

# Congress of the United States

## House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371

[www.science.house.gov](http://www.science.house.gov)

May 24, 2018

The Honorable Scott Pruitt  
Administrator  
Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, D.C., 20460

Re: Comment for proposed rulemaking, “Strengthening Transparency in Regulatory Science.” Docket ID No. EPA-HQ-OA-2018-0259.

Dear Administrator Pruitt,

I wish to comment on the proposed rulemaking entitled, “Strengthening Transparency in Regulatory Science.”<sup>1</sup> As the Ranking Member of the House Committee on Science, Space, and Technology, the issue of scientific integrity is extremely important to me. For the reasons I will outline below, I believe that the proposed rulemaking jeopardizes the integrity of the science that the Environmental Protection Agency (EPA) relies upon, and will consequently endanger the health of Americans that the EPA is sworn to protect.

The EPA’s proposed rulemaking provides:

“that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.”

This rulemaking bears a remarkable similarity to highly partisan legislation that the Chairman of the Committee on Science, Space, and Technology has attempted to enact for the past three Congresses.<sup>2</sup> In each of the past three Congresses, this legislation has failed to be enacted into law. Committee Chairman Lamar Smith was present and

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<sup>1</sup> Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768 (2018) (to be codified at 40 C.F.R. 30) (proposed April 30, 2018).

<sup>2</sup> H.R. 4012, 113<sup>th</sup> Cong. (2014); H.R. 1030, 114<sup>th</sup> Cong. (2015); and, H.R. 1430, 115<sup>th</sup> Cong. (2017).

standing next to you when you signed the proposed rulemaking on April 24. During the signing ceremony for this proposed rulemaking you acknowledged that the proposed rulemaking was a “culmination of the work” of Chairman Smith’s efforts.<sup>3</sup> Further illustrating the notion that this rulemaking is a direct substitute for Chairman Smith’s failed legislative efforts is the Chairman’s press statement from April 24, when he stated:

“Earlier in this Congress, the House passed the HONEST Act with bipartisan support. The legislation requires that scientific information relied upon by EPA for regulations be publicly available for independent analysis. Administrator Pruitt’s actions enable us to put the principles of this bill into practice.”<sup>4</sup>

Article I of the Constitution vests the power to legislate solely in the hands of the U.S. Congress.<sup>5</sup> Despite the repeated efforts of Chairman Lamar Smith, Congress has never enacted a “Secret Science” bill into law. I believe your efforts to administratively implement the provisions of Chairman Smith’s failed “Secret Science” bills oversteps your authority under the U.S. Constitution. For that reason, I urge you to withdraw the proposed rulemaking.

I would also like to note some substantive concerns with the proposed rulemaking. Fundamentally, this rulemaking effort rests on the false notion that EPA rulemaking is being based on “secret science.” As you noted in your proposed rulemaking, EPA must use the best available science as the foundation of its regulatory actions. However, oftentimes the best available science (or the only available science) may include data of a sensitive nature like personal health information or Confidential Business Information. Your proposed rulemaking would restrict the use of studies relying upon this type of information unless that data could be made available. Thus, the perverse result of this proposed rulemaking could be that EPA precludes itself from using the best available science in its regulatory actions.

Below I have commented on some specific questions posited in the proposed regulatory action.

**1. EPA solicits comment on the effects of this proposed rule on individual EPA programs, including whether certain activities are appropriate to be excepted or if other requirements would affect implementation.**

If this rule is implemented as currently written, many relevant studies that rely on personal health information or Confidential Business Information, may be excluded from the Agency’s decision-making process. This would reduce the total number of studies that utilize the best available science being used in the EPA’s regulatory process.

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<sup>3</sup> Statement by Administrator Scott Pruitt (April 24, 2018), found at: <https://www.youtube.com/watch?v=OM7p7SCifn8&feature=youtu.be>

<sup>4</sup> “Smith Remarks on Administrator Pruitt’s Scientific Transparency Announcement,” Press Release by Chairman Lamar Smith, Committee on Science, Space, and Technology (April 24, 2018), found at: <https://science.house.gov/news/press-releases/smith-remarks-administrator-pruitt-s-scientific-transparency-announcement>

<sup>5</sup> United States Const. art. I § 1.

Restricting the number and type of scientific studies used would lower the overall quality of regulatory review at the Agency, and would also impact the scientific integrity of the regulatory work conducted by the Agency. A non-comprehensive list of EPA programs that may be negatively impacted by the proposed rule include: the Integrated Risk Information System (IRIS); the Integrated Science Assessment (ISA) for the National Ambient Air Quality Standards (NAAQS); Provisional Peer Reviewed Toxicity Values (PPRTV); the Toxic Substances Control Act (TSCA); pesticide reviews under Federal Insecticide Fungicide Rodenticide Act (FIFRA); other chemical review programs; and programs under the jurisdiction of the Safe Drinking Water Act (SDWA) and Clean Water Act (CWA).

