan*⁸⁴

⁸³ https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf

⁸⁴https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf

EPA's Open Data policy specifically recognizes the need to temper data disclosure with privacy and other confidentiality concerns and says nothing that would support EPA's proposed policy.

4. *Scientific Integrity Policy*⁸⁵

The Scientific Integrity Policy has a specific purpose not directly relevant to the issues raised by this proposal. Specifically, it establishes and promotes a culture of scientific integrity for all of its employees. This policy provides a framework intended to ensure scientific integrity throughout the EPA and promote scientific and ethical standards, including quality standards; communications with the public; the use of peer review and advisory committees; and professional development. It also describes the scope and role of a standing committee of agency-wide scientific integrity officials to implement this policy.

IV. Other Government Agencies and Private Groups

A. Assertion

EPA's proposal refers to the experience of the National Science Foundation, National Institute of Science and Technology, the National Institutes of Health,⁸⁶ and the U.S. Census Bureau. It also states that it "takes into consideration" "the policies or recommendations of third party organizations who advocated for open science," referring in particular to policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data, and Access to Research Data in the 21st Century; the Health Effects Institute; Center for Open Science; members of the

⁸⁵ https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf

⁸⁶ We address why the NIH data sharing for new studies does not support the EPA proposal in the main body of our comments above.

Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.

B. Response

We here discuss two of the most prominent of those references with the confidence that none of the other references support the proposition for which the proposal cites them. As previously discussed, a major deficiency of this proposal is that it throws the burden on those commenting to first construct for the agency the information it should have provided the public in support of its proposal, and then analyze and answer. Had the agency been doing its job, those commenting would be able to understand what parts of each of these references the agency thought supported its proposal and thereby responded accordingly. In any case, we believe other references will be covered by other commenters.

1. *The Administrative Conference*

The author of the Administrative Conference studies, Wendy Wagner, a law professor at the University of Texas, addressed EPA's use of her study as follows:

I really don't know what problem they think they are fixing. They don't adopt any of our recommendations, and they go in a direction that is completely opposite, completely different....,, They don't adopt the recommendation of any of the sources they cite. I'm not sure why they cited them. (Atlantic Magazine (April 25) online <https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/>)

2. *The Bipartisan Policy Center*

As noted earlier in these comments, the Bipartisan Policy Center Assembled a thoroughly bipartisan roster of experts to research, consider and then issue a 2009 report of recommendations for both the Executive Branch and the Congress on how to improve the way

science is used in making regulatory policy across the government's areas of responsibility. When it reviewed EPA's proposal, it concluded that its views had been misrepresented; the importance of this cannot be understated, which is why it is repeated here:

While the Science for Policy Project panel encouraged greater transparency and access to data, the report never suggested excluding studies from consideration in developing regulations if data from those studies were not publicly available. Indeed, the panel's overarching recommendation for assembling the "best available science" reads: "Agencies and their scientific advisory committees should cast a wide net (emphasis added) in reviewing studies relevant to regulatory policy, and should make their methods for filtering and evaluating those studies more transparent."

V. Major Researchers and Scientific Journals

A. Assertion

Finally, EPA says the proposal is "informed by" policies recently adopted by major scientific journals, spurred in part by the "replication crisis," and cites to web sites for proceedings of the National Academy of Sciences, PLOS ONE (*Public Library of Science*), Science, Nature and *The Economist*.

