August 16, 2018

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Office of the Science Advisor
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

RE: Comments of Clean Air Task Force on the Proposed Rule "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18,768 (Apr. 30, 2018); Docket ID No. EPA-HQ-OA-2018-0259.

Clean Air Task Force (CATF) respectfully submits these comments on the U.S. Environmental Protection Agency (EPA or Agency) proposal concerning the Agency's use of scientific studies in environmental and public health decision making, captioned above (the Proposal). The use of the best science by the Agency, including the significant public health science linking air pollution and the risk of serious public health harms, is an issue at the heart of CATF's mission. Our lawyers, scientists, policy analysts and advocates seek to help safeguard against the worst impacts of climate change and air pollution through our work in research, analysis, public advocacy, and on projects to catalyze the rapid deployment of lower carbon energy technologies.

I. Introduction

As set forth in our oral comments to the Agency at the public hearing on the Proposal on July 17, 2018,[1] and in more detail below, we disagree with the fundamental premise that this rule is either necessary or within the Agency's authority to propose, never mind to finalize. First, there is no evidence that EPA rulemakings are based upon faulty science. Second, there is no evidence that requiring the release of protected data would improve the studies on which EPA relies. And, third, preventing the Agency from relying on studies where the underlying data must be kept confidential would impermissibly remove plainly relevant information from consideration during critical environmental and public health rulemakings.

CATF agrees that "[t]he best available science must serve as the foundation of EPA's regulatory actions."[2] But the Proposal fails to advance that goal. On the contrary, the Proposal would hand the EPA Administrator the unbounded ability to preclude the Agency from considering certain best available science, unless the raw underlying data is released to the "public." In the Clean Air Act (CAA) context, we understand the Agency to be focused on the fundamental science linking

[1] Comments of James Duffy, CATF, Strenghtening Transparency in Regulatory Science Public Hearing, Wash. D.C. (July 17, 2018), Doc. ID No. EPA-HQ-OA-2018-0259-5117.

[2] 83 Fed. Reg. at 18,769 & n.1. The CAA, for example requires that National Ambient Air Quality Standards (NAAQS) are based on criteria "*accurately* reflect[ing] the *latest scientific knowledge* indicating the kind and extent of all identifiable effects on public health and welfare" from ambient exposures to the air pollutant in question. 42 U.S.C. § 7408(a)(2) (emphasis added).

particulate matter and ozone air pollution with human discomfort, disease and early death.[3] We express that understanding of the rule here, so that it is clear what we are concerned about – as the internal contradictions in the Proposal make it so vague that its purposes can more easily be gleaned from the former Administrator's public statements than from the text of the proposed rule itself.[4]

In fact, the only transparent thing about the Proposal is that it is a transparent attempt to undercut the benefit-cost rationale for numerous major air pollution regulations by disqualifying the key health studies underpinning them.[5] While vague and opaque on its face, statements by former Administrator Pruitt make clear that the Proposal takes aim at the two seminal studies linking fine particulate matter pollution to premature death.[6] Opponents of protective air pollution regulations have tried to undermine the use of these studies for a quarter century because they provide the lion's share of the quantifiable benefits from the major EPA air pollution regulations.[7] Because these PM2.5 mortality studies have been independently replicated and reproduced and their conclusions confirmed however, opponents of EPA air regulations have had to resort to a different tactic: attacking them because the study researchers have not made the data underlying the studies publicly available. In fact, as the researchers have consistently maintained for over two decades, by statute and contract, they may not make the underlying data involving the human subjects of the study

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[3] *Cf.* "Repeal of Carbon Pollution Emission Guidelines for Stationary Sources: Electric Utility Generating Units," 82 Fed. Reg. 48,035, 48,043 (Oct. 16, 2017); "Regulatory Impact Analysis for the Review of the Clean Power Plan: Proposal," (Oct. 2017) (stressing throughout the document a generalized view that the science linking ozone and fine particle exposures with human health damage and premature death is uncertain and that there may be thresholds below which emissions do not cause harm). CATF again stresses here that EPA may not discount the health benefits of reducing air pollution once the ambient air meets the national ambient air quality standards (NAAQS) or is below the lowest measured level. *See generally* Kimberly M. Castle & Richard L. Revesz, *Environmental Standards, Thresholds, and the Next Battleground of Climate Change Regulations*, 103 MINN. L. REV. __ (2018) (forthcoming).

[4] *Compare*, *e.g.*, Michael Bastasch "Exclusive: Scott Pruitt Will End EPA's Use of 'Secret Science' to Justify Regulations," THE DAILY CALLER, (Mar. 20, 2018), *available at*: http://dailycaller.com/2018/03/19/epa-scott-pruitt-secret-science/ (clearly stating that if the data cannot be publicly released EPA will not rely on the study on which it is based), *with* 83 Fed. Reg. at 18,773-74 (proposed 40 C.F.R. §§ 30.2, 30.5 requiring public release of "dose-response data" – which in practice is based on the analysis of medical records, while at the same time in proposed § 30.10 demanding consistency with existing laws and guidelines - that exempt from otherwise required release any data the disclosure of which would constitute an invasion of privacy). Only buried in the Proposal's preamble in footnote 3 is the intention made clearer: "EPA is proposing to exercise its discretionary authority to establish a policy that would *preclude* it from using [confidential data that cannot be released to the public] in future regulatory actions." 83 Fed. Reg. at 18,769, n.3.

[5] This Proposal would also undercut and contradict the CAA 1990 Amendments, Section 812 benefit and cost studies. *See* EPA, "Benefits and Costs of the CAA," https://www.epa.gov/clean-air-act-overview/benefits-and-costs-clean-air-act (last accessed Aug.15, 2018).

[6] *See* Unedited Transcript of *The Fiscal Year 2019 Environmental Protection Agency Budget*, Hearing before Subcomm. on Envt. of H. Comm. on Energy & Commerce, 115th Cong. (Apr. 26, 2018) (testimony of Admin. Scott Pruitt, at 1095-1139), *available at*: https://docs.house.gov/meetings/IF/IF18/20180426/108218/HHRG-115-IF18-Transcript-20180426.pdf (confirming that EPA intends to disregard seminal studies including Six Cities if the study authors do not "provide the data and methodology to the Agency.").

[7] Joel Achenbach, "Scientists denounce Pruitt's effort to block 'secret science' at EPA," WASH. POST (Apr. 25, 2018), *available at*: https://www.washingtonpost.com/news/energy-environment/wp/2018/04/25/scientists-denounce-pruitts-effort-to-block-secret-science-at-epa/?utm_term=.22ebcfdce468 (describing 25 year history of industry and legislative efforts to undermine these seminal studies that have been reconfirmed over and over by additional studies and third-party reviewers, including demands for public release of patient data and introduction of the failed HONEST Act).

public due to confidentiality concerns. Knowing this, industry and ideological opponents of the air regulations, including the leadership of the current Administration doing their bidding, now seek to disqualify these two studies from providing the benefits rationale for current and future air pollution regulations.

However, the current Proposal entirely fails to signal, much less justify, the significant shift it represents from long-standing EPA policy and practice and is otherwise arbitrary and capricious. We focus these comments on the Proposal's inconsistencies with the CAA, as that is most within our expertise, but note that the Proposal is both so wide-ranging and inchoate that it is clear only that EPA intends this to apply broadly across the statutes it implements. EarthJustice submitted comments to this docket, to which CATF is a signatory, and which address these other statutes and rules[8] – we will confine our discussion to the implications for CAA rulemaking.

As we explain below, the Proposal runs afoul of law, procedure, facts and longstanding practice at every turn. History shows that existing laws and guidelines provide for validation of studies without public release of confidential data. The record underlying the Proposal fails to demonstrate that Agency decisions have been based on flawed studies and does not support the Proposal's changes. Further, the Proposal is not authorized by any statute and is in conflict with the statutes' requirements to consider all relevant information and ground regulations in the best available science. The Proposal would also infringe on privacy laws. The Proposal represents an unlawful, arbitrary and capricious rulemaking, which fails to ground a dramatic change in a longstanding Agency position in law or fact. Moreover, the Proposal itself fails to meet the requirements for rulemaking – in that it is impermissibly vague and fails to cite the authority it rests upon, and therefore does not allow for meaningful comment. Finally, the Proposal does not comply with various executive orders, which, for example, require the Agency to consider both the costs and benefits of a proposed rulemaking.

