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STRENGTHENING TRANSPARENCY OR SILENCING SCIENCE? THE FUTURE OF SCIENCE IN EPA RULEMAKING

HEARING

BEFORE THE

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

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STRENGTHENING TRANSPARENCY OR SILENCING SCIENCE? THE FUTURE OF SCIENCE IN EPA RULEMAKING

WEDNESDAY, NOVEMBER 13, 2019

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Committee met, pursuant to notice, at 10:02 a.m., in room 2318 of the Rayburn House Office Building, Hon. Eddie Bernice Johnson [Chairwoman of the Committee] presiding.

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*,[1] introduced in the 113th 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,[2] 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."[3]

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.[4] The Congressional Budget Office estimated that EPA would spend "$250 million annually over the next few years" carrying out the provisions of the Act. [5] Facing a veto threat from the White House,[6] the legislation passed the House on largely party lines but did not receive a vote in the Senate.

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[1] "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

[2] "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

[3] "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

[4] "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

[5] "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

[6] 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.[7] 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 115th 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.[8] 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)."[9]

EPA officials commenced the rulemaking process in an initial effort to complete an Agency rule by the end of February 2018.[10] 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."[11] On April 24, 2018, then-Administrator Pruitt signed the proposed rule, entitled "Strengthening Transparency in Regulatory Science."[12] Former Chairman Smith offered positive comments on the proposed rule, stating that it would "ensure that data will be secret no more."[13] EPA submitted the proposed rule to the Federal Register on April 30, 2018, with an initial 30-day public comment period.[14] EPA later extended the public comment period until August 16, 2018, and held a public hearing for the proposed rule on July 17, 2018.[15]

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[7] "H.R. 1430 – HONEST Act," Congress.gov, March 8, 2017, accessed here: https://www.congress.gov/bill/115th-congress/house-bill/1430

[8] 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/.

[9] 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.

[10] *Id.*

[11] 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.

[12] 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.

[13] *Id.*

[14] 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.

[15] 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/frl-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.[16] 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."[17] 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."[18] The proposed rule noted that it was "intended to apply prospectively to final regulations."[19] 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."[20] In a statement accompanying the proposed rule, then-Administrator Pruitt called the policy "vital for the integrity of rulemaking process."[21]

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.[22] 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.[23] For example:

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[16] 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.

[17] 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.

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] 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.

[22] 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/.

[23] 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.[24]
- 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."[25]
- 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.[26]
- 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.[27]
- 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.[28]

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."[29]

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.[30] 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.[31] EPA pledged to consider the public

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[24] 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/.

[25] 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.

[26] 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/.

[27] 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.

[28] 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.

[29] 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/.

[30] 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.

[31] *Id.*

comments and public reaction to the proposed rule, declaring that it was "committed to public participation and transparency in the rulemaking process."[32]

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."[33] 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).[34] The SAB agreed to answer these questions, but also voted to conduct a more thorough review of the rule.[35] EPA answered a selection of questions from SAB and declined to answer others in a July 25, 2019 document, obtained by E&E News.[36]

On September 30, 2019, SAB transmitted the results of its consultation on PII and CBI to EPA.[37] 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.[38]

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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[32] 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/.

[33] 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.

[34] 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.

[35] 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

[36] "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

[37] 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

[38] 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

required to review, the Agency designated the rule as a "long-term action" on the Trump Administration's regulatory agenda in October 2018.[39] 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.[40] 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.[41]

On September 19, 2019, Administrator Wheeler testified at a hearing of the House Committee on Science, Space, and Technology.[42] 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."[43] Later in the hearing, Administrator Wheeler elaborated on the timeline of the supplemental proposed rule, stating it would be published "early next year."[44]

As a general principle, a federal agency may opt to issue a supplemental proposed role when the public comment period has raised matters that require significant changes to the original proposed rule.[45] 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.[46]

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[39] 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.
[40] 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.
[41] 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.
[42] 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.
[43] *Id.*
[44] *Id.*
[45] 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.
[46] 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.

Chairwoman JOHNSON. The hearing will come to order. And without objection, the Chair is authorized to declare a recess at any time.

Good morning, and let me welcome our witnesses today, "Strengthening Transparency or Silencing Science? The Future of Science in EPA Rulemaking." We're here today to discuss a proposed rule that EPA (Environmental Protection Agency) released last year, entitled, "Strengthening Transparency in Regulatory Science."

This is not a new issue for this Committee. Between 2014 and 2017, we saw three markups of legislation mirroring the so-called transparency principles of the proposed rule. The *Secret Science Reform Act*, the *HONEST Act*, and now the "Strengthening Transparency in Regulatory Science" rule have all been met with the same passionate negative response from the scientific community. This rule makes dangerous, sweeping assertions about what does and does not count as good science.

With the public availability of data as the determining factor, EPA will eliminate many fundamental public health studies from consideration, effectively gutting health-protective regulations that keep our air and water clean.

I am attaching to my statement a letter from over 60 public health groups, including the Michael J. Fox Foundation and the Center for Open Science, both represented on our second panel, where they express serious concerns about this proposed rule's impact on public health.

No one in this room is against the principles of transparency in science or in our government. However, this rule warps the noble goal of transparency into a misleading, black-or-white test of the legitimacy of individual studies. I've said it many times in this very hearing room: The requirement for data to be publicly available is nothing more than an attempt to undercut EPA's mandate to use the best available science. I believe this is part of an effort to destroy regulations that protect public health but are opposed by some regulated industries.

The public comment period for this rule was remarkable. Around 600,000 comments were filed, the vast majority of which were highly critical. Commenters panned the harmful consequences of the rule for public health and the dubious legal justification for the rule. Because EPA neglected to offer definitions for some of the fundamental terms it describes, terms like "reproducible" and even "data," many comments wondered what parts of the rule even mean.

In his September appearance before this Committee, Administrator Wheeler announced that a supplementary rule would be issued in early 2020. I think today's hearing is critically important to the Committee Members, as well as our distinguished second panel of scientists that will express our concerns before the rule is finalized. I am very worried that EPA is ignoring its mission to protect human health and the environment in an effort to make it easier for regulated industry.

However, I am hopeful that the Agency takes to heart what our esteemed panel of scientists has to say about the rule as it works to finalize a supplemental proposal. Thank you.

[The prepared statement of Chairwoman Johnson follows:]

Good morning. I would like to welcome our witnesses to today's hearing -- "Strengthening Transparency or Silencing Science? The Future of Science in EPA Rulemaking."

We are here today to discuss a proposed rule that EPA released last year, entitled "Strengthening Transparency in Regulatory Science." This is not a new issue for this Committee. Between 2014 through 2017, we saw three markups of legislation mirroring the so-called "transparency" principles of the proposed rule. The Secret Science Reform Acts, the HONEST Act, and now the "Strengthening Transparency in Regulatory Science" rule have all been met with the same passionate negative response from the scientific community.

