



August 13, 2018

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US Environmental Protection Agency  
EPA Docket Center  
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Washington, DC 20460  
Attn: Docket ID # EPA-HQ-OAR-2018-0259

**RE: EPA-HQ-OAR-2018-0259, Strengthening Transparency in  
Regulatory Science**

To Whom It May Concern:

The National Tribal Air Association (NTAA) is pleased to submit these comments regarding the proposed rule to strengthen transparency in regulatory science.

The NTAA is a member-based organization with 135 principal member Tribes. The organization's mission is to advance air quality management policies and programs, consistent with the needs, interests, and unique legal status of Indian Tribes. As such, the NTAA uses its resources to support the efforts of all federally recognized Tribes in protecting and improving the air quality within their respective jurisdictions. Although the organization always seeks to represent consensus perspectives on any given issue, it is important to note that the views expressed by the NTAA may not be agreed upon by all Tribes. Further, it is also important that the State of Arizona understands interactions with the organization do not substitute for government-to-government consultation, which can only be achieved through direct communication between the federal government and Indian Tribes.

On April 30, 2018, the United States Environmental Protection Agency (EPA) published a notice in the Federal Register (FR) of a proposed rule that would drastically reduce the types of scientific studies that can be used to inform EPA regulations protecting public health under the guise of improving transparency. NTAA is troubled by this proposal, as we believe it would vastly undermine the mission of the EPA, which is to protect human health and the environment. It is curious that this proposal champions "transparency" when it seems certain to serve the opposite purpose. NTAA opposes this proposal for the following reasons:

1) This proposal states that "...EPA solicits comment on this proposal and how it can best be implemented in light of existing law and prior statements of policy that have called for increasing public access to data and influential scientific information used to inform federal regulation. EPA has not previously implemented these policies and guidance in a robust and consistent manner," but provides absolutely no evidence to support this statement. This appears to be a solution in search of a problem. EPA does not offer any evidence that its past decision-making has been



inadequate or arbitrary. EPA also does not explain how its proposed approach will ensure that it relies on the “best available science” which is an oft-repeated standard in various environmental laws. In fact, for the reasons discussed below, it is possible that EPA’s proposed regulation will actually result in a failure to rely on the “best available science” as EPA will arbitrarily disqualify important scientific studies if the underlying data cannot be disclosed to the public and/or cannot be independently validated.

2) The EPA itself seems to question whether it has the authority to promulgate this rule. The FR notice asks commenters to provide information on what areas of the CAA they feel may demonstrate this type of authority. The EPA should have a solid foundation before it proposes rules and should not have to seek answers for questions about its own authority.

3) The term "pivotal regulatory science" is used several times in the notice and appears to be the main focus for this rule. However, it is not defined in the FR notice and, indeed, does not appear anywhere else in the legal records, court decisions, or rules that address environmental protection or the role of the EPA. Therefore, it is impossible to determine exactly what the ramifications of this rule would be. Not only is EPA’s interpretation of this phraseology not clear, but its origins and basis in the law are also not identified. For instance, it is unclear whether the term "pivotal regulatory science" would apply to studies or modeling conducted by industry groups, meaning that the research performed by these groups could be held to be more reliable than research performed by reputable scientists around the world. With no grounding in the law, it is unclear what EPA is trying to achieve by designating certain research as “pivotal regulatory science.”

4) The proposal is strikingly similar to both the Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (H.R. 1430 – 115<sup>th</sup> Congress, 2017-2018) and the Secret Science Reform Act of 2014 (H.R. 4012 – 113<sup>th</sup> Congress, 2013-2014) and 2015 (H.R. 1030 – 114<sup>th</sup> Congress, 2015-2016), all of which repeatedly failed to pass in the Senate despite being supported by the energy, manufacturing, and chemical industries. All of these nearly interchangeable bills would have required all research data used in agency actions to be made available to the public. This is a problem from the viewpoint of participant confidentiality. Research linking air pollution to premature deaths often requires collecting decades' worth of information from members of the public, including dietary and physical activity habits, smoking status, home addresses, and detailed health information. Our nation's health privacy laws were enacted to address citizen's concerns about this type of information being made public or getting into the wrong hands. Some of this data is collected from children, whose information is particularly sensitive, but critically important to studying the impacts of pollution on public health. Individuals typically will only agree to participate if their health information is kept confidential. Studies such as the Harvard School of Public Health's Six Cities study (which has been in progress since 1993 and has contributed greatly to findings linking fine particulate matter and mortality rates) may have to go back and require participants (some of whom have since died) to sign forms allowing them to release private details, creating all sorts of delays, regulatory confusion, and places an unnecessary burden on researchers and participants. EPA also fails to mention that the data underlying this Harvard study has been shared with other research entities and has been replicated several times and validated by scientific peers. Thus, there is no rational basis to reopen this study and its origins.