In short, we share the perspective of Professor John Ioannidis of Stanford University, whose work as an advocate for data transparency is cited as supporting the Proposal,[9] who has written specifically to disavow any support for this Proposal, concluding that it is aimed at banning scientific studies unless all the underlying raw data are widely and publicly available. If finalized as proposed, this new rule would effectively ensure that "science will be practically eliminated from all decision-making processes. … [leaving regulatory decision making] "depend[ent] uniquely on opinion and whim."[10]

II. EPA's Proposal Rule is Unjustified, Unnecessary, and Impracticable

EPA's Proposal, at its core, is a redundant and flawed solution in search of a problem. The Agency asserts that although there are longstanding laws, policy statements and guidance describing ways in

[8] *See generally* Earthjustice, *et al.*, Comments on "Transparency" in Regulatory Science, (Aug. 15, 2018) [hereinafter "Earthjustice Comments"].

[9] *See* 83 Fed. Reg. at 18,770, n. 12 (citing John P.A. Ioannidis, *Why Most Published Research Findings are False*, 2 PLOS MED. 8 (Aug. 30, 2005), *available at*: http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124; and John P.A. Ioannidis, *et al.*, *What does research producibility mean?*, 8 SCI. TRANS. MED. 34 (June 1, 2016), *available at*: http://stm.sciencemag.org/content/8/341/341ps12.full.)

[10] John P. A. Ioannidis, *All science should inform policy and regulation*, 15 PLOS MED. 5 (May 3, 2018).

which influential scientific information can be made public, questioned, confirmed and expanded upon (even replicated), "EPA has not previously implemented these policies and guidance in a robust and consistent manner."[11] But there is no support, attribution, or example given for that statement, nor does the Agency elsewhere describe the need for a radical change in the way EPA relies on scientific studies. *See* discussion *infra* at Sec. III.e.ii of Agency's failure to identify and justify the change in policy. EPA offers no explanation of why existing statutes, guidelines, and other policies – many cited by the Agency in the Proposal – are not sufficient to ensure data quality, transparency, or the ability to verify, to reproduce, or otherwise confirm or expand on the results of existing scientific analysis.

EPA's attempt to justify its action on the basis that courts previously have found it has the disctretion to rely on non-public data in decision making, *see* 83 Fed. Reg. 18,769 n.3, simply does not explain why *this* proposed action – to *cut off* access to studies based on non-public data - is justified. The cases, upholding earlier Agency decisions *not* to release sensitive data underlying regulatory decisions, were decided based on a hard look at the statute, on grounds "that 'the CAA 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.'"[12] Nor is EPA's suggestion that various third-party independent organizations have called for "open science"[13] at all persuasive, as discussed below. This issue has been debated – and transparency has improved, over many years – but even commentators in the initial rounds of the conversation, noted that there is no empirical evidence supporting the idea that there is a "bad science" problem.[14]

a. The Proposal is impractical and unnecessary because existing laws and guidelines provide for controlled release of underlying data to permit reanalysis where there are questions about study results.

Longstanding statutory authorities govern the quality, objectivity, utility, and integrity of scientific data relied on by federal agencies, as implemented by policies and formal guidelines in place for

[11] 83 Fed. Reg. at 18,769. *But see* Steven Salzberg, "EPA Adminsitrator Scott Pruitt's New Transparency Rule is Not What it Seems," FORBES (May 7, 2018), *available at*: https://www.forbes.com/sites/stevensalzberg/2018/05/07/epa-administrator-scott-pruitts-new-transparency-rule-is-not-what-it-seems/ (noting that the Editors-in-Chief of Science, Nature, the Public Library of Science, and the Proceedings of the National Academy of Sciences published a rebuttal in *Science* magazine to this idea); Comments of the Bipartisan Policy Center, at 2 (May 22, 2018), Doc. ID No. EPA-HQ-OA-2018-0259-0670 (stating that *"[t]he Proposed Rule is not consistent with the BPC Report [cited by the Agency] in substance or intent.*") (emphasis in original); Comment Letter from 985 Scientists, (Apr. 23, 2018), Doc. ID No. EPA-HQ-OA-2018-0259-0070 (urging the cessation of any plans "to adopt restrictions on research similar to those contained in two pieces of proposed legislation (the Secret Science Reform Act and the HONEST Act).").

[12] *Coal. of Battery Recyclers v. EPA,* 604 F.3d 613, 623 (D.C. Cir. 2010) (quoting *Am. Trucking Ass'ns v. EPA,* 283 F.3d 355, 372 (D.C. Cir. 2001)). While the *American Trucking* case related to requests for data underlying several studies, the *Battery Recyclers* petitioners contended that their complaint (which was that the Agency had a duty to produce data underlying only one study), could be distinguished; the court disagreed, noting as well that the study results in question had been reconfirmed in a later analysis of the data, without requiring its release. *Id.* at 623-624.

[13] 83 Fed. Reg. at 18,770 & nn. 10-12.

[14] Wendy E. Wagner, S*cience in the Regulatory Process: The "Bad Science" Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation*, 66 L. & CONTEMP. PROB. 63, 72 n. 38 (2003) [hereinafter "'Bad Science' Fiction"] (citing Paul Locke, *Legal Answer to a Scientific Question*, at 60, Envtl. F. (Nov/Dec 2000)).

decades. These authorities have been effective at ensuring the quality of studies relied on by EPA, offering a process for questioning study results and for the controlled reanalysis or use in new studies of sometimes confidential or proprietary human health data and models. Adding additional regulatory requirements and constraints is both impractical and unnecessary to achieve those goals. The Data Quality Act, in force since the early 2000s, directs transparency in analysis and a process for questioning the results of science used in Agency decision making.[15] The Freedom of Information Act (FOIA) also offers a pathway for the release of data that have been the basis of Agency decisions.[16] Exempted from "public" disclosure are "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy," in the words of FOIA.[17]

i. Data Quality Act and OMB and EPA Guidelines

The Information Quality Act, also called the Data Quality Act, requires that the White House Office of Management and Budget (OMB) must issue, and require each agency also to issue "guidelines under [44 U.S.C. §§ 3504(d)(1) & 3516] that provide policy and procedural guidance … for ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by Federal agencies…."[18] These provisions amended the Paperwork Reduction Act, under which OMB was already responsible for overseeing and implementing policies ensuring the quality and usefulness of the studies and data agencies rely on in regulatory decision making.[19] The OMB and EPA guidelines implementing the Data Quality Act provide a process by which such information can be released to "qualified persons"[20] for analysis and study, *without* identifying or otherwise violating the privacy of the original human patient subject or the confidential basis under which the information was originally provided.

While EPA's Proposal claims that it is "consistent with the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies* (OMB Guidelines),"[21] the Agency simply does not explain either (a) why that is the case, or if it is, why (b) the regulations it now proposes are necessary in light of the OMB Guidelines' directives. For example, the OMB Guidelines insist that transparency "does not override other compelling interests such as privacy, trade secrets, intellectual property, and other

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[15] *See generally,* Curtis Copeland & Michael Simpson, *CRS Report to Congress, The Information Quality Act: OMB's Guidance, and Initial Implementation*, (Aug. 19, 2004) (describing the Act's history and the OMB implementing Guidelines).

[16] 5 U.S.C. § 552.

[17] *Id.* at § 552(b)(6)).

[18] Pub. L. 106-554, § 515(a) (Dec. 2000), *codified at* 44 U.S.C. §§ 3504(d)(1), 3516.

[19] *See* 44 U.S.C. § 3506(b)(1)(C).

[20] OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*; 67 Fed. Reg. 8,452, 8,455, 8,456 (Feb. 22, 2002) [hereinafter "OMB Guidelines"]; also, *id.* at 8,460 (OMB Guidelines § V(d)(b)(ii)(B)).

[21] 83 Fed. Reg. at 18,769.

confidentiality protections."[22] Instead, where data cannot be released "due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken."[23] That is not consistent with the Proposal's statement that EPA would be "preclude[d]"[24] from using proprietary or confidential data in regulatory actions. Indeed, the OMB Guidelines encourage agencies "to address ethical, feasibility, and confidentiality issues with care,"[25] pointing to the Harvard Six Cities Study reanalysis discussed *infra* at Sec. II.b, as an example of how to handle and meet a request to validate a study's results, when the underlying data cannot be released:

> 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.[26]

The OMB Guidelines also establish and reflect a presumption of objectivity and favored status for peer-reviewed science, which the EPA Proposal flips on its head.[27] That presumption of objectivity and favor for externally peer-reviewed studies is also an element of the EPA Data Quality Act Guidelines, which also reflect the overall principle that "[a]gencies should adopt a common sense approach that build on existing processes and procedures[, and] … do not impose unnecessary administrative burdens or inhibit agencies from disseminating quality information to the public."[28] Adding a mandatory agency-conducted 'independent' peer review process (as this Proposal does) for

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[22] 67 Fed. Reg. at 8,460, OMB Guidelines at § V(3)(b)(ii)(B)(i).

