

**COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY  
U.S. HOUSE OF REPRESENTATIVES**

**HEARING CHARTER**

***Strengthening Transparency or Silencing Science?  
The Future of Science in EPA Rulemaking***

Wednesday, November 13, 2019

10:00 a.m.

2318 Rayburn House Office Building

**PURPOSE**

The purpose of the hearing is to assess the Environmental Protection Agency's (EPA) proposed rule entitled "Strengthening Transparency in Regulatory Science." The Committee will discuss the substance of the rule and the process by which it has been crafted. The Committee will also examine the consequences for EPA and the scientific community if the rule is implemented.

**WITNESSES**

**Panel 1:**

- **Dr. Jennifer Orme-Zavaleta (ORM Zah-vah-let-ah)**, Principal Deputy Assistant Administrator for Science, EPA Office of Research and Development (ORD); EPA Science Advisor

**Panel 2:**

- **Dr. Linda S. Birnbaum (BURN-baum)**, Scientist Emeritus, National Institute of Environmental Health Sciences (NIEHS); Director of NIEHS, 2009-2019
- **Dr. Mary B. Rice**, Assistant Professor of Medicine, Harvard Medical School; Pulmonary and Critical Care Physician, Beth Israel Deaconess Medical Center
- **Dr. David Allison**, Dean, School of Public Health, Indiana University-Bloomington; Member, "Reproducibility and Replicability in Science" Committee, The National Academies of Sciences, Engineering and Medicine
- **Dr. Brian Nosek (NO-sek)**, Co-Founder and Executive Director, Center for Open Science
- **Dr. Todd Sherer (SHE-rur)**, CEO, The Michael J. Fox Foundation for Parkinson's Research

**OVERARCHING QUESTIONS**

- How was EPA's original "Strengthening Transparency" proposed rule developed? What stakeholders, both internal and external to the agency, were engaged in the drafting of the proposed rule prior to publication in the federal register?

- What is the current status of the rule?
- What kind of an impact will the rule have on EPA’s ability to regulate environmental and public health dangers?
- How will the rule influence the conduct of environmental and public health research?
- What are the views of key stakeholders towards the rule?
- Is the rule consistent with EPA’s mandate to consider the best available science in its policymaking process?

## **Legislative Precursors to the “Strengthening Transparency” Rule**

While the “Strengthening Transparency” rule is the first iteration of this idea in EPA rulemaking, its principles stem from the *Secret Science Reform Act of 2014*,<sup>1</sup> introduced in the 113<sup>th</sup> Congress by Science Committee member Rep. David Schweikert. The bill arose after years of former Chairman Lamar Smith’s arguments that the EPA was using “secret science” to underpin air pollution regulations. Former Chairman Smith had issued numerous document requests, and finally a subpoena,<sup>2</sup> to EPA in order to obtain the raw data relating to the Harvard Six Cities Study and the American Cancer Society Study, foundational studies pertaining to air pollution and mortality. As EPA was not the custodian of the data, the Agency complied to the extent it was legally able. Former Chairman Smith was ultimately unable to obtain the raw data he sought, so he announced his intention to introduce legislation that “will stop the EPA from basing regulations on undisclosed and unverified information.”<sup>3</sup>

The *Secret Science Reform Act of 2014* failed to gain traction in the Senate, and it was reintroduced in February 2015 with additional text on what constitutes “scientific and technical information” and language forbidding EPA from spending more than \$1 million per fiscal year on carrying out the Act.<sup>4</sup> The Congressional Budget Office estimated that EPA would spend “\$250 million annually over the next few years” carrying out the provisions of the Act.<sup>5</sup> Facing a veto threat from the White House,<sup>6</sup> the legislation passed the House on largely party lines but did not receive a vote in the Senate.

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<sup>1</sup> “H.R. 4012 – Secret Science Reform Act of 2014,” Congress.gov, February 6, 2014, accessed here:

<https://www.congress.gov/bill/113th-congress/house-bill/4012>

<sup>2</sup> “Smith Subpoenas EPA’s Secret Science,” Committee on Science, Space, & Technology Republicans, August 1, 2013, accessed here: <https://republicans-science.house.gov/news/press-releases/smith-subpoenas-epa-s-secret-science>

<sup>3</sup> “Smith to Introduce Bill to Bar EPA from Basing Regulations on Secret Science,” Committee on Science, Space, & Technology Republicans, November 14, 2013, accessed here: <https://republicans-science.house.gov/news/press-releases/smith-introduce-bill-bar-epa-basing-regulations-secret-science>

<sup>4</sup> “H.R. 1030 – Secret Science Reform Act of 2015,” Congress.gov, February 24, 2015, accessed here:

<https://www.congress.gov/bill/114th-congress/house-bill/1030>

<sup>5</sup> “Congressional Budget Office Cost Estimate – H.R. 1030 Secret Science Reform Act of 2015,” Congressional Budget Office, March 11, 2015, accessed here: <https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf>

<sup>6</sup> Puneet Kollipara, “Update: White House issues veto threat as House prepares to vote on EPA’s ‘secret science’ bills,” *Science*, March 3, 2015, accessed here: <https://www.sciencemag.org/news/2015/03/update-white-house-issues-veto-threat-house-prepares-vote-epa-secret-science-bills>

In March 2017, former Chairman Smith introduced the *Honest and Open New EPA Science Treatment Act of 2017*, or the HONEST Act.<sup>7</sup> The HONEST Act removed the stipulation that EPA must not spend over \$1 million annually on implementation, but it did not authorize any funding for the Agency to carry out the Act. Once again, the HONEST Act passed the House largely on party lines but did not advance out of Committee in the Senate.

### **Overview of the Proposed “Strengthening Transparency” Rule**

During the 115<sup>th</sup> Congress, supporters of the HONEST Act urged EPA to use the rulemaking process to write an Agency regulation that would achieve similar policy aims as the legislation. On January 9, 2018, former Chairman Smith met with then-EPA Administrator Scott Pruitt at EPA headquarters.<sup>8</sup> An EPA official in attendance informed colleagues that former Chairman Smith made a “pitch that EPA internally implement the HONEST Act (no regulation can go into effect unless the scientific data is publicly available for review).”<sup>9</sup>

EPA officials commenced the rulemaking process in an initial effort to complete an Agency rule by the end of February 2018.<sup>10</sup> Then-Administrator Pruitt disclosed publicly in March 2018 that EPA was working on the rule, which would “no longer allow the agency to use studies with nonpublic scientific data to develop rules on public health and pollution.”<sup>11</sup> On April 24, 2018, then-Administrator Pruitt signed the proposed rule, entitled “Strengthening Transparency in Regulatory Science.”<sup>12</sup> Former Chairman Smith offered positive comments on the proposed rule, stating that it would “ensure that data will be secret no more.”<sup>13</sup> EPA submitted the proposed rule to the Federal Register on April 30, 2018, with an initial 30-day public comment period.<sup>14</sup> EPA later extended the public comment period until August 16, 2018, and held a public hearing for the proposed rule on July 17, 2018.<sup>15</sup>

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<sup>7</sup> “H.R. 1430 – HONEST Act,” Congress.gov, March 8, 2017, accessed here: <https://www.congress.gov/bill/115th-congress/house-bill/1430>

<sup>8</sup> Juliet Eilperin and Brady Dennis, “Pruitt unveils controversial ‘transparency’ rule limiting what research EPA can use,” *Washington Post*, April 24, 2018, accessed here: <https://www.washingtonpost.com/news/energy-environment/wp/2018/04/24/pruitt-to-unveil-controversial-transparency-rule-limiting-what-research-epa-can-use/>.

<sup>9</sup> Scott Waldman and Niina Heikkinen, “Trump’s EPA wants to stamp out ‘secret science.’ Internal emails show it is harder than expected,” *E&E News*, April 20, 2018, accessed here: <https://www.sciencemag.org/news/2018/04/trump-s-epa-wants-stamp-out-secret-science-internal-emails-show-it-harder-expected>.

<sup>10</sup> *Id.*

<sup>11</sup> Valerie Volcovici, “EPA staff see hurdles in Pruitt science revamp, internal emails show,” *Reuters*, April 20, 2018, accessed here: <https://www.reuters.com/article/us-usa-epa-science/epa-staff-see-hurdles-in-pruitt-science-revamp-internal-emails-show-idUSKBN1HR366>.

<sup>12</sup> Environmental Protection Agency, “EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations,” April 24, 2018, accessed here: <https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations>.

<sup>13</sup> *Id.*

<sup>14</sup> Environmental Protection Agency, “Strengthening Transparency in Regulatory Science,” Published in the Federal Register on April 30, 2018, accessed here: <https://www.govinfo.gov/content/pkg/FR-2018-04-30/pdf/2018-09078.pdf>.

<sup>15</sup> Environmental Protection Agency, “Strengthening Transparency in Regulatory Science; Extension of Comment Period and Notice of Public Hearing,” May 22, 2018, accessed here: [https://www.epa.gov/sites/production/files/2018-05/documents/fri-9978-31-ord\\_science\\_transparency\\_frn\\_extension\\_and\\_hearing\\_prepublication.pdf](https://www.epa.gov/sites/production/files/2018-05/documents/fri-9978-31-ord_science_transparency_frn_extension_and_hearing_prepublication.pdf).