This rule makes dangerous, sweeping assertions about what does and does not count as good science. With the public availability of data as the determining factor, EPA will eliminate many foundational public health studies from consideration, effectively gutting health-protective regulations that keep our air and water clean. I am attaching to my statement a letter from over 60 public health groups - including the Michael J. Fox Foundation and the Center for Open Science, both represented on our second panel - where they express serious concerns about this proposed rule's impact on public health.

No one in this room is against the principle of transparency in science or in our government. However, this rule warps the noble goal of transparency into a misleading, black-or-white test of the legitimacy of individual studies. I've said it many times in this very hearing room: The requirement for data to be publicly available is nothing more than an attempt to undercut EPA's mandate to use the best available science. I believe this is part of an effort to destroy regulations that protect public health but are opposed by some regulated industries.

The public comment period for this rule was remarkable. Around 600,000 comments were filed, the vast majority of which were highly critical. Commenters panned the harmful consequences of the rule for public health and the dubious legal justification for the rule. Because EPA neglectedto offer definitions for some of the fundamental terms it describes - terms like "reproducible" and even "data" - many commenters wondered what parts of the rule even mean.

In his September appearance before this Committee, Administrator Wheeler announced that a supplemental rule would be issued in early 2020. I think today's hearing is critically important so that Committee Members, as well as our distinguished second panel of scientists, can express our concerns before the rule is finalized.

I am very worried that EPA is ignoring its mission to protect human health and the environment in an effort to make life easier for regulated industry. However, I am hopeful that the Agency takes to heart what our esteemed panel of scientists has to say about this rule as it works to finalize a supplemental proposal.Thank you.

Chairwoman JOHNSON. I now would recognize our Ranking Member, Mr. Lucas, for an opening statement.

Mr. LUCAS. Thank you, Madam Chairwoman, and thank you to our witnesses for being here today.

Transparency and reproducibility are an important part of ensuring the quality of the science that supports Federal regulations. By providing access to research data, scientists can replicate previous results to assure validity, relevance, and accuracy. We all want Federal agencies to rely on the best available science when making policy. I believe that we need a broader conversation on the best way for the Federal Government to conduct and to use transparent science that can be independently verified.

Unfortunately, this hearing is narrowly focused on one proposed rule from one agency. This is about attacking the EPA under the current Administration, not about improving transparency and scientific integrity. I believe this is a missed opportunity to have a more holistic, productive discussion on an important topic.

Ensuring that government research is transparent and can be independently verified is not a new goal. The Obama Administration issued memos on the need to promote public access to scientific

information and include the underlying data for policy decisions. So in 2018, the EPA issued "Strengthening Transparency in Regulatory Science," a rule that would prioritize those efforts.

I think this is a laudable goal. After all, if taxpayers are expected to follow costly regulations, they should be able to trust that they stem from the best available science that can be independently verified. If Federal agencies are relying on data that can't be used for future research, it's impossible to know if the initial results were obtained by accurate science or simply by chance.

I believe the EPA's proposed rule is well-intended, but there's still work to be done. That's why I was pleased to hear Administrator Wheeler confirm that the Agency is currently working on a supplemental rule for this topic. And while today's hearing will focus on the proposed rule, which was issued by the previous EPA administrator, we already know this won't be the final proposal from the Agency. So why are we holding a hearing on the original proposed rule that will be irrelevant in just a month or so?

What's worse, Dr. Jennifer Orme-Zavaleta, and from now on, Doc, I'll refer to you as "Dr." if you don't mind, who joins us from the EPA today, will be unable to comment on the development of the proposed rule, as she did not serve in the relevant office at the time it was issued. And because the supplemental rule is currently in the drafting process, the Doctor is also unable to comment on its specific requirements or details. It is my understanding that, once it's released, the supplemental rule will receive its own comment period and then move through the regular implementation process.

I can't help but think this hearing would be more productive if we had waited for the supplemental rule to be published and then provided our comments and direction on the most current proposal.

In closing, I'd like to emphasize that I think we could have a much more productive hearing if we had a broader discussion about the best way to improve reproducibility and transparency. I also want to say that if we can't improve the transparency of underlying data, then Congress should do our job and authorize the funding necessary to update and replicate vital research in a more transparent manner.

I'm hopeful that our second panel today can address the broader issues of transparency in science. I'm particularly interested in the testimony from Dr. David Allison on behalf of the National Academies of Science, who currently completed a study on reproducibility initiated by the Committee.

I'm also pleased to welcome Dr. Brian Nosek, who joins us from the Center for Open Science, and is currently exploring ways to facilitate and encourage transparency in the research community from the ground up. I look forward to hearing about constructive ideas on how policymakers and agencies can balance the reproducibility and the need to protect individual privacy and maintain data security.

I thank our witnesses for taking the time to appear before us. I hope we can have an open and productive conversation on the broad issue of transparency in science.

With that, I yield back, Madam Chair.

[The prepared statement of Mr. Lucas follows:]

Thank you, Madam Chairwoman, and thank you to our witnesses for being here today.

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I look forward to hearing about constructive ideas on how policymakers and agencies can balance reproducibility with the need to protect individual privacy and maintain data security.

I thank our witnesses for taking the time to appear before us today and I hope we can have an open and productive conversation on the broad issue of transparency in science. I yield back, Madam Chair.

Chairwoman JOHNSON. Thank you, Mr. Lucas.

If there are Members who wish to submit additional opening statements, your statements will be added to the record at this point.

And at this time I'd like to introduce the witness for our first panel. Dr. Jennifer Orme-Zavaleta is the Principal Deputy Assistant Administrator for Science with the Office of Research and Development (ORD) and the Science Advisor for the Environmental Protection Agency. This is her second time testifying before this Committee during the 116th Congress. I welcome you back and thank you for your time.

You will have 5 minutes for your spoken testimony. Your written testimony will be included in the record for the hearing. And when you have completed your spoken testimony, we will begin with questions. Each Member will have 5 minutes for questions.

You now may proceed, and thank you for being here.

TESTIMONY OF DR. JENNIFER ORME-ZAVALETA, PRINCIPAL DEPUTY ASSISTANT ADMINISTRATOR FOR SCIENCE, OFFICE OF RESEARCH AND DEVELOPMENT, AND SCIENCE ADVISOR, ENVIRONMENTAL PROTECTION AGENCY

Dr. ORME-ZAVALETA. Good morning, and thank you.

Madam Chairwoman Johnson and Ranking Member Lucas, as noted, my name is Jennifer Orme-Zavaleta, please call me Jennifer. I'm the Principal Deputy Assistant Administrator for Science in the U.S. Environmental Protection Agency's Office of Research and Development, and I also act as the Agency's Science Advisor. My responsibility as the career lead for ORD is to ensure that we provide solid and robust science to inform Agency decisions. I have worked at EPA since 1981, and of the 38 years I've been with EPA, I've spent 25 years in ORD.