[23] *Id.* at 8,459-60, OMB Guidelines at § V(3)(a), V(3)(b)(ii)(A), (B)(ii).

[24] 83 Fed. Reg. at 18,769 n.3.

[25] 67 Fed. Reg. at 8,455.

[26] *Id.* at 8,456.

[27] *Compare id.* at 8,454 (quoting OMB Guidelines at § V.3.b.i. "technical information that has been subjected to formal, independent, external peer review [i]s presumptively objective") *with* 83 Fed. Reg. 18,774, proposed 40 C.F.R. § 30.7 (stating "EPA shall conduct independent peer review on all 'pivotal regulatory science' used to justify 'regulatory decisions'," whether or not that science has been subject to formal external peer review).

[28] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, at 9, 19 (2002, updated May 2005), *available at*: https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf [hereinafter "EPA Guidelines"].

all "pivotal regulatory science" used in making "regulatory decisions"[29] does not comport at all with the EPA or OMB Guidelines implementing the Data Quality Act, EPA's statements in the Proposal notwithstanding.

So, while the Proposal claims to be "consistent with" the OMB and EPA Data Quality Act Guidelines, clearly it is not. That misstatement perhaps can be attributed to the fact that OMB/OIRA review was a mere three working days long.[30]

ii. Freedom of Information Act.

To the extent that the Proposal would require release of the underlying confidential data as a prerequisite for EPA to be able to use a federally-funded study in making a rulemaking decision, it also is in conflict with the regulations implementing the FOIA. Those regulations, following the 1998 Shelby Amendment to the 1999 Supplemental Appropriations Act, provide access through FOIA to federally supported studies' "research data" – so long as its confidentiality is preserved. The Shelby Amendment had directed changes to OMB Circular A-110 and FOIA. The implementing rules state that:

> [i]n response to a Freedom of Information Act (FOIA) request for *research data* relating to published research findings produced under a Federal award that were used by the Federal government in developing an agency action that has the force and effect of law, the Federal awarding agency must request, and the non-Federal entity must provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA.[31]

But the same rules make clear that "research data" does *not* include:

> Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and (ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.[32]

The reasons for this policy are clear: researchers have shown that it takes only two or three factors to permit the identification of a study participant using study data, even if most of the features are

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[29] 83 Fed. Reg. 18,774 (proposed 40 C.F.R. § 30.7 requires EPA to "conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions*" - two phrases that are defined in the Proposal but not found in, or supported by, the statutes EPA claims authorize its action, or in the rules and guidelines the Agency references).

[30] *See* Sean Reilly, "Pruitt signed 'secret science' plan before OMB ended review," GREENWIRE, (Apr. 27, 2018), *available at*: https://www.eenews.net/stories/1060080209. EPA sent the Proposal to OIRA on April 19, 2018 and the Administrator signed it on April 24, 2018. *See also infra* at note 126, discussing the Exec. Order No. 12,866 requirement that OIRA have at least ten working days to work with a proposed rule.

[31] 2 C.F.R. § 200.315(e)(1) (emphasis added).

[32] *Id.* at § 200.315(e)(3); *see also* 5 U.S.C. § 552(b)(6) (codifying Pub. L. 89-487).

made "blind," so that the data set can be shared without exposing confidential information. First, the researchers eliminated as much information as possible from the raw data about a health study's participants, to disguise them. But in order to permit others to meaningfully use the data set, *some* identifying information had to be preserved. For example, geographic location (the place of death, for example), is required to study the correlation between air quality in that location and deaths. Age is a necessary criterion to account for the effects of normal aging and also the sex of the patient, to factor in any possible sex-related issues. The researchers, who included Douglas Dockery of the Six Cities team, found that even retaining this small number of identifying features meant that the patient could be identified by any researchers wishing to use that data to reproduce a study's results.[33]

Thus, by statute, the public may not access raw underlying data - or protected intellectual property. To the extent that the Proposal would, if finalized, require the public release of such data, it is unlawful.

b. EPA's CAA rulemaking history illustrates that the Proposal is not necessary: scientific results and methods can be questioned and validated without exposing protected underlying data to public scrutiny.[34]

The Proposal seeks comment[35] on whether its new public data release paradigm should be applied even to "dose response data and models…developed prior to the effective date." To be clear (which the Proposal is not) this would have the potential effect, on CAA rulemakings, of prohibiting the use of the well-developed dose response information resulting from two landmark studies, the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality, that have been called "the poster children of good-science reforms."[36] We strongly oppose such an outcome, as it would remove from EPA's rulemaking toolbox the "best available science" on the link between air quality and health. That is both unnecessary and unjustified.

The Proposal's focus on public release of the underlying data used in studies – particularly "dose response data" and studies,[37] evinces a clear lack of understanding of the way science is conducted

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[33] National Research Council, *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties*, at 10-11 (2002), *available at*: https://www.nap.edu/catalog/10302/access-to-research-data-in-the-21st-century-an-ongoing [hereinafter "2002 NRC Report"]; *See also* Latanya Sweeney, *et al.*, *Re-identification Risks in HIPAA Safe Harbor Data: A Study of Data from One Environmental Health Study*, TECH . SCI . 2017082801 (Aug. 28, 2017), https://techscience.org/a/2017082801 (finding that the researchers could re-identify approximately one-quarter of the records in a subset of a HIPAA-compliant environmental health data set).

[34] *See* Earthjustice Comments at 8.

[35] 83 Fed. Reg. at 18,772 (seeking comment on whether the new framework should be applied to studies in the existing prior records for NAAQS, and to "dose response data and models if those data and models were developed prior to the effective date" for a final rule). *See* Earthjustice Comments,at 90 (discussing unlawful retroactive application of the Proposal).

[36] Bad Science Fiction, *supra* note 14, at 79.

[37] 83 Fed. Reg. at 18,773 (proposed 40 C.F.R. §§ 30.2, 30.3, 30.5) defining "dose response data" and requiring it to be "publicly available in a manner sufficient for independent validation," when it is used to justify regulatory actions).

and verified. While replicating the results of a study with the same data set certainly verifies it, as the National Research Council said in 2002, "[f]or large epidemiological studies, repeating a study is seldom either possible or desirable."[38] More effective, instead, is some combination of new studies testing the same question in different places, and/or an independent analysis with the same data.[39] Formal peer review, whether or not prior to publication, also validates the outcome of scientific studies,[40] as reflected in the OMB Guidelines presumption of objectivity and usefulness for scientific studies that have undergone formal peer review, described above.

An example of this is the series of studies, re-analyses, verifications, and extensions of work begun in 1974 on the prospective "respiratory health effects of respirable particles and sulfur oxides on a sample of adults and children in six U.S. cities."[41] This work, first undertaken by researchers at the Harvard School of Public Health, became known as the Harvard Six Cities Study. The Six Cities Study, published in 1993, tracked 20,000 people in six U.S. cities for two years and found a definitive link between particulate matter pollution and serious health effects, including death. The American Cancer Society Study, published in 1995, linked air pollution to cardiovascular disease, respiratory disease and lung cancer. Since their publication the studies have been reanalyzed and extended and consistently validated.[42] EPA has found that these additional studies provide "consistent and

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[38] 2002 NRC Report at ch. 2, p. 7.

[39] *Id.* at ch. 2, p. 7-8; *see also* Douglas W. Dockery, Health Effects of Particulate Air Pollution, 19(4) ANN. EPIDEMIOL. 25 (Apr. 2009) [hereinafter "Dockery"] ("True replication requires not reanalyzing existing work but independent investigators producing independent data."). Notably, the Harvard Six Cities and ACS studies hypotheses have been subject to all kinds of reanalysis at this point, including new studies with new data, similar studies in different areas by independent researchers using the same (but masked) data, as described herein.

[40] 2002 NRC Report at 7-8 (discussing that the soundness of a study is demonstrated through the "strength of the design, methods, and statistical results," as well as its consistency with the data "other studies and scientific theories.").