B. Response

1. *The Replication Crisis*

John P.A. Ioannidis, author of the seminal paper calling attention to the "replication crisis," has publicly denounced EPA's proposal. Ioannidis, Professor of Medicine and of Health Research and Policy at Stanford University School of Medicine and a Professor of Statistics at Stanford University School of Humanities and Sciences, pointed out in detail the disastrous effects of what EPA proposes to do:

Making scientific data, methods, protocols, software, and scripts widely available is an exciting, worthy aspiration. Government-based regulatory and funding incentives can be instrumental in making this happen at large scale. *However, we should recognize that most of the raw data from past studies are not publicly available. In a random sample of*

the biomedical literature (2000–2014) [6], none of 268 papers shared all of their raw data. Only one shared a full research protocol. The proportion of studies that have had all their raw data independently re-analyzed is probably less than one in a thousand. The number of studies that have been exactly replicated in new investigations is quite larger, but still a minority in most fields. A new standard currently proposed for the Environmental Protection Agency [7] aims to ban the use of scientific studies for regulatory purposes unless all their raw data are widely available in public and can be reproduced. If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim. (John P.A. Ioannidis, All science should inform policy and regulation, PLOS (May 3, 2018), <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002576>.) (emphasis added)

2. Scientific Journals

The editors of Science, Nature, PLOS, Proceedings of the National Academy of Sciences, and Cell issued a joint statement denouncing the proposal, stating:

It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes. (<http://science.sciencemag.org/content/early/2018/04/30/science.aau0116>)

Clearly, their policies on publication offer no support for the premise that studies are unreliable unless their underlying data is made publicly available.

Neither does the *Economist* article come anywhere near endorsing EPA’s proposal. *The Economist* discusses the importance of the verification of scientific studies and how it is problematic that much current science cannot be replicated due to many causes. Proposed solutions include: tightening standards, particularly in statistics, registering research protocols in advance and monitoring them, and: “[w]here possible, trial data also should be open for other researchers to inspect and test.”

No reasonable person, including those who oppose this proposal, would disagree.

Authorities Cited to Show that Data Disclosure Will Be Easy

I. Background

The authorities cited in the proposal all appear to have set policies with prospective effect. Such policies cannot support one of the central features of EPA’s proposal, namely its barring of any future reliance on studies conducted in the past where various historical reasons may bar the disclosure of background data. But even as applied to current or future studies, the documents cited do not support the position taken in the proposal.

The proposal begins its discussion of this issue by stating that “concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government,” referring to what they claim are examples from U.S. Department of Health and Human Services (HHS), National Institute of Standards and Technology, U.S. Department of Education, the U.S. Census Bureau., and the Bipartisan Commission on Evidence Based Policy. It refers to a statement of the National Academies that “Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach.”

It then suggests that owing to the variety of different circumstances that will arise, different approaches to data disclosure may be appropriate, citing here policies of NIH, publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature, and stating that these provisions are “consistent with” recommendations of Lutter & Zorn.

II. Discussion of Cited Authorities

As noted above, this proposal inappropriately throws the burden on those who comment to tease out the purpose of various references, and in most cases guess which provisions the agency might think provide support and then respond. We have diligently examined what we can under these circumstances.

A. HHS

EPA provides no details as to what HHS policies it has in mind, again unfairly throwing the burden of explanation on those who comment. The only one known to us is far more nuanced and far less supportive of EPA than the proposal suggests. The link in the proposal points to HHS's guidance on de-identification of protected health information to satisfy the requirements of HIPAA (the Health Insurance Portability and Accountability Act of 1996 that required the Secretary of HHS to develop regulations protecting the privacy and security of certain health information.)

HHS provides two acceptable methods: (1) expert determination, where an expert determines, after application of statistical and scientific principles and methods, that the risk is very small that the information alone or with other available information could be used to identify the subject; and (2) safe harbor, requiring that the following identifiers are removed: names, geographic subdivisions smaller than a state, except for the initial three digits of the ZIP code if encompassing a minimum number of individuals, key dates, telephone numbers, vehicle identifiers and serial numbers, fax numbers, device identifiers and serial numbers, email addresses, URLs, social security numbers, IP addresses, medical record numbers, biometric identifiers, health plan beneficiary numbers, full-face photographs and any comparable images,

account numbers, any other unique identifying number, characteristic, or code, certificate/license numbers. See generally 45 C.F.R. §§160, 164.