I appreciate the opportunity to talk with you today about EPA's proposed rule to strengthen transparency in regulatory science.

EPA is committed to transparency and giving public access to its data and research, and we have made great strides on this. EPA's efforts span administrations, from 2013 OSTP (Office of Science and Technology Policy) memo to increase access to federally funded research, to the *Evidence-Based Policymaking Act of 2018* and to OMB's (Office of Management and Budget's) 2019 memo on improving the *Information Quality Act*. For example, EPA's plan to increase access to results of EPA-funded scientific research was finalized in 2016. Since then, EPA has implemented all three phases outlined in the plan. This includes working to ensure EPA's own research publications and the underlying data for these publications are publicly accessible, as well as working to increase access to EPA-funded research. These efforts are more outlined on some of our websites.

In addition to these efforts, EPA initiated a rulemaking process in 2018 to increase transparency and public access to scientific data. EPA's proposed rule, 'Strengthening Transparency in Regulatory Science,' seeks to ensure that the science underlying EPA's actions is publicly available in a manner sufficient for independent validation.

The proposed rule would require that data and models underlying studies to support significant EPA regulatory actions, regardless of who generated or funded them, be made publicly available. EPA intends to release a supplemental proposed rule for public comment in early 2020 to provide clarifications on certain terms and aspects of the proposed rule.

While EPA believes that maximizing transparency is important, the Agency understands that there may be instances in which data and models cannot be made available. Thus, the proposed rule states that the EPA Administrator may grant an exception if it is not practicable to ensure that data and models are publicly available.

EPA issued the proposed rule on April 30, 2018 and held a public hearing that summer, in which some of you participated, and provided comment. The public comment period was extended after request from the public and from Congress, and it closed on August 16, 2018. During that time, we received nearly 600,000 comments. More than 9,200 of these were unique comments, many of which raised very complex issues.

Comments were submitted by professional organizations, States, tribes, industry, environmental groups, health groups, universities, the general public, and more. Almost all commenters supported the goal of greater transparency even if they disagreed with the approach in the proposed rule. And these comments covered many complex topics, and EPA is currently working hard to address these issues.

EPA also solicited feedback from the Science Advisory Board (SAB) on personally identifiable information or PII and confidential business information, CBI. EPA received these comments in September, and the comments are publicly available and are being considered as we develop the final rule. The SAB is also providing comments on the entire rule, and we anticipate receiving those comments soon.

EPA has just sent a supplemental rule to OMB for interagency review. The supplemental rule was developed because we received so many public comments, and we wanted to provide clarifications on certain terms and aspects of that proposed rule. We are committed to ensuring adequate time for public review of the supplemental rule, and we anticipate releasing it for public comment in early 2020.

Since the supplemental rule is not yet public and is still undergoing review, I cannot speak to particular details, but once we get further in the process, I'd be happy to offer briefings on the supplemental rule.

As you know, an older draft version of the supplemental rule leaked to *The New York Times*, and I would like to clarify a few things. First, the version that was published in *The New York Times* was an outdated version and is not what was sent to OMB for interagency review. Second, the supplemental rule is a supplement to the proposed rule. It is not a new rule or a new draft of the proposed rule. Rather, it's a supplement that contains clarifications, modifications, and additions to certain provisions in the proposed rule.

And last, the proposed rule applies prospectively to regulations. It does not apply to already-established rules and regulations. The proposed rule does apply to dose-response data and models that inform significant rules made in the future, including data and models that were previously developed. The supplemental rule will be available for public comment, as I noted, in early 2020, and we anticipate finalizing the proposed rule next year.

So EPA is committed to greater transparency, protecting PII and CBI, following all applicable laws and regulations, and continuing to protect public health and the environment. Thank you again for the opportunity to appear before you today, and I'm happy to answer any questions.

[The prepared statement of Dr. Orme-Zavaleta follows:]

Testimony of

Jennifer Orme-Zavaleta, Ph.D.

Principal Deputy Assistant Administrator for Science and Science Advisor

Office of Research and Development

U.S. Environmental Protection Agency

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

Before the

Committee on Science, Space, and Technology

U.S. House of Representatives

November 13, 2019

Good morning, Chairwoman Johnson and Ranking Member Lucas. My name is Jennifer Orme-Zavaleta. I am the Principal Deputy Assistant Administrator for Science in the U.S. Environmental Protection Agency's Office of Research and Development (ORD). I also act as EPA's Science Advisor. My responsibility as the career lead for ORD is to ensure that we provide solid and robust science to inform Agency decisions.

I have worked at EPA since 1981 in the areas of human health and ecological research, risk assessment, policy development, strategic planning, and program implementation. Of the 38 years I've been at EPA, I've spent 25 years in the Office of Research and Development (ORD).

I appreciate the opportunity to talk with you today about EPA's proposed rule to Strengthen Transparency in Regulatory Science.

Transparency and Open Data at EPA

EPA is committed to transparency and giving the public access to its data and research results. In recent years, EPA has made great strides in increasing access to public data. EPA's efforts in these regards span administrations, consistent with goals outlined in the 2013 OSTP memo *Increasing Access to the Results of Federally Funded Scientific Research*, the Evidence-Based Policymaking Act of 2018, and most recently in OMB's 2019 memo *Improving Implementation of the Information Quality Act.* For example, EPA's *Plan to Increase Access to Results of EPA-Funded Scientific Research* was finalized in 2016. Since then, EPA has implemented all three phases outlined in the plan. This includes: actively working to ensure all research publications by our own scientists and the data underlying these publications are publicly accessible, after a one-year embargo period, in the National Institute of Health's PubMed Central; creating a cross-Agency forum to provide oversight for the public access plan and its implementation; releasing an EPA policy to increase access to results (publications and underlying data) of EPA-funded extramural scientific research; and creating training materials so that both intramural and extramural scientists understand EPA's public access requirements. These efforts are all outlined at epa.gov/open.

In addition to these efforts, EPA initiated a rulemaking process in 2018 to increase transparency and public access to scientific data. EPA's proposed rule, *Strengthening Transparency in Regulatory Science,* seeks to ensure that the science underlying EPA's actions is publicly available in a manner sufficient for independent validation. The proposed rule would require that dose-response data and models underlying the studies or analyses used to support the

requirements and/or quantitative analysis of EPA significant regulatory actions, regardless of who generated or funded them, be made publicly available. EPA intends to release a supplemental proposed rule for public comment in early 2020 to provide clarifications on certain terms and aspects of the proposed rule.

While EPA believes that maximizing transparency is important, the Agency understands that there may be instances in which data and models cannot be made available. Thus, the proposed rule states that the Administrator may grant an exception if it is not practicable to ensure that data and models are publicly available.