[41] Dockery, *supra* n. 39 at 258. As the National Research Council noted: "the [original] data were encumbered by several types of confidentiality constraints. The investigators had assured the participants in the study that their identity and their relationship to any information obtained would be kept confidential. Special agreements were signed by each participant, the study director, and a witness. Assurances of confidentiality are typical in studies of this kind." 2002 NRC Report at 10-11. In addition to the confidentiality agreements with individual study participants, the investigators had had to sign certain statements in order to obtain death certificates from the states. They had had to agree that they would (1) limit access to the records to only the members of the research staff, (2) destroy records upon the completion of the study, and (3) not release the records to other agencies, publish data so individuals could be identified, or contact family members of decedents. Furthermore, the investigators had had to sign non-disclosure agreements to obtain information from the National Death Index. Hence, although investigators were willing to share data sets, which is a common scientific practice, they believed that to open their thousands of boxes of original records would be unethical. *Id.*

[42] EPA, *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards*, at 2-31, 2-19 (Apr. 2011) [hereinafter "Policy Assessment"] (citing *e.g.* EPA, *Integrated Science Assessment for Particulate Matter (Final Report)*, 7-84 to 7-85; fig.7-6 (Dec. 2009) *available at*: http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_isa.html; Krewski D, *et al.*, Health Effects Institute, *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality. A special report of the Institute's particle epidemiology reanalysis project,* (2000), *available at*: http://pubs.healtheffects.org/view.php?id=6; Pope CA, *et al.*, Health Effects Institute, *Cardiovascular mortality and long-term exposure to particulate air pollution: epidemiological evidence of general pathophysiological pathways of disease*, 109 CIRCULATION 71-77; Jerrett M, *et al.*, *Spatial analysis of air pollution and mortality in Los Angeles*, 16 EPIDEMIOLOGY 727-36 (2005); Laden F, *et al.*, *Reduction in fine particulate air pollution and mortality: extended follow-up of the Harvard Six Cities Study*, 173 AM. J. RESPIR.

stronger evidence of an association with mortality at lower air quality distributions than had previously been observed."[43]

Some of the early peer reviewed Harvard Six Cities work was relied on by EPA in setting the particulate matter NAAQS in 1987.[44] Industry challenged the 1987 24-hour particulate matter standards in part by questioning that work.[45] The court held that EPA must "take into account all the relevant studies revealed in the record,"[46] and noted the precautionary nature of the CAA.

The Harvard researchers and others continued to explore the effects of ambient particulate matter exposures on human health and mortality, in the six cities, and various other places around the country and the world.[47] As those results came out, industry-sponsored researchers again challenged them, in professional meetings and journals, arguing that because they could not reproduce or use the (confidentially provided) human health data set, the results could not be relied on. They claimed to come up with different results using other data.

The Health Effects Institute was brought in to manage an evaluation of the studies. HEI, funded by industry and EPA, is an independent arbiter, which chose a new team of scientists to reconstruct the Six Cities data set and verify the original results.[48] Subsequently, over 100 other studies were peer-reviewed and published by 2004, building on, expanding, corroborating, and verifying the relationship between particulate matter exposures and adverse respiratory health effects and even early death. These included follow up using "the sample of adults in the Harvard Six Cities Study," that found an approximately two-year reduction in life expectancy for those living in the most polluted areas. [49]

CRIT. CARE. MED. 667-672 (2006); Schwartz J, *et al.*, *The effect of dose and timing of dose on the association between airborne particles and survival*, 116 ENVIRON HEALTH PERSPECT. 64-69 (2008)).

[43] Policy Assessment at 2-5.

[44] *NRDC v. EPA*, 902 F.2d 962, 969-970 & nn. 8, 9 (D.C. Cir. 1990) (citing Dockery, *et al.*, *Change in Pulmonary Function in Children Associated with Air Pollution Episodes*, 32 J. AIR POLLUTION CONTROL ASS'N. 937 (1982); Ware, *et al.*, *Effects of Ambient Sulfur Oxides and Suspended Particles on Respiratory Health of Preadolescent Children*, 133 AM. REV. RESPIRATORY DISEASE 834 (1986)).

[45] *NRDC,* 902 F.2d at 969.

[46] *Id.* at 970 (quoting *Am. Petroleum Inst. v. Costle,* 665 F.2d 1176, 1187 (D.C. Cir. 1981), *cert. denied,* 455 U.S. 1034 (1982)).

[47] Dockery, *supra* n. 39, at 258-59 & nn. 15-21 (citing Schwartz & Marcus, *Mortality and air pollution in London: a time series analysis*, 131 AM. J. EPIDEMIOLOGY 185 (1990); Schwartz & Dockery, *Particulate air pollution and daily mortality in Steubenville, Ohio*, 135 AM. J. EPIDEMIOLOGY 12, 20 (1992); Schwartz & Dockery, *Increased mortality in Philadelphia associated with daily air pollution concentrations*, 145 AM. REV. RESPIRATORY DISEASE 600 (1992); Pope, *Respiratory disease associated with community air pollution and a steel mill, Utah Valley*, 79 AM. J. PUB. HEALTH 623 (1989); Pope, Schwartz & Ransom, *Daily mortality and PM10 pollution in Utah Valley*, 47 ARCH ENVIRON. HEALTH 211 (1992); Bates, *Health indices of the adverse effects of air pollution: the question of coherence*, 59 ENVIRON. RES. 336 (1992); Dockery & Pope, *Acute respiratory effects of particulate air pollution*, 15 ANN'L REV. PUB. HEALTH 107 (1994)).

[48] Dockery, *supra* note 39, at 259.

[49] *Id.*

These results, and the methodologies underlying them, were then validated by the original Harvard Six Cities researchers, in collaboration with a team funded by the American Cancer Society, using new cohort data – a combined data sample of more than 500,000 adults.[50] The collaborative work was peer-reviewed and published.[51] That work then became the focus of new debate over the 1997 particulate matter NAAQS standard-setting, including new industry attacks based on industry's asserted lack of access to the health data in which they were grounded – raising the *same* questions that are still underlying this 2018 Proposal – namely, arguing that EPA needed to make public the data underlying any study on which it relied. Again, however, HEI was brought in to validate the results, and the resulting work was published in 2000.[52] The D.C. Circuit Court reviewing the 1997 standard determined in 2002 that releasing the data was neither required by the Act, nor was it practical or necessary.[53]

The HEI review validated the previous work, and "demonstrated the robustness of the PM-mortality risk estimates to many alternative model specifications….[and] also made a number of innovative methodological contributions that…substantially contributed to subsequent analyses."[54]

c. EPA's cited independent third-party organizations neither support this Proposal nor do their publications call for its draconian measures.

The Proposal asserts that it "takes into consideration the policies and recommendations of third-party organizations who advocated for open science,"[55] but fails to identify with any precision what those policies or recommendations are. The Agency merely names the organizations, and cites certain studies they have issued, without offering PIN citations to statements that would support the EPA Proposal.[56] Our review reveals that there is no support in them for the draconian measures EPA proposes here. For example, the Bipartisan Policy Center study cited by the Agency recommends that decisionmakers should "cast a wide net" and "base policy on a thorough review of all relevant research and provisions of the relevant statutes," giving peer reviewed papers "great

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[50] *Id.* at 260.

[51] Dockery, *et al.*, *An association between air pollution and mortality in six U.S. Cities*, 329 NEW ENG. J. MED. 1753 (1993); Pope, *et al.*, *Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults,* 151 AM. J. RESPIRATORY CRITICAL CARE MED. 669 (1995).

[52] Krewski, *et al.*, *supra* note 42. Krewski D, *et al.*, Health Effects Institute, *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality. A special report of the Institute's particle epidemiology reanalysis project* (2000), *available at*: http://pubs.healtheffects.org/view.php?id=6.

[53] *Am. Trucking Ass'ns v. EPA,* 283 F.3d 355, 372 (D.C. Cir 2002).

[54] Dockery, *supra* n. 39, at 260.

[55] 83 Fed. Reg. at 18,770.

[56] *Id.* at nn. 10-12; *see also* EPA, "Memorandum: Omitted Hyperlinks for Footnotes in Proposed Rule," (May 25, 2018), Doc. ID No. EPA-HQ-OA-2018-0259-0812 (offering the hyperlinks, but again without page references or any indication where the claimed support for the Agency's position may be found if at all).

weight,"[57] but nowhere promotes the idea that sensitive or confidential raw data should be publicly released. To the contrary, the paper recommends reliance on existing authorities and guidance, such as the Data Quality Act and the OMB Guidelines, discussed s*upra* at Sec. II.a.i.[58]

EPA also cites the Administrative Conference of the United States' Science in the Administrative Process Project – but that study merely recommends releasing study data only "[t]o the extent practicable and permitted by law and applicable policies."[59] The report does not call for any additional public release of sensitive health information.