It is unclear whether these methods would be adequate/suitable to de-identify information from data relied upon by EPA, and the expert determination method does not really identify any one particular tool or method to accomplish this. Nor does the proposal attempt to explain who would pay for this and what would happen if the available de-identifying methods did not meet the applicable standards.

B. National Academies

Similarly, the National Research Council (an arm of the NAS) in *Expanding Access to Research Data: Reconciling Risks and Opportunities*, National Research Council. 2005. Washington, DC: The National Academies Press. <https://doi.org/10.17226/11434>, far from supporting an automatic bar to the consideration of studies with undisclosed data, analyzed the issue as one in which many competing factors would need to be balanced in the interest of making gradual progress over time. The report states in part

This report offers recommendations that, if implemented, will continue the past record of simultaneous improvement along both dimensions. Such improvement will require strong partnership between the research community and statistical and research agencies in the design of innovative research on disclosure avoidance techniques and data access modalities and in the implementation of the advances that result from such research. Pg.35.

While the passage EPA quotes purports to support a statement that simple techniques are available to address privacy and confidentiality issues, the report actually says that increased concerns require ever more advanced techniques and continuing research and that:

Initially, relatively simple data masking techniques. . . were used to generate restricted data products. During the last decade the increasing risks of confidentiality breaches have led researchers to develop increasingly sophisticated methodologies for restricted data Products (references omitted). Pg. 27.

The authors note,

more research is clearly needed to assess the relative ability of different masking methods, and of synthetic data, to reduce the risk of disclosure while preserving data utility. Pg. 28.

The report presents a summary of recommendations on pgs. 3-5. They conclude :

no one way is optimal for all data users or all purposes. To meet society's needs for high quality research and statistics, the nation's statistical and research agencies must provide both unrestricted access to anonymized public-use files and restricted access to detailed, individually identifiable confidential data for researchers under carefully specified conditions.

Research using detailed confidential data is needed not only for well informed policy making but also to improve the quality of public-use files, which are the most widely used microdata products made available by statistical and other data collection agencies. In turn, wide access to public-use data leads to new analyses and conclusions that must be tested on the more detailed confidential data available only through restricted access.

The report also recognizes that protecting confidential information can be critical to getting good data in the first place.

The reason for confidentiality pledges and for stringent procedures to prevent disclosure is that they improve the quality of data collected from individuals, households, and firms. It is essential that respondents believe they can provide accurate, complete information without any fear that the information will be disclosed inappropriately. Indeed, if the information was disclosed, harm might come to an individual respondent. Many government- sponsored surveys ask about sensitive topics (e.g., income or alcoholic beverage consumption), as well as about stigmatizing and even illegal behavior. The disclosure of such information might subject a respondent to loss of reputation, employment, or civil or criminal penalties. Furthermore, the breach of a confidentiality pledge would violate the principle of respect for those consenting to participate in research, even if the disclosure involved innocuous information that would not result in any social, economic, legal, or other harm. P. 51.

The report concludes:

Ultimately, decisions about how much disclosure risk is acceptable in order to achieve the benefits of greater access to research data involve weighing the potential harm posed by disclosure against the benefits potentially foregone, as well as a judgment about who should make those decisions. The panel does not resolve these difficult issues. Rather, in Chapter 5 we recommend research to reduce disclosure risk while preserving data utility. We also recommend research that improves estimation of disclosure risk and procedures for monitoring the actual frequency of disclosure. Finally, we recommend continuing consultation with data users and data providers about all of these issues. P.62

C. Bipartisan Commission on Evidence Based Policy

Likewise, the Commission on Evidence Based Policymaking, another cited source, highlights the challenges and difficulties remaining to protect privacy and confidentiality (pp. 51, 55). This report does not address the issue of raw data in scientific studies and its relevance here is unclear and, of course, unspecified in the proposal.