Additionally, the proposed rule states "...EPA should ensure that the data underlying those (studies) are publicly available in a manner sufficient for independent validation." However, the proposal does not say by whom. Scientists who are familiar with these types of studies are also familiar with the protocols under which these studies are carried out and the studies are peer-reviewed, providing an independent, critical assessment of the studies. Scientists of this caliber understand the assumptions and limitations that have been made during the course of the study and can make judgments as to whether the studies are valid or not. EPA has not identified any deficiencies with the current, time-tested approach, and thus, EPA's desire for "independent validation" is misguided as it is unclear who EPA believes would be best suited to provide this validation and how they would execute this independent review. Lastly, it is telling that there have been attempts in Congress to enact legislation regarding the issue of data confidentiality as those legislative efforts demonstrate that the executive branch lacks the authority to undertake a rulemaking to address these issues.

5) While EPA states that the new rule would be applied prospectively, it notes that the rule could impact prior records for prior, older rules that are subject to recurring updates and reviews, such as the National Ambient Air Quality Standards. The new rule does not point to any basis in law or fact to question the validity and rationality of prior EPA rulemakings, such as National Ambient Air Quality Standards, and thus, it would be improper and contrary to the Administrative Procedures Act for EPA to reopen prior regulations for review based on the specious, unsupported claim that there were fundamental, substantive issues due to alleged lack of transparency in past scientific studies. Without specific evidence, particular findings, and robust legal analysis regarding individualized federal agency decisions, it is wholly unorthodox and legally suspect for EPA to issue a new regulation based on blanket assertions of a generalized, non-specific nature.

6) Both the proposed HONEST and Secret Science Reform Acts, along with this regulatory proposal, would likely prevent the EPA from using any studies that could not be independently reproduced. This requirement would disallow many extremely beneficial types of studies, such as those examining the results of natural disasters or industrial accidents. These studies look at health impacts on people exposed to high levels of smoke from wildfires or to high levels of chemicals resulting from industrial accidents or exposures. Such incidents could not be replicated from practical, safety, or ethical points of view, yet the information they provide regarding real time exposure and dose-response interactions is invaluable. Additionally, many studies performed using data from industrial sources would be excluded because they contain confidential business information, such as product formulations. Indeed, under federal law, there are criminal penalties for disclosing confidential business information – a serious risk of liability for EPA that the agency does not address except to say generically that all such laws will be followed, without demonstrating how compliance will be achieved in tandem with making research data publicly available.

This proposal calls for "replication" and "reproducibility" of studies, yet there are questions within the scientific community as to what these terms mean, and to what degree they are needed. From an opinion piece written by Dr. Bernard Goldstein (former dean of the University of Pittsburgh Graduate School of Public Health) and published in The Hill on April 20, 2017:



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Supporters cloak this requirement (*that the EPA cannot consider any scientific work unless raw data are available to anyone wishing to repeat the study*) in the seemingly innocuous argument that replication of research is a central tenet of science. But scientific replication is not attained by simply repeating the exact details of an experiment – that is from a grade school science class. Replication is best achieved when the findings of the initial study are supported by other studies approaching the same question in different ways.<sup>1</sup>

Thus, EPA is approaching the issue in an ill-informed and convoluted manner that will not yield more reliable results, and will yield to questionable agency decision making by removing reliance on certain scientific studies on a wholesale basis and based on misguided concerns. Replicating studies will also result in further, unnecessary delays in determining the scope of agency oversight, which may be viewed as a benefit from a deregulatory perspective, but undermines EPA’s mission of protecting Americans from threats to human health and the environment in a competent and timely fashion.

7) The proposed HONEST Act, the Secret Science Reform Act, and this proposed rule all directly contradict a 2002 ruling and a 2010 ruling from the D.C. Circuit Court of Appeals which stated “[w]e agree with EPA that requiring agencies to obtain and publicize the data underlying all studies on which they rely ‘would be impractical and unnecessary’”. *American Trucking Associations, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002) (citation omitted); *see also Coalition of Battery Recyclers Assoc. v. EPA*, 604 F.3d 613, 622-23 (D.C. Cir. 2010) (rejecting claim that EPA was arbitrary and capricious for not making public data from its studies).