Likewise, the two National Research Council Reports EPA cites also fail to support requiring release to the public of "data and models underlying scientific studies that are pivotal to the regulatory action."[60] Far from supporting the concept of allowing reliance on studies only where the data are available to the public, these reports suggest "exploiting the research potential of microdata and maintaining acceptable levels of confidentiality"[61] and advocate "nuanced case-by-case judgment[s]"[62] for releasing underlying data. Nor do the articles the Agency cites on the reproducibility of studies support its Proposal, and EPA does not explain why it thinks they do.[63] In fact at least one of the cited articles, by Steven Goodman,[64] is entirely irrelevant - it does not demonstrate that there is a problem with the reliability of science in support of Agency decision making, nor does it attempt to. Rather, it discusses the confusion in the lexicon about reliability, and

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[57] Bipartisan Policy Center, Science for Policy Project, *Improving the Use of Science in Regulatory Policy*, at 5, 8 (Aug. 5, 2009), *available at*: http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf; *but, see also* Comments of the Bipartisan Policy Center, at 2 (May 22, 2018), Doc. ID No. EPA-HQ-OA-2018-0259-0670 (stating that *"[t]he Proposed Rule is not consistent with the BPC Report [cited by the Agency] in substance or intent*.") (emphasis in original).

[58] *Id.* at 43.

[59] Administrative Conference of the United States' Science in the Administrative Process Project, *Science in Administrative Process* (June 14, 2013), *available at*: https://www.acus.gov/recommendation/science-administrative-process.

[60] 83 Fed. Reg. at 18,769.

[61] *See* National Research Council, *Improving Access to and Confidentiality of Research Data*, at xi, xii, 5 (2000) [hereinafter "2000 NRC Report"]; *see also* 2002 NRC Report at 2 ("our society continues to place a very high premium on the protection of individuals' medical information, and this desire stands opposed to unlimited access to information used in research.").

[62] 2002 NRC Report at 27.

[63] 83 Fed. Reg. at 18,770, n. 12. (citing John P.A. Ioannidis, *Why Most Published Research Findings Are False*, PLOS MED. (Aug. 5, 2005), *available at*: http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124 (explaining that w]hat matter is the totality of evidence" and that research can be improved through "larger studies," "enhanced research standards," "curtailing of prejudices," and "upfront registration of studies."); Marcia McNutt, *Reproducibility*, 343 SCI. 229 (Jan. 17, 2014), *available at*: http://science.sciencemag.org/content/343/6168/229 (explaining that the Science initiative to increase transparency cited does not require disclosure of underlying data either but rather a more fulsome description of how the study was conducted before it will publish the results in its journal); and *How Science Goes Wrong*, THE ECONOMIST (Oct. 21, 2013), *available at*: https://www.economist.com/leaders/2013/10/21/how-science-goes-wrong (calling for registering research protocols up front, post publication evaluation, and financing more "uninteresting" work)).

[64] Steven N. Goodman, *et al.*, *What does research reproducibility mean?*, 8 SCI. TRANSLATIONAL MED. 341 (June 1, 2016).

attempts to more properly define the term "reproducibility." But in no way does it support *eliminating* consideration of studies because the underlying data is not publicly available.

Finally, the industry-funded Mercatus Center paper cited by the Agency does not support the proposition that it is necessary to limit or forbit EPA's use of scientific studies where the data are not publicly available. Rather, Mercatus recommends an avenue for the Agency to follow where there is a need to reproduce or validate study results and the researchers *cannot* release the underlying data, but the "[A]gency still believes that relying on the results of the study is warranted."[65] In that situation, the paper recommends that the Agency would provide a more extensive explanation of why it has "sufficient confidence to use the study."[66]

III. EPA's Proposal is Not Lawfully Grounded, and both Represents, and Sets the Stage for, Arbitrary and Capricious Decision Making.

a. EPA's Proposal to limit the scientific basis for the Agency's decision making is not authorized by the CAA

EPA, like all federal agencies, is a creature of statute, and "may act only pursuant to authority delegated … by Congress."[67] But the Proposal fails to state clearly under what authority EPA is proposing these rules, providing only a list of statutes that require the Agency affirmatively to take scientific information into account, but not explaining why they would offer the Agency authority to *disregard* certain relevant studies.[68] Indeed, EPA seems unsure of its authority, requesting comment on "additional or alternative sources of authority."[69]

Nor does the EPA Administrator's authority "to prescribe such regulations…as are necessary to carry out the Agency's functions"[70] present an opening to disregard relevant information, as EPA suggests. To the contrary, courts have held that the Administrator must take into account *all* relevant studies in the record.[71] Other CAA sections, not cited by the Agency, lay out and define some of the Administrator's rulemaking "functions under the Act" as requiring for example, the use of "the

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[65] Randall Lutter & David Zorn, Mercatus Center, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, at 32 (Sept. 2016).

[66] *Id.* at 32-33.

[67] *Clean Air Council v. EPA*, 862 F.3d 1, 9 (D.C. Cir. 2017).

[68] *See generally*, Dan Farber, "The Questionable Legal Basis of the 'Transparency' Rulemaking," (Apr. 30, 2018), http://legal-planet.org/2018/04/30/the-questionable-legal-basis-of-the-transparency-proposal/.

[69] 83 Fed. Reg. at 18,769.

[70] *Id.*

[71] *See, e.g., Am. Petroleum Inst. v. Costle*, 665 F.2 1176, 1187 (D.C. Cir. 1981) (in setting NAAQS based on an 'adequate margin of safety' to protect public health, the Administrator must consider all relevant studies revealed in the record, not only the studies favoring a particular position). The Agency's Proposal does not define the word "relevant" to exclude studies based on confidential data, nor could it argue that human health findings are not relevant to an assessment of human health effects.

latest scientific knowledge useful in indicating the kinds and extent of all identifiable effects on public health or welfare...."[72] So, the Proposal to permit him to *disregard* some studies is contrary not only to his general rulemaking authority, but to his specific authority to, *inter alia*, set NAAQS based on the "latest scientific knowledge."[73]

The seminal CAA air quality standard-setting provisions have twice been held not to require the release of data underlying studies relied on by the Agency, as discussed above. Indeed, in both situations, the court has described such release as "unnecessary and unjustified."[74]

The Proposal also is inconsistent with the overall precautionary nature of the CAA.[75] Congress did not intend EPA to limit itself to considering only 'sure things' but asks the Administrator to protect the public against uncertain dangers due to exposure to air pollution. Primary NAAQS are to be set with an "adequate margin of safety,"[76] meaning that "the Administrator need not regulate only the known dangers to health but may 'err' on the side of overprotection."[77] This precautionary approach is reflected also in the various technology-forcing sections of the Act, which Senator Muskie said "may [require] that people and industries will be asked to what seems to be impossible at the present time."[78] Under this scheme, the Administrator must consider all relevant studies placed in the record, and "may apply his expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as 'fact' and the like,"[79] in order to protect public health as Congress intended. This context simply does not authorize the Administrator to decline to consider any studies – but particularly not those representing the best available science – because the underlying data is confidential.

b. The Proposal's substance is in conflict with the CAA requirement that EPA consider relevant matter presented in the rulemaking record.

CAA section 307(d)(6)(B) requires that when finalizing a proposed rule, and after taking comment, an Agency must "respon[d] to each of the significant comments, criticism, and new data submitted in written or oral presentations during the comment period."[80] And, while both proposed and final

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[72] 42 U.S.C. § 7408(a)(2), describing the criteria document that must form the basis for a NAAQS setting process under CAA section 109, 42 U.S.C. § 7409.

[73] *Id.*

[74] *See supra* at note 12 .

[75] *NRDC*, 902 F.2d at 968 (describing the "precautionary nature" of the CAA).

[76] 42 U.S.C. § 7409(b)(1).

[77] *Envtl. Def. Fund v. EPA,* 598 F.2d 62, 80-81 (D.C. Cir. 1978).

[78] *Union Elec. Co. v. EPA*, 427 U.S. 246, 258-59 (1976).

[79] *NRDC*, 902 F.2d at 968.