**2. EPA also seeks comments on which criteria the Agency should use to base any exceptions, including whether case-by-case exceptions may be appropriate.**

Exceptions to the proposed rule should include studies that were previously conducted or already underway prior to the implementation of this regulation as the protocols of these studies were set before the rule was finalized. Studies that were conducted and utilized by the Agency to make regulatory decisions prior to the implementation of this rule should be exempted as these studies had met the requirements previously set for inclusion in regulatory decision-making at the time, and the protocols used in these studies were already determined before the rule was finalized.

Case-by-case exceptions shrouded in secrecy are not appropriate and violate the nominal title of this proposed rule. If case-by-case exceptions are sought, every step in the process of determining the exception should be made publically available from the initial request, to the decision-making steps taken by the Administrator, in addition to the final decision.

**3. EPA solicits comments on how it can build upon other federal agencies' policies regarding grantee and cooperator requirements for data access and data sharing.**

The National Science Foundation (NSF) has long required data sharing as a condition of funding. Investigators are expected to share with other researchers the primary data, samples, physical collections and other supporting materials created or gathered in the course of work under NSF grants. Since 2007, the National Institutes of Health has required public access to publications for all of its funded research after 12 months. NIH has also long promoted data sharing among researchers. Additionally, an interagency committee set up by Office of Science and Technology Policy to develop and coordinate federal policies for long term data stewardship and dissemination of federally funded research has seen at least 17 agencies phase in such data policies. I want to stress, however, that all of the Agency plans exempt data that is legally protected from disclosure.

**4. EPA also solicits suggestions for a platform that would enable the Agency to implement the provisions of this proposal related to increasing public access to EPA-funded data. EPA also seeks comment on methodologies and technologies designed to provide protected access to identifiable and sensitive data, such as**

**individual health data, and on commenters experience with the use of such methodologies and technologies and their strengths and limitations.**

If this rule is to be implemented as written, it is likely that fewer scientists or research institutions will want to participate in EPA funded research if they are concerned that the personal health information they collect may have to be publicly disclosed. Scientists and researchers may also find it difficult to recruit participants for long-term, large-scale studies that are needed to understand air and water quality issues if the participants are concerned that their medical records may be made publically available. With a reduced number of EPA-funded research studies conducted, a platform to increase access to the data collected is likely to be irrelevant. The methodology and technology used to provide access to the underlying data would also be irrelevant if the overarching policy precludes the use of certain data sets that would provide the most comprehensive information.

**5. Similarly, EPA seeks comment on how to balance appropriate protection for copyrighted or confidential business information, including where protected by law, with requirements for increased transparency of pivotal regulatory science.**

The structure of this solicitation does not seek comments on how to balance patient privacy or confidentiality with requirements for increased transparency, which is also protected by federal law. This omission makes it seem that protections for Confidential Business Information are being given higher priority by the EPA over protections for personal health information. Prioritizing the confidentiality of private entities could lead to the publication or release of data that is supported by industry and could bias the usable body of evidence for the EPA towards a particular industry position.

**6. For regulatory programs, like the National Ambient Air Quality Standards program, in which future significant regulatory actions may be based on the administrative record from previous reviews—particularly where the governing statute requires repeated review on a fixed, date-certain cycle—EPA seeks comment on the manner in which this proposed rule should apply to that previous record. EPA also solicits comments on whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date. In addition, EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available.**

This proposed rule should not retroactively apply to previously set standards and regulations, such as the National Ambient Air Quality Standards (NAAQS). Retroactive application of this proposed rule would open up a tremendously convoluted process that could undermine existing public health protections and set the Agency up for years of legal challenges. It would also cause needless delays in the already beleaguered NAAQS review process. Retroactive or prospective application of this proposed rule would ultimately bias the timeliness and quality of the scientific information available by

introducing procedural hurdles to the Agency's review process and only allowing studies that support industry positions, which could bias the EPA towards that position. As previously stated, data, studies and research that were initiated or conducted prior to the final date of this proposed rule should be excepted from this proposed rule as the protocols were already set before the rule was finalized. Similarly, regulatory actions that are based on administrative record from previous reviews should be excepted from the proposed rule to prevent introducing needless procedural hurdles into the EPA's regulatory review process.

**7. EPA also seeks comment on any additional implementation challenges not discussed in this notice that commenters may be aware of as well as suggestions for addressing them.**

Reproducibility is not free, and the amount of time and resources spent trying to recreate a study identically expends time and resources that might otherwise be used to conduct new or novel research. One of the most prominent examples of reproducing a study with limited benefit was the Health Effects Institute (HEI) reanalysis of the Harvard Six Cities Study and the American Cancer Society Study.<sup>6</sup> This reanalysis was conducted at significant cost and proved to be of limited utility as the conclusions of the reanalysis matched with those of the original studies.<sup>7</sup> The monies used for the reanalysis could have been better spent in conducting new air pollution studies to see if the results of the Harvard and American Cancer Society studies could be reproduced. The independent reproduction of results is a far more scientifically useful effort than the replication of existing research studies, and a better use of agency resources.