At a hearing before this Committee just a few weeks ago, Administrator Wheeler discussed this issue and explained that "if we put the science out for everybody to see and understand, then there'd be more acceptance of our regulatory decisions."

Through these efforts to improve transparency, EPA is working to increase public trust, to help raise understanding about important environmental issues, and to ensure the public has access to information so they can make decisions to protect their health and environment.

Proposed Rule Feedback and Public Comment

EPA issued the proposed rule on April 30, 2018. EPA also held a public hearing in July 2018, where the public could provide comments in person – some of you attended this hearing and provided comments. The public comment period originally closed on May 30, 2018, but after requests from the public, as well as the House and Senate, the public comment period was extended to August 16, 2018. During that time, we received nearly 600,000 comments. More than 9,200 of these were unique comments, many of which raised complex issues. Comments were submitted by: professional organizations and journal editors; states and tribes; state

associations; industry; environmental groups; health groups; labor unions; universities; and the general public. Almost all commenters supported the goal of greater transparency, even if they disagreed with the approach in the proposed rule. These comments covered topics such as: personally identifiable information (PII) and confidential business information (CBI); peer review; costs to non-federal researchers; statutory authority to promulgate the rule; consistency with the Administrative Procedures Act; comparison of the proposed rule requirements with statutory requirements; and more. EPA is currently working hard to address all of these comments.

EPA also solicited feedback from the Science Advisory Board (SAB) on PII and CBI. SAB members are non-EPA scientists, engineers, economists, and other social scientists who are recognized experts in their respective fields. Members come from academia, industry, research institutes, non-governmental organizations, and federal, state, and tribal governments. EPA received SAB's comments on PII and CBI on September 30, 2019. These comments are publicly available and are being considered as we develop the final rule. The SAB is also providing comments on the entire rule – these comments will also be publicly available. We anticipate receiving those comments soon.

Next Steps

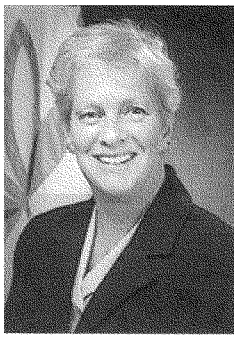
EPA has just sent a supplemental rule that provides clarifications on certain terms and aspects of the proposed rule to OMB for review under E.O. 12866. The supplemental proposed rule is designed to provide clarifications on certain terms and aspects of the proposed rule, as Administrator Wheeler noted during his hearing with this Committee in September. Once we get further in the process, we'd be happy to offer briefings on the supplemental rule. The

supplemental rule will be available for public comment in early 2020, and we are committed to ensuring adequate time for public review. EPA anticipates finalizing the rule next year.

Thank you again for the opportunity to appear before you today. I am happy to take any questions you may have.

Jennifer Orme-Zavaleta

Principal Deputy Assistant Administrator for Science for the Office of Research and Development, and EPA Science Advisor



Jennifer Orme-Zavaleta, Ph.D., is the Principal Deputy Assistant Administrator for Science for the Office of Research and Development and the EPA Science Advisor. Dr. Orme-Zavaleta has been with EPA since 1981, working in the areas of human health and ecological research, risk assessment, policy and regulation development, strategic planning, and program implementation. The focus of her experience includes the evaluation of risks to human and ecosystem health, and the influence of environmental change on human health in response to a variety of stressors including synthetic organic and inorganic chemicals, radionuclides, microorganisms, and vector-borne disease.

Dr. Orme-Zavaleta received her B.A. in Zoology from Ohio Wesleyan University, M.S. in Zoology and Toxicology from Miami University, and Ph.D. in Wildlife Science and Public Health from Oregon State University.

Jennifer has held a number of positions within EPA in the Offices of Toxic Substances, Water and Research and Development. Most recently she served as the Director of EPA's National Exposure Research Laboratory. She also served as the Interim National Program Director for Safe and Sustainable Water Resources, where she led the development of research to achieve safe, resilient and sustainable solutions to the increasingly complex water challenges facing US regions, states, tribes, cities and rural areas.

Chairwoman JOHNSON. Thank you very much. We will now begin our questioning period. And I will yield to myself 5 minutes.

Doctor, the EPA cannot carry out its mission to protect public health and the environment without considering the best available science. Congress requires that the Agency's decisions be informed by the latest, most accurate scientific data. By preventing EPA from considering critical scientific studies, the proposed rule would exclude the best available science and endanger the public. Does the Agency consider it reasonable or wise to categorically eliminate studies, for example, all human epidemiology studies based on that one factor?

Dr. ORME-ZAVALETA. So the Agency is committed to using the best available science in its decisions while also providing greater transparency to help the public understand how those science informations were used in reaching those decisions. This is a point that we received a number of comments on and also what's contributing to the supplemental rule because we need to seek further information before we make decisions on that final rule.

Chairwoman JOHNSON. Now, tell me then, how can EPA meet the statutory obligations to use the best available science in laws such as the *Safe Drinking Water Act* and the *Toxic Substances Control Act* if the rule would prevent it from considering certain studies even if they are considered definitive by the research community?

Dr. ORME-ZAVALETA. So the issue of science and public trust, there's a couple of aspects to keep in mind. When looking at good science, there are other tenets that weigh heavily in looking at how well studies were conducted, their quality assurance, what type of external peer review they went through, and overarching scientific integrity. And that's what contributes to good science.

The idea with the transparency rule is to provide the data available to the public so they understand how that science was used in making decisions.

Chairwoman JOHNSON. The rule has a provision wherein the Administrator can unilaterally exempt a study from the rule. Would EPA scientists, including yourself, consider it appropriate for a political appointee to have this arbitrary power over EPA's science?

Dr. ORME-ZAVALETA. So this is also a topic that we received a number of comments on from a variety of different sectors, and that's something that we're weighing very heavily as we look through in developing the final rule.

Chairwoman JOHNSON. OK. In your nearly 40 years at EPA, can you personally recall any instance in which considering less science led to a better policy decision by the Agency?

Dr. ORME-ZAVALETA. So my time at EPA has been in a variety of different facets, some involving some rulemaking, but, again—so I can't speak to that specifically from my own experience. But we are working hard to ensure that the Agency is evaluating the best available science while meeting all of the other requirements for providing the public information so that they can understand how we made the decisions that we made.

Chairwoman JOHNSON. Thank you very much. I'll now recognize Mr. Lucas.

Mr. LUCAS. Thank you, Madam Chair.

Jennifer, and you said I could call you Jennifer——

Dr. ORME-ZAVALETA. Indeed.

Mr. LUCAS [continuing]. You addressed it in your testimony, and I think all of us read some of the news media, so it's no secret that a version of the supplemental rule was leaked and reported by *The New York Times*. And, by the way, for the record I happen to have a copy of the document that was used in that story. And just for note again to repeat one more time, is this the most recent version of the supplemental rule?