[80] 42 U.S.C. § 7607(d)(6)(B).

rules under the CAA must be accompanied by a statement of basis that *summarizes* studies and data on which the Agency relies, in no way does that requirement authorize the public release of the raw data. Nor does the Act's requirement that the record underlying rules include a "summary of … the factual data on which the … rule is based,"[81] require the *public release* of such data. Nor does the Act elsewhere require or allow data to be released to the public. Where "new data" is submitted by commenters, that must be responded to by the Agency and that response made part of the record, but the statute does not require public release of new data either.[82] Indeed, Agency proposals, including this one, describe measures by which commenters can submit so-called "confidential business information" – which the Agency can consider but protect from public release.[83]

Therefore, to the extent that the Proposal envisions authorizing EPA to ignore or disregard or not to consider some studies submitted during a rulemaking comment period, whether or not the data is publicly released, such agency action would be taken in direct violation of the CAA.[84] Nor is there any basis elsewhere in the CAA for EPA to decide to exclude or prohibit the consideration of otherwise relevant matter because it is based on confidential information not available to the general public.

i. The Proposal does not meet CAA procedural requirements.[85]

As noted *supra*, the CAA requires, with any proposed rule, a summary of "the factual data on which the proposed rule is based; the methodology used in obtaining the data and in analyzing the data; and the major legal interpretations and policy considerations underlying the proposed rule."[86] But this Proposal is not accompanied by *any* record in support. Nor has the Agency even attempted to explain in the preamble why current statutes and guidelines do not adequately provide for the public to question scientific studies, seek validation, replication (or reproducibility)[87] of study results, and to comment on methodologies, without "public" release of confidential data. It therefore does not satisfy the CAA's requirements or provide the public with a meaningful opportunity to fully

[81] *Id.* at §§ 7607(d)(3) & (6)(a).

[82] *Id.* at § 7607(d)(6)(b).

[83] 83 Fed. Reg at 18,768-69.

[84] *See, e.g.*, *NRDC,* 902 F.2d at 971 ("the Administrator must take into account *all* the relevant studies revealed in the record and make an informed judgment based on available evidence") (internal citations omitted) (emphasis added).

[85] *See* Earthjustice Comments at 64.

[86] 42 U.S.C. § 7607(d)(3) (subsection headers omitted). As originally published, the Proposal also violated the CAA's requirement that proposed rules be subject to an opportunity for oral comment. The Agency has since corrected that flaw. EPA, News Release, "EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations," (May 24, 2018), https://www.epa.gov/newsreleases/epa-announces-extended-comment-period-and-public-hearing-proposed-rule-strengthen.

[87] The Proposal uses these terms seemingly interchangeably and certainly without defining what they mean. *See, e.g.,* 83 Fed. Reg. 18,768, *ibid.* (stating that the public disclosure must be "sufficient for independent validation);" *id.* at 18,770 (claiming a "replication crisis"); *id.* (mentioning a "standard for reproducibility" and "reproducible scientific assessments.").

comment on the proposal.

c. The Proposal does not meet the Administrative Procedure Act's Requirements.

The Proposal claims to be "consistent with the principles underlying the Administrative Procedure Act" (APA).[88] But, the Proposal does not clearly identify the authority under which it is promulgated, is so vague as to undermine the ability to meaningfully comment, and in its substance contradicts the APA requirement that agencies must consider all the relevant matter presented in a rulemaking record.[89]

i. The Proposal does not clearly identify the authority under which EPA has promulgated it.

As discussed above, the CAA does not authorize the Proposal, which is clearly aimed at limiting the studies EPA can rely on and consider in CAA rulemaking. Additionally, APA section 553(b)(2) requires a proposed rule to provide a "reference to the legal authority under which the rule is proposed." While the Proposal's preamble *lists* various statutes the Agency claims support its action, a closer look reveals that none of those sections actually authorizes EPA to disregard scientific studies.[90] Certainly that is the case for the CAA sections listed by the Agency in the Proposal, including the general rulemaking authority under the Act which requires the evaluation of all material in the record. EPA's suggestion that it has "general authority" to make rules to comply with its obligations is similarly unavailing here, as the general authority does not exist to make rules that are outside EPA's statutory obligations, or in violation of them[91] – and a rule that would enable EPA to disregard relevant studies in a CAA rulemaking record is clearly outside the Agency's authority. Nowhere does the Act permit EPA to limit its own access to relevant science.

ii. The Proposal's terms are so vague as to fail to afford an opportunity for meaningful comment.

Significant issues are presented in the Proposal only in the broadest terms, despite an APA requirement that a proposed rule includes "the terms and substance of the proposed rule or a description of the subjects and issues involved," 5 U.S.C. § 553(b)(3), and with enough specificity "to permit interested parties to comment meaningfully."[92] As noted *supra*, we assume (as we must, given no other information from the Agency), that the Proposal is aimed at precluding EPA's reliance on studies for which the data are not made public. That is the natural reading of the proposed regulatory language, which is the most choate information offered in the Proposal. But

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[88] 83 Fed. Reg. at 18,769. CAA rulemaking has governing requirements found in the Act, 42 U.S.C. § 7607d)(1). To the extent that what EPA is attempting to argue is that this Proposal is not covered by 42 U.S.C § 7607(a)(1), but is consistent with the APA, that too is incorrect.

[89] 5 U.S.C. § 553(c).

[90] 83 Fed. Reg. at 18,769 (listing statutory sections but not explaining why the cites authorize the Proposal).

[91] *See Am. Petroleum Inst.,* 52 F.3d at 1119 ("EPA cannot rely on its general authority to make rules necessary to carry out its functions when a specific statutory directive defines the relevant functions of EPA in [an] area").

[92] *Honeywell Int'l, Inc. v. EPA,* 372 F.3d 441, 445 (D.C. Cir. 2004).

even that reading is not certain, given the very broad discretionary nature of the exemptions provided for in the rule text (*see, e.g.,* 83 Fed. Reg. 18,774, proposed 40 C.F.R. § 30.9, giving the Administrator the ability to grant an exemption to the data publication requirement if that is "impracticable," which is undefined in the Proposal). As a result, it is unclear how this rule would apply to EPA decision making, and how it would be different than the Agency's current protocol for considering studies relevant to specific rulemaking proposals.

As one example, EPA alludes to "transparency" multiple times, but without defining what that concept means, or explaining why it believes existing statutes, regulations, guidelines and protocols fail to meet it.[93] While asserting an interest in "ensur[ing] that the data and models underlying science is [sic] publicly available in a manner sufficient for validation and analysis,"[94] there is no more specific statement explaining how that would be implemented or why releasing confidential health and business information is necessary. Nor is the Agency's rationale completely clear in the Proposal. When commenters are left to guess, that is not lawfully sufficient notice of the subjects and issues involved.

iii. The Proposal's substance conflicts with the APA requirement that Agencies consider relevant matter presented in the rulemaking record.

Section 553(c) of the APA requires that when finalizing a proposed rule, and after taking comment, an agency must "consider[] the relevant matter presented" in the record.[95] To the extent that the Proposal envisions authorizing EPA to ignore or disregard or not to consider some studies submitted during a rulemaking comment period, such Agency action would be taken in direct violation of this provision of the APA.[96] Nor is there any basis in the APA for EPA to decide to exclude or prohibit the consideration of otherwise relevant matter because it is based on confidential information not available to the general public.

d. The Proposal is inconsistent with federal regulations governing the protection of human health information, including the Health Insurance Portability and Accountability Act (HIPAA).

Depending on the entity conducting the research, the source of the information and the subject matter, a variety of federal laws and their implementing regulations apply to scientific researchers who use human health data in their work. These regulations include the Health and Human Services' "Federal Policy for the Protection of Human Subjects" regulations, 45 C.F.R. § 46.101 *et seq*., and the Food and Drug Administration's "Protection of Human Subjects," 21 C.F.R. § 50.1 *et seq*., and

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[93] In 83 Fed. Reg. at 18,768-18,774, EPA includes 13 preamble references to "transparency," and one rule text reference, at proposed 40 C.F.R. § 30.7, without providing any indication of the intended meaning of that term. *Also see generally*, Dan Farber, "Pruitt's Utterly Opaque Transparency Proposal," (Apr. 26, 2018), *available at*: http://legal-planet.org/2018/04/26/pruitts-utterly-opaque-transparency-proposal/.

[94] 83 Fed. Reg. at 18,769.

[95] 5 U.S.C. § 553(c).

[96] *NRDC*, 902 F.2d at 971 ("the Administrator must take into account *all* the relevant studies revealed in the record and make an informed judgment based on available evidence") (internal citations omitted) (emphasis added).

"Institutional Review Board" regulations, 21 C.F.R. § 56.101 *et seq*. Most relevant here, however, are the rules implementing the Health Insurance Portability and Accountability Act (HIPAA). HIPAA Privacy Rule," 45 C.F.R §§ 160.101 *et seq*., 164.102 *et seq*. (Privacy Rule).