The EPA's proposed "Strengthening Transparency" rule was based upon the HONEST Act and pursued broadly similar objectives.<sup>16</sup> Under the rule, EPA could only consider a scientific study in crafting environmental and public health regulations if the data underlying the study was made publicly available. According to the proposed rule itself, all EPA regulations would be required to "ensure that the data underlying those [studies] are publicly available in a manner sufficient for independent validation" in order to "strengthen the transparency of EPA regulatory science."<sup>17</sup> The proposed rule asserted that the focus of the new policy was "the dose response data and models" that were critical for the Agency's "pivotal regulatory science," and that the policy would "increase transparency of the assumptions underlying dose response models."<sup>18</sup> The proposed rule noted that it was "intended to apply prospectively to final regulations."<sup>19</sup> Finally, the proposed rule solicited public comment on a wide range of issues, including the scope of the rule, the impact of the rule on EPA offices, how the Agency should determine exceptions to the rule, the definitions of key terms in the rule, and "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."<sup>20</sup> In a statement accompanying the proposed rule, then-Administrator Pruitt called the policy "vital for the integrity of rulemaking process."<sup>21</sup>

### **Reaction to the Proposed Rule**

EPA's proposed "Strengthening Transparency" rule elicited a passionate public response. The day before it was signed by then-Administrator Pruitt, a group of 985 scientists signed a public letter urging the EPA to abandon the policy.<sup>22</sup> In response to the proposed rule, EPA received around 600,000 public comments, an unusually large number.

According to the *Washington Post*, "leaders of the scientific community expressed outrage" at the proposed rule's potential impact.<sup>23</sup> For example:

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<sup>16</sup> Lisa Friedman, "The EPA Says It Wants Research Transparency. Scientists See an Attack on Science," *New York Times*, March 26, 2018, accessed here: <https://www.nytimes.com/2018/03/26/climate/epa-scientific-transparency-honest-act.html>.

<sup>17</sup> Environmental Protection Agency, "Strengthening Transparency in Regulatory Science," Published in the Federal Register on April 30, 2018, accessed here: <https://www.govinfo.gov/content/pkg/FR-2018-04-30/pdf/2018-09078.pdf>.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> Environmental Protection Agency, "EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations," April 24, 2018, accessed here: <https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations>.

<sup>22</sup> Juliet Eilperin and Brady Dennis, "Pruitt unveils controversial 'transparency' rule limiting what research EPA can use," *Washington Post*, April 24, 2018, accessed here: <https://www.washingtonpost.com/news/energy-environment/wp/2018/04/24/pruitt-to-unveil-controversial-transparency-rule-limiting-what-research-epa-can-use/>.

<sup>23</sup> Joel Achenbach, "Scientists denounce Pruitt's effort to block 'secret science' at EPA," *Washington Post*, April 25, 2018, accessed here: <https://www.washingtonpost.com/news/energy-environment/wp/2018/04/25/scientists-denounce-pruitts-effort-to-block-secret-science-at-epa/>.

- The President of the National Academy of Sciences voiced her concern that “the very foundations of clean air and clean water could be undermined” by the proposed rule.<sup>24</sup>
- The editors of five leading scientific journals, including *Science* and *Nature*, issued a joint statement noting that “it does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them.”<sup>25</sup>
- A group of 69 professional and public health organizations – including the American Lung Association, the American Heart Association and the American Medical Association – released a public statement expressing opposition to the proposed rule and urging EPA to withdraw it.<sup>26</sup>
- The coalitions representing the primary performers of federally-funded research, including the Association of American Medical Colleges and the Association of American Universities, wrote a letter to EPA asserting that the proposed rule “thwarts the promise of evidence-based policymaking” and contradicts EPA’s mandate to consider the best available science.<sup>27</sup>
- The Department of Defense submitted comments that urged EPA not to permit the policy to “impede the use of otherwise high-quality studies” for which it was unable to obtain underlying data.<sup>28</sup>

Other stakeholders supported the proposed rule, including the American Chemistry Council, which endorsed the policy’s stated aim of increasing “transparency and public confidence in the agency’s regulations.”<sup>29</sup>

At a public hearing held by EPA in July 2018, a “wide array of groups” registered their opposition to the policy, leading to “the majority of testimony heard from more than 100 stakeholders” raising concerns about the potential impact of the proposed rule.<sup>30</sup> A smaller group of stakeholders, including the American Petroleum Institute and the U.S. Chamber of Commerce, endorsed some or all of the proposed rule’s goals.<sup>31</sup> EPA pledged to consider the public

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<sup>24</sup> Juliet Eilperin and Brady Dennis, “Pruitt unveils controversial ‘transparency’ rule limiting what research EPA can use,” *Washington Post*, April 24, 2018, accessed here: <https://www.washingtonpost.com/news/energy-environment/wp/2018/04/24/pruitt-to-unveil-controversial-transparency-rule-limiting-what-research-epa-can-use/>.