Dr. ORME-ZAVALETA. That is not the most current version. That is an older version, and that was not what was submitted to OMB last Friday.

Mr. LUCAS. Thank you. Now, I ask, because, as I said in my opening statement, it seems like this hearing is premature and that it would be more productive if we waited for the supplemental rule to be published, not leaked, and provide our comments and direction on the most current proposal. Can you confirm that the supplemental rule is still in the drafting process?

Dr. ORME-ZAVALETA. So the supplemental rule was submitted to OMB, and it's now part of the interagency review process. We will see what comments come back from that review. We'll work to finalize the supplemental rule and then issue it for public comment early next year.

Mr. LUCAS. Do you agree that a productive hearing would result from conversations based on a published rule, not a leaked version?

Dr. ORME-ZAVALETA. So we are happy to be here today to answer questions that you may have. What input we receive today we will add into all the other comments that we have for consideration. We're happy to provide further briefings as more information becomes available.

Mr. LUCAS. In *The New York Times* article the reporter stated, "The new version does not appear to have taken any of the opposition into consideration." It's my understanding that once it's released the supplemental rule will also be open for public comment and then move through the regular implementation process. Is that correct and consistent with the rulemaking process?

Dr. ORME-ZAVALETA. That's part of the rulemaking process. And I would note that the reason that we have a supplemental rule is actually because of the number of comments that were raised and some of the complex issues and the need for clarification. And so it's because of that input we felt it necessary for a supplement to clarify terms, to seek comment on further aspects and help us with our consideration in going through the rulemaking process.

Mr. LUCAS. It would seem that the process is working.

With that, Madam Chair, I yield back the balance of my time.

Chairwoman JOHNSON. Thank you very much. Ms. Bonamici.

Ms. BONAMICI. Thank you, Chairwoman Johnson.

Thank you to our witness for being here today.

Chairwoman Johnson, I request unanimous consent to submit for the record a copy of *The New York Times* article from November 11, 2019, titled, "EPA to Limit Science Used to Write Public Health Rules" and also the EPA press release in response to that article from November 12, 2019.

Chairwoman JOHNSON. Without objection.

Ms. BONAMICI. Thank you. The EPA's proposed rule titled "Strengthening Transparency in Regulatory Science" isn't about transparency. It's an attack on sound science. We've had this conversation in this hearing room many times. Transparency is a laudable goal, and it can be accomplished through collaboration with and input from the scientific community. This rule, unfortunately, will detrimentally limit the science that EPA can rely on in regulatory decisionmaking and, if implemented, will have negative consequences for the EPA and its mission to protect public health and the environment and for every person who benefits from clean air and clean water.

In his testimony before this Committee in September, Administrator Wheeler stated, "We intend to issue a supplemental proposed rule to our science transparency regulation early next year." According to the record, I then asked if the supplemental rule would be published prior to 2020. The Administrator clearly stated, "I'm told early next year."

And then earlier this week *The New York Times* reported that the EPA draft supplemental proposed rule is currently headed for White House review. The EPA press release yesterday then stated that the final text has been submitted to the Office of Management and Budget for interagency review. And, Dr. Orme-Zavaleta, you just confirmed that.

Dr. ORME-ZAVALETA. Yes.

Ms. BONAMICI. I'm concerned that the EPA was not transparent with Congress during this process. The OMB review of the proposed rule took only 4 days in the past, so assuming that the timing is similar, the supplemental proposed rule could very well be ready to publish before 2020. At best, the Administrator's testimony was misleading and at worst it was deliberately deceptive, and either is unacceptable.

So Dr. Orme-Zavaleta—did I get that right?

Dr. ORME-ZAVALETA. You're doing great.

Ms. BONAMICI. Close?

Dr. ORME-ZAVALETA. You're——

Ms. BONAMICI. Please answer yes or no. Are you aware of the Administrator's testimony from when he was here in September?

Dr. ORME-ZAVALETA. Yes.

Ms. BONAMICI. And the timing in these press reports indicates that the final agency review (FAR) meeting has already taken place. So when Administrator Wheeler testified before the Committee on September 19, had the final agency review meeting already been scheduled?

Dr. ORME-ZAVALETA. So I'm not sure I'm entirely understanding final agency review.

Ms. BONAMICI. The final agency review meeting, had that already been scheduled?

Dr. ORME-ZAVALETA. So you're talking about the FAR process?

Ms. BONAMICI. Yes.

Dr. ORME-ZAVALETA. So we were in the—I think we hadn't even initiated—by the time of his testimony, I think it might have just—just been initiated in that FAR process, but we didn't resolve that until late last week, then—and then getting the draft supplemental to OMB.

Ms. BONAMICI. Well, the Administrator was here on September 19.

Dr. ORME-ZAVALETA. So the FAR is completed now.

Ms. BONAMICI. Well, it's my understanding that the final agency review meeting was on September 30, 2019.

Dr. ORME-ZAVALETA. And I'm checking to see—yes.

Ms. BONAMICI. OK. So when the Administrator was here on September 19 it's reasonable to assume that he knew about the meeting that was scheduled on September 30. Is that correct?

Dr. ORME-ZAVALETA. I don't know that he knew that it was actually scheduled at that point in time, so I can't speak, but we can get further clarification from him regarding that particular testimony.

Ms. BONAMICI. Thank you.

Dr. ORME-ZAVALETA. But the FAR didn't complete until the week after.

Ms. BONAMICI. And I want to get another topic in. In light of the submission of the supplemental rule to OMB, please clarify the timeline for us. Will the supplemental rule be published prior to 2020?

Dr. ORME-ZAVALETA. I am not aware that it'll be published prior to 2020. We are anticipating after the beginning of the new year. The OMB process can vary in time, and the typical process can be anywhere from 90 days. So I can't say whether they'll have that completed prior to that.

Ms. BONAMICI. I also want to clarify, you mentioned something in your oral testimony that's not in your written testimony about retroactive application. In response to one of my questions during his testimony, Administrator Wheeler stated, "Our proposal did not retroactively apply." Those were his words. But according to the news reports, the draft supplemental rule states that the rule would apply to all data and models, regardless of when the data and models were generated. The EPA press release states, "The proposal and supplemental will not apply to any regulations already in place."

So please clarify for the record, even if, as the EPA stated yesterday, the proposal and supplemental will not apply to regulations already in place, does the language in the supplemental rule suggests that the EPA is still considering some type of retroactive application? And if so, what does that mean?

Dr. ORME-ZAVALETA. So the proposed rule—and this is the thing that we wanted to clarify with *The New York Times* article because I think it did get confused. So the supplement, you know, it does not apply to already-established rules and regulations. It does apply to dose-response data and models that could inform significant rules made in the future, including the data and models that were previously developed.