This proposed rule underplays the total administrative burden that the Agency would face when implementing this proposed rule as written. Requiring all raw underlying data be made available, and having the Agency conduct an "independent peer review on all pivotal regulatory science used to justify regulatory decisions" is time consuming and would likely hamstring the Agency if additional resources and staff are not provided for this express purpose. This proposed rule has many similarities to the HONEST Act of 2017, an update on the previously introduced "Secret Science" bills I noted above.<sup>8</sup> That legislation was estimated by EPA staff to cost the Agency an additional \$250 million per year to implement.<sup>9</sup> In this proposed rule, EPA has written that it "believes the benefits of this proposed rule justify the costs," however no estimation of either the potential costs or benefits has been provided. In addition to the cost and manpower required to undertake this task, the amount of data that would be generated to conduct these independent peer reviews would need to be stored somewhere which would require the use of large servers. There would also need to be management of, and controlled access to, the data to ensure

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<sup>6</sup> Krewski D, Burnett R, Goldberg MS, Hoover K, Siemiatycki J, Jerrett M, et al. Reanalysis of the Harvard Six Cities study and the American Cancer Society study of particulate air pollution and mortality. *Health Eff Inst Special Rep* 2000; July doi: 10.1080/15287390306424.

<sup>7</sup> *Id.*

<sup>8</sup> H.R. 1430, 115th Cong. (2017).

<sup>9</sup> Dabbs, Brian, *EPA Leaders Trashed Staff Comments Critical of Data Overhaul Bill: Officials*, Bloomberg BNA Environment & Energy Report, April 4, 2017, available at: <https://www.bna.com/epa-leaders-trashed-n57982086175/>

that confidentiality requirements are met. It is also important to note that public availability does not necessarily equate to or reflect the quality of a study.

In addition to these implementation challenges, the instance of scientific studies of unique and unreproducible events is a cause for concern. Studies of unique events such as the 2010 Deepwater Horizon oil spill could be problematic under this proposed rule. These unique types of events are not reproducible in any meaningful way, but the science that is gained from studying these events is incredibly valuable to an agency like the EPA. It is unclear from the proposed rulemaking if the proposal would lead to the disuse of these types of scientific studies in EPA rulemaking or even the reduction in EPA efforts to study these events. Either result would be detrimental to the EPA's efforts to use the best available science in its mission to protect public health.

8. **The proposed rule includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science are publicly available in a fashion that is consistent with law, protects privacy and confidentiality, and is sensitive to national and homeland security, or in instances where OMB's Information Quality Bulletin for Peer Review provides for an exemption (Section IX). The agency requests comment on whether these exemptions are appropriate, and on whether there are other situations in which specific significant regulatory actions, or specific categories of significant regulatory actions should be exempted.**

Having different standards for different sets of data, such as Confidential Business Information (CBI) compared to personal health information, is not transparent and instead favors entities that the EPA is responsible for regulating. The EPA is introducing bias into their independent peer review by essentially building in a loophole in the proposed rule for industry to not have to disclose internal studies that have not been peer-reviewed by claiming them as CBI, but requiring all the raw data in studies that include personal health information to be made publicly available. There should be no large-scale exemption of certain types of studies, information, or data. If a case-by-case exemption is sought, it should be made in a transparent fashion with the request, along with the reasoning behind the Administrator's final determination, made publically available.

OMB Circular A-110 limits the kind of data produced under a federally funded award that is required to be made public, in order to strike a balance between preserving the integrity of the research process and the need for public access to data. This is accomplished by permitting such access through the procedures established under FOIA, and including appropriate exemptions such as "personnel, medical, or similar files whose release would constitute an unwarranted invasion of privacy." Much of the data from the previously cited air pollution studies would fall under this exemption. This proposed rule could potentially contradict these protections by requiring sensitive data that would have previously been exempted to be made "publically available in a manner sufficient for independent validation." This requirement stipulated in the proposed rule is particularly

concerning as “publically available” is further defined as “information necessary for the public to understand, assess, and replicate findings.”

For the past five years, I have strongly opposed the efforts of Chairman Lamar Smith to enact the “Secret Science Act,” and I equally oppose the EPA’s current efforts to administratively enact rules which the Chairman failed to legislatively enact.

Finally, I’d like to note that your own handpicked Science Advisory Board (SAB) recently sent a memo expressing their concern over the proposed rulemaking.<sup>10</sup> In the memo, your Science Advisory Board recommends that:

“This action merits further review by the SAB. The proposed rule deals with issues of scientific practice and proposes constraints that the agency may apply to the use of scientific studies in particular contexts. As such, this rule deals with a myriad of scientific issues for which the Agency should seek expert advice from the Science Advisory Board.”<sup>11</sup>

It seems to reason that when you propose a rule which directly affects how the EPA uses science, you’d want to consult with scientists. I hope that you heed their advice and consult, not just with your SAB, but with the many scientific organizations and societies which have previously expressed concerns about the “Secret Science Act.” In the meantime, I strongly urge you to withdraw this proposed rulemaking.

Thank you for your attention to this matter.

Sincerely,



EDDIE BERNICE JOHNSON

Ranking Member

Committee on Science, Space, and Technology

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<sup>10</sup> Memorandum re: Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14) (May 12, 2018).

<sup>11</sup> *Id* at 2.