<sup>25</sup> Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel and Deborah Sweet, “Joint statement on EPA proposed rule and public availability of data,” *Science*, May 4, 2018, accessed here: <https://science.sciencemag.org/content/360/6388/eaau0116>.

<sup>26</sup> Robinson Meyer, “Even Geologists Hate the EPA’s New Science Rule,” *The Atlantic*, July 17, 2018, accessed here: <https://www.theatlantic.com/science/archive/2018/07/scott-pruitts-secret-science-rule-could-still-become-law/565325/>.

<sup>27</sup> Andrew Kreighbaum, “The Wrong Kind of Transparency?” *Inside Higher Ed*, July 24, 2018, accessed here: <https://www.insidehighered.com/news/2018/07/24/researchers-say-proposed-epa-rule-would-throw-out-good-science>.

<sup>28</sup> Sean Reilly, “Pentagon fires a warning shot against EPA’s ‘secret science’ rule,” *E&E News*, August 28, 2018, accessed here: <https://www.sciencemag.org/news/2018/08/pentagon-fires-warning-shot-against-epa-s-secret-science-rule>.

<sup>29</sup> Juliet Eilperin and Brady Dennis, “Pruitt unveils controversial ‘transparency’ rule limiting what research EPA can use,” *Washington Post*, April 24, 2018, accessed here: <https://www.washingtonpost.com/news/energy-environment/wp/2018/04/24/pruitt-to-unveil-controversial-transparency-rule-limiting-what-research-epa-can-use/>.

<sup>30</sup> Chemical Watch, “Groups unite against US EPA ‘science transparency’ proposal,” accessed here: <https://chemicalwatch.com/68840/groups-unite-against-us-epa-science-transparency-proposal#overlay-strip>.

<sup>31</sup> *Id.*

comments and public reaction to the proposed rule, declaring that it was “committed to public participation and transparency in the rulemaking process.”<sup>32</sup>

### **Science Advisory Board and the Proposed Rule**

The EPA’s Science Advisory Board (SAB) provides independent advice to the Administrator on scientific and technical aspects of environmental issues. On June 28, 2018, the SAB wrote to then-Administrator Pruitt with a summary of its May meeting, where its members had discussed the “Strengthening Transparency” rule issued the month before and determined that the proposed rule would “benefit from expert advice and comment from the SAB.”<sup>33</sup> The SAB cited the Environmental Research, Development and Demonstration Authorization Act of 1978 (ERDDAA) requirement that the Agency provide relevant documents to the SAB for formal review and comment. It also outlined preliminary concerns about the proposed rule and noted the areas that would benefit from SAB advice.

Nearly a year later, Administrator Wheeler declined to accept the SAB’s request for a full review of the proposed rule. Instead, he asked the SAB to address a narrower set of questions relating to the treatment of personally identifying information (PII) and confidential business information (CBI).<sup>34</sup> The SAB agreed to answer these questions, but also voted to conduct a more thorough review of the rule.<sup>35</sup> EPA answered a selection of questions from SAB and declined to answer others in a July 25, 2019 document, obtained by E&E News.<sup>36</sup>

On September 30, 2019, SAB transmitted the results of its consultation on PII and CBI to EPA.<sup>37</sup> According to a status update sent to the Agency on September 25, SAB anticipates issuing its self-initiated review of the science supporting the proposed rule in the first quarter of 2020.<sup>38</sup>

### **Announcement of a Supplemental Proposed Rule**

The public comment period for the proposed “Strengthening Transparency” rule ended on August 16, 2018. As a result of the unusually large number of public comments that EPA was

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<sup>32</sup> Robinson Meyer, “Even Geologists Hate the EPA’s New Science Rule,” *The Atlantic*, July 17, 2018, accessed here: <https://www.theatlantic.com/science/archive/2018/07/scott-pruitts-secret-science-rule-could-still-become-law/565325/>.

<sup>33</sup> Letter from the EPA Science Advisory Board to Administrator Pruitt, June 28, 2018, accessed here: [https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/4ECB44CA28936083852582BB004ADE54/\\$File/EPA-SAB-18-003+Unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf).