The Privacy Rule "protect[s] the privacy of health information that identifies individuals who are living or dead."[97] The rule is applicable to health care providers but establishes the conditions under which researchers may use private health information generated by the provider. The provider may only provide the researcher or otherwise disclose health information if it is de-identified. The Privacy Rule requires the removal of at least 18 comprehensive categories of information that could be used to identify an individual.[98] The individual must also provide informed consent allowing the use of the information.[99]

Additionally, criteria for Institutional Review Board approval of research – a requirement for federally funded research on humans – includes informed consent[100] and "adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."[101] These provisions are at the very least in tension with the Proposal's directive that "dose response data" are "publicly available in a manner sufficient for independent validation," as the Proposal defines that concept.[102] The Proposal provides no discussion of how underlying data of relevant studies can be released consistent with the various laws and regulations protecting privacy and prohibiting disclosure. The failure to "consider an important aspect of the problem" renders the Proposal arbitrary and capricious.[103]

e. EPA's Proposal, if finalized, would be arbitrary and capricious.

An agency's decision is arbitrary and capricious where it fails to consider important aspects of the problem, is counter to the evidence before it, or relies on factors Congress has not intended it to consider.[104] When the action rescinds, or represents a significant about face from, previous agency rules or longstanding practice, it must provide a reasoned basis for doing so.[105] If finalized as

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[97] U.S. Dep't of Health and Human Services, *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule*, at i (July 13, 2004), *available at:* https://privacyruleandresearch.nih.gov/pr_02.asp.

[98] *Id.* at 10.

[99] *Id.*

[100] 45 C.F.R. § 46.116; and *id.* at § 46.116(b)(5) (requiring "[a] statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.").

[101] *Id.* at § 46.111(a)(7).

[102] 83 Fed. Reg. at 18,773-74, (proposing 40 C.F.R. § 30.5, to require "public" access to, *inter alia,* "data" and "recorded factual materials").

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

[104] *Id.* at 43-44.

[105] *FCC v. Fox Television Stations*, 566 U.S. 502, 515-16 (2009) (internal citation omitted).

proposed, EPA's attempt to cut off access to significant scientific results would fall short on all of these factors and would also lead to further arbitrary and capricious agency decision making.

i. EPA's Proposal fails completely to consider or propose consideration of factors relevant to its decision making.

As described *supra*, there are "significant and viable and obvious alternatives" to this Proposal,[106] which the Agency has failed adequately to consider, nor has the Agency explained why it believes such alternatives are not sufficient.

Additionally, EPA failed even to confer with its chartered Science Advisory Board (SAB), and seek its input, as required under the Environmental Research Development and Demonstration Authorization Act (ERDDAA), 42 U.S.C. § 4365(c)(1), even though EPA claims authority under the CAA, and admits in the Proposal that it is a "significant regulatory action" submitted to OMB for review.[107] As EPA's SAB recently wrote to the Administrator, a proposal like this, which "focus[es] on the EPA's foundational policies related to the use of science in rulemaking and policy development," is within the SAB's purview and should have been submitted to it for review."[108] EPA's failure even to submit the Proposal to SAB review, never mind take account of the SAB review results, is evidence of the arbitrary and capricious nature of this whole undertaking.[109]

Similarly, despite its admission that this is a significant regulatory action that requires OMB review, the Agency fails to provide analysis accompanying the Proposal, as required by Executive Order 12,866, "assess[ing] both costs and benefits" to assure "a reasoned determination that the benefits of

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[106] *Nat'l Shooting Sports Found. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013).

[107] 42 U.S.C. § 4365(c)(1)(requiring, *inter alia,* EPA to make available to the SAB any CAA rule that is provided to any other Federal agency for formal review and comment); 83 Fed. Reg. at 18,772; *see also* Bad Science Fiction, *supra* note 14 at 79-80 & n. 66 ("Science advisory boards are mandatory for EPA's promulgation of air quality standards and for regulatory action on pesticides. See 7 U.S.C. § 136w(d)-(e) (requiring the scientific advisory panel established under FIFRA to review the scientific basis for major regulatory proposals concerning pesticides and to adopt peer-review procedures for scientific studies carried out pursuant to FIFRA); 42 U.S.C. § 7409(d)(2)(B)-(C) (2000) (establishing the Clean Air Scientific Advisory Committee (CASAC) to review EPA's ambient air quality standards). …[S]ee also 42 U.S.C. 4365(c)(1) (2000) (establishing a science advisory board to review scientific and technical information relevant to any proposed action under EPA's authority if EPA is forwarding the proposal to any other federal agency for formal review). The FDA, EPA, and OSHA each has advisory bodies available to them for various regulatory activities, but the agencies are not required to seek their assistance. See, e.g., 42 U.S.C. 4365 (2000) (creating a Science Advisory Board to assist EPA in its research initiatives and science-based regulatory determinations). EPA's SAB "has played an increasingly influential role in reviewing the agency's science….The agencies have also developed, without legislative direction, a variety of peer review and science consensus panels. The NIH, for example, has developed an innovative expert panel to reach consensus on issues of medical import.").

[108] Letter from Dr. Michael Honeycutt, Chair, EPA SAB, to Administrator Scott Pruitt, EPA, at 3 (June 28, 2018). *See also* Memorandum from Alison Cullen, Chair, SAB Work Group to Members of the Chartered SAB (May 12, 2018) (raising numerous and significant concerns with the Proposal).

[109] *Public Employees v. Hopper*, 827 F.3d 1077, 1083 (D.C. Cir. 2016) (holding that where an agency relies "solely on data…roundly criticized by its own experts, [it] fail[s] to fulfill [its] duty" to exercise its discretion in a reasoned manner.).

the intended regulation justify its costs."[110] Instead, EPA makes unsupported statements about its "belie[f that] the benefits of the proposed rule justify the costs."[111] The only further discussion on this point is a reference to the industry-funded Mercatus Paper, which rejects a Congressional Budget Office (CBO) projection that proposed legislation, with terms similar to the Proposed Rule here, would cost the country $250 million a year.[112] The Mercatus Paper, however does not find the new policy to be cost-free. Instead it reports that compliance with the proposed legislation would add $2,558 to the costs of each study – and EPA never explains how that compares with the $250 million price tag from the CBO.[113]

EPA baldly asserts that the benefits will outweigh the costs because the Proposal "will improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets,"[114] citing only a 2005 National Research Council report.[115] But the NRC report does not assess the cost of eliminating peer-reviewed quality science from consideration, it merely discusses the tension between providing more transparency and access to data while continuing to protect confidentiality. Indeed, the NRC explicitly states that its work does not "weigh[] the potential harm posed by disclosure against the benefits potentially foregone."[116]

There is, moreover, no attempt made by the Agency to quantify or qualify lost benefits, were the new policy to take effect. There is no analysis of the number of studies that could be affected by the Proposal, the effects of the Proposal on research, the potential for weakening of environmental regulations, and the resulting environmental or public health costs, or any other costs for that matter associated with eliminating dose-response studies and methods from regulatory decision making because the underlying data cannot be released. In fact, EPA does not even seem to understand that there *could* be such costs associated with its Proposal – it asserts (without support) only that making underlying data available "will improve the data and scientific quality of the Agency's actions."[117]

ii. EPA fails to explain why the significant changes to longstanding Agency practice are necessary or justified.

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[110] 83 Fed. Reg. at 18,772 (referencing Exec. Order No. 12,866, but no analysis completed thereunder); *but see* Exec. Order Nos. 12,866 §§ 1(b)(6), 6(a)(3)(B)-(C) & 13,563 § 1(b)(1) (requiring such analysis).

[111] 83 Fed. Reg. at 18,772.

[112] Lutter & Zorn, Mercatus, supra note 65, at 32 (citing CBO, *Cost Estimate: S. 544, Secret Science Reform Act of 2015* (June 5, 2015)).

[113] *Id.* at 23.

[114] 83 Fed. Reg. at 18,772 & n. 23.

[115] *See generally* National Research Council, Expanding Access to Research Data: Reconciling Risks and Opportunities, (2005) [hereinafter "2005 NRC Report"].

[116] 2005 NRC Report at viii.

[117] 83 Fed. Reg. at 18,772.

The failure to adequately justify a changed agency position is one of the hallmarks of arbitrary and capricious decision making.[118] The Agency furthermore must "provide a more detailed justification than would suffice for a new policy…when, for example, its [revised] policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account. It would be arbitrary and capricious to ignore such matters."[119]

EPA, in the Proposal, fails to engage with the reasoning or facts underlying the Agency's longstanding policy position, which respected the confidentiality of underlying data and accounted for all relevant science.[120] Further, this position has engendered significant reliance interests. Many of the "dose response" studies the Agency singles out for attention have been relied on in decision making for many decades, and have been the basis for many other subsequent work, on which the Agency also has relied.[121] The Agency seems not to understand this or have a plan for how to manage the fallout from a final rule that denies access to all of that body of work – whether in an exclusively forward-looking way, or retroactively.[122] But, "[a]n agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past."[123]

iii. If finalized, the Proposal's requirement to disregard relevant studies would ensure further arbitrary decision making.