Ms. BONAMICI. Thank you for that clarification, which I find very concerning. The proposed rule and its implications on the EPA's statutory obligations warrant further consideration and scrutiny. So today I'm sending a letter requesting that the National Academy of Sciences, as an authoritative, independent, nonpartisan scientific organization work with the EPA to review the proposed rule.

I yield back the balance of my time.

Chairwoman JOHNSON. Thank you very much. Mr. Posey.

Mr. POSEY. Thank you, Madam Chair, for holding this hearing today on transparency, and I appreciate your attendance, Dr.——

Dr. ORME-ZAVALETA. Jennifer.

Mr. POSEY [continuing]. Orme-Zavaleta.

Dr. ORME-ZAVALETA. Yes, you're——

Mr. POSEY [continuing]. And I'm glad to see that the Agency is moving more toward better transparency. And I'm sad that it has been maligned by the media and others.

In the past, EPA has relied upon "secret studies" to move forward with a particular political agenda. These studies were used to justify regulations that would have negatively affected thousands of people. For example, the EPA sought to regulate fine particulate matter or airborne dirt. This would have particularly hurt the agriculture business, which is the second-largest industry in the State of Florida. There would be no way to test the data used to make the regulation because it was secret. I have a problem with that obviously, and I believe we should have transparency. And any study funded with taxpayer funds should be made public.

How do you believe the transparency and reproducibility will improve the quality and return on investment on federally funded scientific research?

Dr. ORME-ZAVALETA. So I think that as we look at federally funded scientific research, we are already making that information publicly available. Our published articles are made available through the NIH (National Institutes of Health) PubMed Central. Our data are made publicly available, so that's a provision that we are already doing.

Mr. POSEY. OK. Thank you. Has the EPA's Office of Research and Development incorporated reproducibility and transparency in federally funded research? And how has your office incorporated those measures?

Dr. ORME-ZAVALETA. So we provide the information, the data that we generate. We make that publicly available. And so that's where we're currently at. This particular rule is not final, and we're not implementing the rule as it has been proposed. But again, we're working hard to make sure that the data that we generate, the research that we conduct and implementing the—that particular provision, it's—also includes our external grants, as well as the rest of the Agency. So any research or any publication that the Agency generates, we make those publications available. We make the underlying data available. And that provision is now expected of our grantees as well.

Mr. POSEY. Well, thank you.

Dr. ORME-ZAVALETA. The main thing that I do want to highlight here, though, is that in doing so, we're going to continue to follow the applicable laws that protect PII and CBI.

Mr. POSEY. Thank you. I appreciate your forthrightness. I've had problems with the Agency in the past getting forthright answers from them. Suppose now I wanted to get a copy of a study that was previously deemed "secret" to make a law or rule, a law made by unelected, unaccountable, unrecallable bureaucrats. Would I now be able to get a copy of that secret study having any identification or personal information redacted of course? Would I be able to get

a copy of the study now that they denied someone to see, say, 4 years ago?

Dr. ORME-ZAVALETA. I think I'd have to know some of the specifics, but I think we would work hard—if the study is published and available, we can provide that particular study and the underlying data that are highlighted in that particular study.

Mr. POSEY. Yes. If it was used to promulgate a rule, then it would probably be accessible now to the public even though it were not in the past?

Dr. ORME-ZAVALETA. So we're looking at regulations going forward, so a previously conducted study and the previous regulation, that record stands, but we're looking at regulations going forward. So this particular rule applies prospectively.

Mr. POSEY. So I still can't get a copy of a publicly paid-for study that was used to promulgate a rule in the past?

Dr. ORME-ZAVALETA. It depends on how far past, but the docket that supports that rulemaking, that's what's publicly available now.

Mr. POSEY. I thank you. I yield back the balance of my time.

Chairwoman JOHNSON. Thank you very much. Ms. Stevens.

Ms. STEVENS. Thank you, Madam Chair. I'd like to submit a letter for the record from Dr. Mona Hanna-Attisha, Founder and Director of the Michigan State University Hurley Pediatric Public Health Initiative. Dr. Hanna-Attisha also works as a pediatrician in Flint, Michigan.

It's also worth teasing out some of what Dr. Hanna-Attisha has written before I get into my questions. Dr. Hanna-Attisha wrote that, quote, "I know from my work as a pediatrician in Flint that when the EPA succeeds, people are protected, and when the EPA fails, people get sick. This is especially true for our most vulnerable communities and most desperately for our children both here in Flint and around the State. Let the story of the Flint water crisis serve as a tragic reminder of the consequences of undermining science, not only the science of water treatment but also the science of lead's neurotoxicity."

Quote, "Unfortunately, the newly revised EPA proposal 'Strengthening Transparency in Regulatory Science' undermines essential protections and established science-based decisionmaking processes. Shockingly, it does so to an even greater extent than the original proposed rule would have, despite overwhelming public opposition."

Dr. Orme-Zavaleta, do you acknowledge that the proposed rule would preclude the use of many types of studies that the EPA has used in the past to address environmental threats that disproportionately affect children, low-income populations, or both?

Dr. ORME-ZAVALETA. If I could please get some clarification because it sounds like Dr. Hanna was referring to the supplemental rule that leaked versus the proposed rule, and so is your question specific to the proposal or to the supplemental?

Ms. STEVENS. Well, it's to both frankly.

Dr. ORME-ZAVALETA. So I can't speak to the supplemental——

Ms. STEVENS. Yes.

Dr. ORME-ZAVALETA [continuing]. At this point in time, but again, you know, these echo many of the comments that we re-

ceived, and it's because of some of these issues that we are going out with a supplemental to get further input and to provide some clarifications as we move forward.

Ms. STEVENS. Yes. While we here on the Science Committee protect and support transparency, so I appreciate your response and also wanted to ask, did the EPA consult the Office of Children's Health Protection before it wrote that the proposed rule could ignore the Executive Order 12898 or with the Office of Environmental Justice before it wrote the rule to ignore the E.O.? And the E.O., just for those in the audience, directs the EPA to identify and address disproportionately high and adverse human health or environmental effects.

Dr. ORME-ZAVALETA. So I was not part of the development of the proposed rule, and I can't really speak to which all—which programs were all engaged in——

Ms. STEVENS. OK. So we'll submit that for the record and get back. How can the EPA in part—how is this legally justified in terms of its decision to not perform an assessment on the proposed rule's adverse impacts on vulnerable populations? Is there an ability for you guys to provide legal justification, or is that something else we should submit for the record?

Dr. ORME-ZAVALETA. I think that would be better to submit for the record.

Ms. STEVENS. OK. And so then going forward with the supplemental draft, you know, if you could provide any specific opportunities or insights and ways in which you've engaged minority populations and children's health advocates to participate in the further rulemaking process, is that something that you can speak to at this time?