8) Footnote 5 of the FR proposal cites to Executive Order (EO) No. 13783, 82 FR 16093 (Mar. 31, 2017) to support the appropriateness of the proposed rule. “It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics.” The use of this argument does not make sense because EO 13783 calls for transparency in the *process*, but does not address the issue of transparency in the publication of studies. EO 13783 simply calls for the use of the best available peer-reviewed information.

9) According to the FR notice, “EPA believes 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.” This statement is not supported by any information in the FR notice. Additionally, while solutions may exist, they are not inexpensive or timely. According to the Union of Concerned Scientists, [Administrator Pruitt Ignores EPA Staff Analysis of HONEST Act Costs](#), June 12, 2018:

*An Environmental Protection Agency (EPA) staff-level analysis found that complying with Congress’s proposed “HONEST Act” would cost the agency more than \$250 million per year; however, this analysis was ignored by Administrator Pruitt’s office. “EPA*

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<sup>1</sup> Goldstein, Bernard. Opinion Contributor. “The HONEST Act is actually dishonest and will hurt the EPA” *The Hill*. April 20, 2017. Washington, DC.



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*estimated that it would cost \$10,000-\$30,000 per study” to comply with the HONEST Act, the internal staff analysis stated, “but some studies may cost closer to \$1 million.” This analysis was sent to Administrator Pruitt’s office to be sent on to the Congressional Budget Office (CBO), but was never sent to the CBO.<sup>2</sup>*

It is hard to imagine that these extra costs could be borne in an era where EPA funding has been cut, or at best has remained stagnant. This same study predicted that this policy would reduce by half the number of studies the EPA would rely upon in developing policies and regulations because of the cost of complying with its requirements. The FR does not address any of these issues.

10) While the language of the proposed HONEST Act would have allowed personal data to be redacted, it would also allow that data to be unredacted by the EPA Administrator. However, no information is given about how the Administrator would reach this kind of decision. Therefore, participants from academia, industry, and members of the public would likely be hesitant to participate in studies, not knowing if or when confidential information could be released.

11) The Administrator would also have the power to grant exemptions to studies that do not make information public on a case-by-case basis, even though the draft does not outline any bases for how these decisions would be made except when it is impractical to comply. This would allow the Administrator to selectively exempt industry studies from the restrictions of this proposal at will, and thus, could allow industry to be held to a different standard than academics or regulatory agencies. The potential for abuse of this exemption authority is high and unbounded in the current proposal.

12) State environmental agencies rely on the EPA to provide accurate scientific information. This proposal would slow the EPA’s work to a near standstill or leave it open to criticism in terms of credibility, leaving states with data gaps that they cannot fill. EPA’s leadership in this area provides consistency for state agencies across the country, as well as regulatory certainty for industry and peace of mind for citizens. Likewise, tribal governments also rely on EPA for its technical expertise under a myriad of environmental statutes. Delays and lack of data due to convoluted, ill-defined requirements to achieve “independent validation” will cause harm to tribal governments who need quick, reliable information to address their environmental protection needs.

13) As stated at the outset, there is no indication and no specifics regarding alleged deficiencies in research data relied upon by EPA. Indeed, EPA seeks to apply this new regulation across the board, with no grounding in law or fact as to where and how specific studies have caused regulatory overreach to the public’s detriment. Without a reasonable basis to adopt this broad, sweeping, ill-defined regulation, EPA will likely face multiple lawsuits seeking to strike down this new regulation, distracting the EPA from its true, important mission.

In summary, the NTAA is pleased to provide the aforementioned comments regarding the proposed rule to strengthen transparency in regulatory science. If you have any questions or

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<sup>2</sup> Union of Concerned Scientists. “Administrator Pruitt Ignores EPA Staff Analysis of HONEST Act Crisis.” Last Revised Date March 20 2018.



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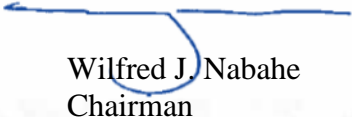
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require clarification from NTAA, please do not hesitate to contact NTAA's Project Director Andy Bessler at 928-523-0526 or [andy.bessler@nau.edu](mailto:andy.bessler@nau.edu).

On Behalf of the National Tribal Air Association's  
Executive Committee,



Wilfred J. Nabahe  
Chairman  
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