Were this rule to be finalized as proposed, it would permit or even require the Agency to disregard certain studies placed in the record in future substantive rulemakings under the CAA, among other statutes. Not only would that render the future substantive rules unlawful under the Act's requirements, but it would also make them arbitrary and capricious, as "failure to consider the evidence proffered renders [a decision] arbitrary and capricious"[124] and the Agency may not "hastily discount[]" relevant studies.[125] The Agency seems completely unaware that its new policy, if finalized, could lead to future rulemaking actions that are unlawful, arbitrary and capricious.

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[118] *State Farm*, 463 U.S. at 43-44.

[119] *Fox Television Stations*, 566 U.S. at 515-16 (internal citation omitted).

[120] *See* Earthjustice Comments at 80-82.

[121] *See*, *e.g.,* Policy Assessment; and Earthjustice Comments at 13.

[122] *See* 83 Fed. Reg. at 18,772 (seeking comment on how the Proposal should apply to previous rulemaking records and studies, data and models "developed prior to the effective date," without explaining how EPA views the consequences of such retroactive application of the proposed policy).

[123] *Fox Television Stations,* 566 U.S. at 537 (Kennedy, J., concurring).

[124] *Southwest Power Pool v. FERC*, 736 F.3d 994, 999 (D.C. Cir. 2013); *see also Mississippi v. EPA*, 723 F.3d 246, 269 (D.C. Cir. 2013) (agency must explain why evidence submitted is not reliable if choosing to ignore it); *see also NRDC v. EPA*, 902 F.2d at 971 (same).

[125] *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 525 (D.C. Cir. 2009) (citing *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 241 (D.C. Cir. 2008) (Agency's inadequate explanation for dismissing empirical studies rendered decision arbitrary and capricious); *cf. Am. Trucking Ass'ns,* 175 F.3d at 1052-53 (EPA arbitrarily and capriciously placed upon some studies "higher information threshold" than it placed upon others"); *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1150-51 (D.C. Cir. 2011) (vacating rule for ignoring relevant studies); and *Chlorine Chem. Council v. EPA*, 206 F.3d 1286 (D.C. Cir. 2000)

IV. EPA has Failed to Follow Required and Customary Rulemaking Process in Issuing this Proposal.

The rulemaking process set forth in the APA, and in more detail in the CAA, provide a Congressionally-directed framework to assure that the Agency's rulemaking decisions are not arbitrary – that they are made transparently and based on an adequate record that is subject to public scrutiny. Similarly, the ERDDAA requirement to submit CAA regulatory proposals to SAB review serves as a check to ensure that the scientific basis underlying the rule is robust.

As discussed above, however, EPA failed to submit the rule to its SAB, and additionally did not prepare a regulatory impacts analysis of the Proposal as required by Executive Order 12,866. Nor did the Administrator provide sufficient time for a meaningful OMB Office of Information and Regulatory Affairs (OIRA) review, having signed the rule on April 24, 2018 after having submitted the Proposal to OIRA on April 19, 2018 – despite the requirement to provide OIRA with at least 10 working days to decide whether to waive review.[126]

Nor did the Agency comply with other Executive Orders requiring analyses of other potential aspects of rulemaking proposals, despite their relevance to this proposed action. For example, the Agency did not satisfy the requirements of Executive Order No. 13,045, "Protection of Children from Environmental Health Risks and Safety Risks," 62 Fed. Reg. 19,885 (Apr. 21, 1997), which requires federal agencies to "make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children," in proposing regulatory actions.[127] Instead, despite the fact that among the "dose response data and studies" the Agency is questioning are those analyzing the disproportionate health effects of air pollution on children's health,[128] and the fact that as Executive Order 13,045 itself notes, children "breathe more air in proportion to their body weight than adults,"[129] EPA simply states that the Proposal "does not concern an environmental health risk or safety risk."[130] Similarly, EPA dismisses Executive Orders 12,898 "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," and 13,175, "Consultation and Coordination with Indian Tribal Governments," with a

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(vacating final rule as "arbitrary and capricious" and in excess of statutory authority because it did not account for the "best available evidence.").

[126] Exec. Order No. 12,866 § 6(b)(2)(A) requires that the Agency give OIRA ten working days to determine whether to waive review; *id.* at § 8 forbids an Agency from publishing "or otherwise issu[ing] to the public," a Proposal until either OIRA waives review or completes it. In this instance, OIRA did not complete its review until one day *after* the Administrator signed the Proposal, which was published only six days later on April 30, 2018, seven working days after the rule was submitted to OIRA. *See also supra* note 30 (press account).

[127] Exec. Order No. 13,045 § 1(a).

[128] *See e.g.* Dockery, *et al.*, *Change in Pulmonary Function in Children Associated with Air Pollution Episodes*, 32 J. AIR POLLUTION CONTROL ASS'N. 937 (1982).

[129] Exec. Order No. 13,045 at §1 1-101 ("Policy").

[130] 83 Fed. Reg. at 18,773.

single sentence stating for each that they do not apply.[131] EPA's failure to subject the Proposal to these required analyses denies the public "transparency" – because information is withheld on which the affected public might base meaningful comments – as well as denying OMB the information it needs to complete its reviews.

EPA's Proposal claims to be "consistent with" Executive Order 13,777, which ordered a Regulatory Reform Task Force to identify regulations that "rely in whole or in part on data, information, or methods that are not publicly available or are insufficiently transparent to meet the standard for reproducibility," and 13,783, which required a focus on energy independence, but also the "achieve[ment of] environmental improvements for the American people."[132] But the Executive Order 13,777 Task Force report does not identify any regulations that rely on insufficiently transparent data,[133] nor is this Proposal - which would deny access to scientific studies - consistent with the goal of advancing environmental improvements for the American public.

V. Conclusion.

The Proposal claims that it "builds upon prior EPA actions."[134] But EPA utterly fails to appreciate "the concepts and lessons learned" from these prior actions, including that:

> While the Agency strives to increase access to its research results, … 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.*[135]

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[131] *Id.*

[132] *Id.* at 18,769, c(iting Exec. Orders Nos. 13,777, 82 Fed. Reg. (Mar. 1, 2017) & 13,783, 82 Fed Reg. 16,093 (Mar. 31, 2017)).

[133] EPA, *Final Report on Review of Agency Actions that Potentially Burden the Safe, Efficient Development of Domestic Energy Resources Under Executive Order 13,783*, (Oct. 25, 2017) ("noting that EPA has coordinated its review with other Administration initiatives, such as … E.O. 13,777").

[134] 83 Fed. Reg. at 18,770.

[135] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research*, at 4-5 (Nov. 29, 2016) (emphasis added). "EPA will require research data underlying a publication are posted to publicly accessible data repositories … unless: … 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." *Id.* at 11. *See also* EPA, *Open Government Plan 4.0*, at 5 (Sept. 2016) (promoting transparency while "ensur[ing] privacy and confidentiality are fully protected"); EPA, Open Data Policy Implementation Plan, at 4 (Feb. 2015) ("Exceptions to publicizing data may result from law, regulation or policy, which address privacy, confidentiality, security or other valid restrictions.").

There are multiple ways by which scientific results and data can be questioned and validated, such that the current Proposal is not necessary. Furthermore, because the Agency has a long history of facilitating the free flow of scientific information and promoting access, while consistently recognizing its obligation to protect confidential information, a new policy qualifying the availability of scientific results based on the public dissemination of such information, is not only unnecessary but impractical.

In the name of "transparency," and for no other articulated reason, then, EPA has issued a Proposal that would enable the Agency to ignore important scientific studies, and thereby gut public health and environmental protections. The Agency has done this without considering the consequences of its proposed action on public health or a cleaner environment for Americans, issues squarely within its duty to promote, and without even analyzing the costs of its proposal on the economy, despite its statements that this is a priority the Proposal is aimed at addressing.

"'Science, and public trust in science, thrives in an environment that shields scientific data and analyses from inappropriate political influence; political officials should not suppress or alter scientific or technological findings.'"[136] This Proposal, by contrast, represents exactly that – an attempt to suppress scientific findings for political reasons. We express our strongest opposition to the finalization of any aspect of EPA's Proposal.

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[136] Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs, OMB, "Memorandum for the Heads of Executive Departments and Agencies, and of Independent Regulatory Agencies, concerning Executive Order No. 13563 'Improving Regulation and Regulatory Review,'" at 4 (Feb. 2, 2011, (quoting John Holdren, Memorandum for the Heads of Agencies and Departments, "Scientific Integrity" (Dec. 17, 2010)), *available at:* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2011/m11-10.pdf.