Dr. ORME-ZAVALETA. So in developing the supplemental, we did utilize an agency workgroup, which had representation across the Agency. I don't believe the Office of Children's Health identified a person to take part, but we did get cross-agency input in reviewing all of the comments and determining where we needed further clarifications, further comment, as well as offering what we are—certain clarifications of terms and aspects. So that's what's going to be coming forward.

Ms. STEVENS. Well, I'd certainly like to recommend that the Agency gets in touch with Dr. Hanna-Attisha and her associates given that the largest public health crisis of our time, those voices would certainly be valued and recommended.

And I'd also like to commend you, Dr. Orme-Zavaleta, for your very lengthy career in civil service at the EPA as a scientist. Thank you for being here with us today.

Dr. ORME-ZAVALETA. Thank you.

Ms. STEVENS. I yield back my time.

Chairwoman JOHNSON. Thank you very much. Mr. Baird.

Mr. BAIRD. Thank you, Madam Chair. I appreciate the witness being here today and your background and experience.

You already mentioned *The New York Times* article, and I understand your address to that, you cannot probably comment on the supplemental rule, but I guess I'm wondering about, is there any scenario where whatever the version of the rule that might be fi-

nalized, this transparency rule would somehow invalidate the existing regulations?

And you mentioned something about not going back or whatever the previous decision was based on that might not change previous decisions, and can you elaborate on any kind of a situation where that might invalidate existing rules? I guess what I'm trying to say is after you've made a rule and then, you know, your colleagues and so on do the research and reproducibility and replicability end up being validations. So if you had additional research that proved what the previous rule and decision was maybe in error, can you adjust that rulemaking——

Dr. ORME-ZAVALETA. So, again, this—this particular rule, once it's finalized, would apply prospectively to future rules and regulations. It would not undo existing rules and regulations. It's only looking forward. And I think in the case of some statutes, whether it's NAAQS (National Ambient Air Quality Standards) or a 6-year review of drinking water regulations, that would be an opportunity where new information can be considered in updating those particular activities, if that gets to what you're looking for.

Mr. BAIRD. We're getting close. You're on the right track. My question is sometimes these rules end up impacting businesses and so on. The airborne rule for agriculture was one of those. I guess my question is, how fast can you make adjustments in the rule? I'm wondering if the process doesn't inhibit or——

Dr. ORME-ZAVALETA. Well, the Agency follows the statutory requirements in developing its different rules and regulations. But the other thing to keep in mind is, first and foremost, we are about protecting public health and the environment. And we want to make sure that our decisions are sound and will meet the mission of the Agency.

Mr. BAIRD. So I understand, and maybe I'll rephrase this, once the rule is finalized and it's put in place, but then if new data was available or became available that made you want to modify that rule, how long would it take to make a change in the rule?

Dr. ORME-ZAVALETA. It would depend on——

Mr. BAIRD. It would have to go back clear through the whole process?

Dr. ORME-ZAVALETA. So that would be in the policy side of EPA, and each would follow their statutory schedule of rulemaking and looking at the contaminants that they control under the different authorities. So it would follow that schedule. There wouldn't be any sort of increased schedule.

Mr. BAIRD. So that could take a year or 2 years or what to make a——

Dr. ORME-ZAVALETA. It depends on——

Mr. BAIRD. Whatever that policy is?

Dr. ORME-ZAVALETA. It depends on the particular—whether it's under the *Clean Air Act*, *Clean Water Act*, *Safe Drinking Water Act*, what have you. It would be that schedule that this rule would apply.

Mr. BAIRD. OK.

Dr. ORME-ZAVALETA. OK.

Mr. BAIRD. Thank you. I yield back.

Chairwoman JOHNSON. Thank you very much. Mr. McNerney.

Mr. MCNERNEY. Well, I thank the Chairwoman, and I thank you, Dr. Orme-Zavaleta, for appearing today. I know you're in for some tough questions.

The EPA cannot unilaterally decide to completely transform the way it uses science in its rulemaking. It needs to receive the authority from Congress, and it needs to justify the use of that authority. If the Agency cannot do that, the rule is not valid.

In its May 2018 notice extending the public comment period, the EPA cited 5 U.S. Code 301. According to *The New York Times*, this is now the sole authority being cited by the Agency. Dr. Orme-Zavaleta, are you familiar with the notice that the EPA published in May 2018 which extended the public comment period and announced a public hearing on the proposed rule, and cited EPA's supposed authority under 5 U.S.C. 301?

Dr. ORME-ZAVALETA. So I'm aware that we extended the public comment period from the end of May until the middle of August, yes.

Mr. MCNERNEY. What about citing the EPA's supposed authority under that code?

Dr. ORME-ZAVALETA. So I'm going to have to defer that to our legal counsel if that's something you want to submit for the record, then we can respond that way.

Mr. MCNERNEY. Well, thank you. In reference to the proposed rule, let's talk about 5 U.S.C. 301. It's a two-sentence law that called the Federal Housekeeping Statute that was enacted 4 years before the EPA was created. Are you aware of any executive department that has relied on this housekeeping statute to fundamentally overhaul its regulatory process?

Dr. ORME-ZAVALETA. So, again, I would have to defer to our general counsel.

Mr. MCNERNEY. Well, I have to advise you that the Committee staff made it clear to the EPA that you should be able to answer all questions on the proposed rule.

Dr. ORME-ZAVALETA. I cover a lot of topics, but I am not a lawyer.

Mr. MCNERNEY. Well, if the EPA's position is that it already has the authority to carry out this rule under 5 U.S.C. 301, why is it promulgating the new rule now?

Dr. ORME-ZAVALETA. Again, I think that's something we'll have to follow up on.

Mr. MCNERNEY. OK. Well, I'm curious about how far the Agency could push the authority that it claims under this statute. Could the EPA invoke 5 U.S.C. 301 to consider only science published by industry?

Dr. ORME-ZAVALETA. Again, I'll have to defer that comment.

Mr. MCNERNEY. Could the EPA invoke 5 U.S.C. 301 to consider science differently in enforcing clean-air regulations within different States based on whether the State voted for or against President Trump?

Dr. ORME-ZAVALETA. Again, I think that's something that we'll have to follow up with you.

Mr. MCNERNEY. Will the EPA at least knowledge that 5 U.S.C. 301 does not convey any authority under the rule that conflicts with existing statutory enforcement obligations?

Dr. ORME-ZAVALETA. And I'll have to defer that as well. So anything on the authority, sir, I'm not going to be able to address.

Mr. MCNERNEY. Well——

Dr. ORME-ZAVALETA. That's not my area of expertise.

Mr. MCNERNEY [continuing]. The EPA was notified that you today would have to answer all these questions.

Dr. ORME-ZAVALETA. I apologize if that was a misunderstanding, but that's beyond my particular expertise.

Mr. MCNERNEY. All right. Well, I'm going to have to yield back. Thank you.

Chairwoman JOHNSON. Thank you very much. Mr. Murphy.