D. NIH

The proposal's reliance on NIH is also misplaced. NIH policies regarding data sharing, discussed here and in the main body of our comments, generally recognize the need for restricting access to protect privacy or confidential business information, and note that in some cases access may need to be restricted to data enclaves or other limited sharing agreements available only to qualified investigators. NIH requires a data sharing plan for extramural research projects requesting \$500,000 or more in a single year, but this requirement is not absolute, since NIH will also accept an explanation for why data sharing is not possible. Under the proposal, EPA would not accept such an explanation as anything but a basis for a waiver request, either for its own science or for NIH's.

For research with such plans, NIH funds the costs of necessary data and methodology sharing arrangements as part of the project.³ EPA’s proposal provides no such funding, and does not even acknowledge that it may be needed.

E. Journal Policies

Academic journals by definition only publish current studies. Their policies therefore cannot address some of the key issues raised by EPA’s proposal. Nor does EPA explain in any way the relevance of these policies to its proposal. With the normal caveats of how commenters should not have to do the work of the agency, however, even a brief review of the policies of the organizations EPA refers to shows that in fact none of them imposes a blanket full disclosure requirement. Here is an overview.

1. *Taylor & Francis – Data Sharing Policies*

Policies range across their journals from a “basic policy” (which applies to many of their journals) where

[the] Journal encourages authors to share and make data open where this does not violate protection of human subjects or other valid subject privacy concerns. Authors are further encouraged to cite data and provide a data availability statement.

to a more stringent “open and fully FAIR policy” where

Authors must make their data freely available to the public, under a license allowing re-use by any third party for any lawful purpose. Additionally, data shall meet with FAIR standards as established in the relevant subject area.

2. *Elsevier – Research Data Policy*

Elsevier policy does not require underlying data be made publicly available. Their principles include: research data should be made available free of charge to all researchers wherever possible and with minimal reuse restrictions. They recognize that expectations and

practices around research data vary between disciplines and discipline specific requirements need to be taken into account.

Elsevier encourages and supports “researchers to share research data where appropriate and at the earliest opportunity,” enhancing its submission processes to make this easier.

3. *PLOS – Data Availability*

PLOS in general requires authors to make underlying data available publicly but allows for exceptions. The policy is meant to encourage:

Validation, replication, reanalysis, new analysis, reinterpretation or inclusion into metaanalyses reproducibility of research; efforts to ensure data are archived, increasing the value of the investment made in funding scientific research; reduction of the burden on authors in unearthing old data, retaining old hard drives and answering email requests; and easier citation of data as well as research articles, enhancing visibility and ensuring recognition for authors

Exceptions apply if:

Data cannot be made publicly available for ethical or legal reasons, e.g., public availability would compromise patient confidentiality or participant privacy.
Data deposition could present some other threat, such as revealing the locations of fossil deposits, endangered species, or farms/other animal enclosures etc.

4. *Springer Nature – Availability of data, material, and methods*

Once again there is no absolute disclosure policy. It is a condition of publication that authors are required to make materials, data, code, and associated protocols promptly available to readers without undue qualifications. Any restrictions on the availability of materials or information must be disclosed to the editors at the time of submission. Any restrictions must also be disclosed in the submitted manuscript.

F. Lutter and Zorn

Lutter and Zorn, cited in the proposal, do generally support efforts to make underlying data more available. However, in their comments on the progenitor of this proposal, the so-called HONEST Act, they repudiated the premise (now proposed here) that studies are unreliable unless their underlying data are publicly available:

The bill should also allow agencies to regulate in instances where they do not possess data. Specifically, agencies may rely on research published in peer-reviewed journals, even if there is not public access to such data and the agency cannot acquire it, provided that the agency states it has unsuccessfully sought the data under an agreement providing for privacy of human subjects and protecting trade secrets. In this case the agency, however, would have to state that it is using research based on non-public data and explain why it believes the research is nonetheless sufficiently reliable to be used for regulation.

(<https://smartregs.org/the-data-that-our-government-uses-must-be-transparent-caa16b3dc19d>)