<sup>34</sup> Rebecca Beitsch, “Battle over science roils EPA,” *The Hill*, June 9, 2019, accessed here: <https://thehill.com/policy/energy-environment/447520-battle-over-science-roils-epa>.

<sup>35</sup> Jonathan Behrens, “EPA Advancing Transparency Rule as Science Board Pushes Back,” *American Institute of Physics*, July 2, 2019, accessed here: <https://www.aip.org/fyi/2019/epa-advancing-transparency-rule-science-board-pushes-back>

<sup>36</sup> “EPA Responses to SAB Questions Concerning the Proposed Rule *Strengthening Transparency in Regulatory Science*,” July 25, 2019, accessed here: [https://www.eenews.net/assets/2019/08/28/document\\_gw\\_03.pdf](https://www.eenews.net/assets/2019/08/28/document_gw_03.pdf)

<sup>37</sup> Letter from the EPA Science Advisory Board to Administrator Wheeler, September 30, 2019, accessed here: [https://yosemite.epa.gov/sab%5Csabproduct.nsf/41042C652229CA398525848500595458/\\$File/EPA-SAB-19-005.pdf](https://yosemite.epa.gov/sab%5Csabproduct.nsf/41042C652229CA398525848500595458/$File/EPA-SAB-19-005.pdf)

<sup>38</sup> Letter from the EPA Science Advisory Board to Administrator Wheeler, September 25, 2019, accessed here: [https://yosemite.epa.gov/sab%5Csabproduct.nsf/B3635EA455B6DD978525848000535980/\\$File/EPA-SAB-19-004.pdf](https://yosemite.epa.gov/sab%5Csabproduct.nsf/B3635EA455B6DD978525848000535980/$File/EPA-SAB-19-004.pdf)



required to review, the Agency designated the rule as a “long-term action” on the Trump Administration’s regulatory agenda in October 2018.<sup>39</sup> This designation suggested that EPA did not expect to finalize the rule over the next twelve months, shifting the timeline for a final rule to the end of 2019 at the earliest.<sup>40</sup> However, at the same time, Administrator Wheeler denied that EPA was making the proposed rule a lower priority and stated that the Agency intended to finalize the rule in 2019.<sup>41</sup>

On September 19, 2019, Administrator Wheeler testified at a hearing of the House Committee on Science, Space, and Technology.<sup>42</sup> In his prepared testimony, he affirmed that EPA was moving forward with the “Strengthening Transparency” rule. He also announced that EPA intended to issue a “supplemental proposed rule in 2020.”<sup>43</sup> Later in the hearing, Administrator Wheeler elaborated on the timeline of the supplemental proposed rule, stating it would be published “early next year.”<sup>44</sup>

As a general principle, a federal agency may opt to issue a supplemental proposed rule when the public comment period has raised matters that require significant changes to the original proposed rule.<sup>45</sup> A supplemental proposed rule is followed by another public comment period before the rule can be finalized. During his testimony, Administrator Wheeler pledged that the supplemental “Strengthening Transparency” rule would be submitted for public comment before EPA attempted to finalize it.<sup>46</sup>

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<sup>39</sup> Timothy Cama, “EPA puts science ‘transparency’ rule on back burner,” *The Hill*, October 17, 2018, accessed here: <https://thehill.com/policy/energy-environment/411839-epa-puts-science-transparency-rule-on-back-burner>.

<sup>40</sup> Stephanie Ebbs and Anne Flaherty, “EPA fight against ‘secret science’ slowed amid pushback from researchers,” *ABC News*, October 17, 2018, accessed here: <https://abcnews.go.com/Politics/epa-slows-fight-secret-science-amid-pushback-researchers/story?id=58564686>.

<sup>41</sup> Timothy Cama, “EPA to pursue final ‘science transparency’ rule in 2019,” *The Hill*, December 14, 2018, accessed here: <https://thehill.com/policy/energy-environment/421479-epa-to-pursue-final-science-transparency-rule-in-2019>.

<sup>42</sup> House Committee on Science, Space, and Technology, “Science and Technology at the Environmental Protection Agency,” September 19, 2019, accessed here: <https://science.house.gov/hearings/science-and-technology-at-the-environmental-protection-agency>.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> Office of the Federal Register, “A Guide to the Rulemaking Process,” January 2011, accessed here: [https://www.federalregister.gov/uploads/2011/01/the\\_rulemaking\\_process.pdf](https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf).

<sup>46</sup> House Committee on Science, Space, and Technology, “Science and Technology at the Environmental Protection Agency,” September 19, 2019, accessed here: <https://science.house.gov/hearings/science-and-technology-at-the-environmental-protection-agency>.