Mr. MURPHY. Thank you, Madam Chairman. And thank you, Doctor, for your service. It's a testament to dedication in science that we have great people in government that have dedicated their lives to that, so thank you very much.

I've been in medicine for 30 years and done a different type of dedication, and I've read and continue to read many, many medical journals, as I'm sure you do. And I think it's important that people know that when you and I read journals, we look at articles, we look at studies with a very, very discerning eye. I personally don't believe anything in the literature until I believe it. And I think that's the way our scientists have pointed out.

And so it bothers me to think or imply that folks would think that the people in the EPA would do anything less. I think scientists, we hold ourselves to a different standard, that we look for the true objective facts, and we base that upon that. So I thank you for the work that you're doing in that.

I will ask one question. Have you by any chance had a chance to review the news release from the EPA yesterday?

Dr. ORME-ZAVALETA. Yes, I saw it after it came out.

Mr. MURPHY. OK. In quick summary, it talks about *The New York Times* and several glaring inaccuracies of their article. And I think, to be very honest with you, it's just seemingly a theme that goes on around here about reckless reporting, inaccurate reporting, and flat out lying.

And so I wondered, you know, since you have read this, it talks about false information being stated, things that are bad reporting, things that are not true. I wondered if you might have a comment for the Committee about this news release and how you feel. Is this an accurate depiction of the inaccuracies put out by *The New York Times*?

Dr. ORME-ZAVALETA. Well, I think the key clarification from the press release, again, is just to highlight that this is a supplement. It's not a new rule. It is a supplement to what was proposed, and the Agency wanted to clarify terms. We wanted to also get additional comment as we continue our deliberations in finalizing the rule. I think that was one of the key pieces of clarification.

The other key clarification, again, was to note that this rule applies prospectively to new rules and regulations, not to the past rules and regulations.

Mr. MURPHY. Yes, thank you. Do you think there's anybody at the EPA that does not have the interest of the American people at heart?

Dr. ORME-ZAVALETA. I have not come across anyone at EPA—the thing that is remarkable about all of the Agency employees is their dedication to the mission of the Agency and protecting public health and the environment.

Mr. MURPHY. Thank you. I think that we owe a great debt to the EPA for keeping the country safe, keeping our waterways safe, keeping what we take in safe. We're not perfect in this regard, and there are a lot of times that we go back and look at things that we could've done differently. So I appreciate that.

You know, you talked about in your prepared testimony how the rulemaking was just one step in a long effort to improve scientific integrity and transparency. Can you expand upon that a little bit? Has this been a bipartisan effort? Tell me a little bit more or tell us a little bit more about how this process really has been one of collectiveness.

Dr. ORME-ZAVALETA. Well, again, I think, as I noted earlier, as science has come across increased scrutiny, we have been working hard to build public trust in the quality of our science, and we do that primarily through strong quality assurance, strong, independent expert peer review of our work, as well as a strong scientific integrity program.

Combined with that, building public trust is also helping to enable the public to understand what information was used in the decisions the Agency makes. So if they choose, they can go back and try to understand how we came to the conclusions that we came to. And that's where the transparency piece comes in.

Mr. MURPHY. Thank you. Just one final question. Is non-government-funded research currently subjected to the same transparency requirements that the EPA's intramural research and extramural grants have?

Dr. ORME-ZAVALETA. So this particular rule—the proposed rule applies only to EPA.

Mr. MURPHY. OK. All right. Thank you, Madam Chair. I'll yield back my time.

Chairwoman JOHNSON. Thank you very much. Mr. Tonko.

Mr. TONKO. Thank you, Madam Chair, and thank you, Dr. Orme-Zavaleta, for joining us.

For 5 years, I have fought against these deceptively named science transparency proposals. I said this when we were debating the *Secret Science* and *HONEST Acts*, and it's still true today. These efforts pay cheap lip-service to improving scientific integrity and transparency, but their true purpose is to undermine the decades of sound science on which EPA relies to protect our air, water, and the health and safety of the American people. Any form of this rule, any form essentially guarantees that political agendas are given more weight than science in EPA rulemaking.

I asked EPA to withdraw this rule at the summer 2018 public comment session. I and others pointed out that its effect would be to undermine necessary science and endanger public health. When the supplemental rulemaking came to light, I hoped this meant that EPA was re-evaluating. But based on reports, this EPA is going down that same path and will endanger the health and safety of millions of Americans for many generations to come.

So, Dr. Orme-Zavaleta, the proposed rule tracks closely with the *Secret Science Reform Act of 2015*, legislation previously debated by this Committee. In fact, the language is virtually identical. Congress has repeatedly considered this legislation, and time and time again we have declined to move it forward.

Out of the *Secret Science Reform Act of 2014*, of 2015, or the *HONEST Act of 2017*, how many ever became law?

Dr. ORME-ZAVALETA. I guess I'm not sure—of those particular that you just cited, I don't believe Congress passed a law——

Mr. TONKO. OK. So the answer is zero. To your knowledge, were EPA officials aware that Congress had already rejected the *Secret Science* and *HONEST Acts*?

Dr. ORME-ZAVALETA. I would assume so, but I don't know for a fact.

Mr. TONKO. How many comments were issued with concerns about the rule?

Dr. ORME-ZAVALETA. So, again, we received nearly 600,000 comments, about 9,200 which were unique. And, as I noted earlier, you know, I think many of the comments supported the concept of transparency, and where they differed was in the way that we approach that.

Mr. TONKO. OK. And did any comments raise the issue that this rule would endanger the health and safety of Americans?

Dr. ORME-ZAVALETA. We received a number of comments from all sectors, a variety of different topics, and so those were similar to some of the comments that we received.

Mr. TONKO. That they did raise the concern of health and safety of Americans?

Dr. ORME-ZAVALETA. Yes.

Mr. TONKO. Thank you. Have any EPA officials expressed concern that this rule would endanger the health and safety of Americans?

Dr. ORME-ZAVALETA. I don't believe we've come into that conversation yet. I mean, Administrator Wheeler has asked that we continue to proceed with the development of this rule.

Mr. TONKO. But do you know of any officials at EPA that expressed concerns?

Dr. ORME-ZAVALETA. I do not know, no.

Mr. TONKO. You do not know. Have career staff expressed concerns about being left out of the process of drafting the proposed rule?

Dr. ORME-ZAVALETA. I haven't heard about specific comments related to the drafting, but when we were asked to take up that proposed rule and move it forward through the process, we are ensuring that career staff are engaged in our workgroup process so that we can go through the comments and go through the clarifications and the decisions moving forward.

Mr. TONKO. Right. To be involved but you then again do not know of any staff that expressed concerns about being left out?

Dr. ORME-ZAVALETA. Personally, no.

Mr. TONKO. When was the decision made to write a supplemental proposed rule? When did you learn about it, and how many career staff are now involved in drafting it, including yourself?

Dr. ORME-ZAVALETA. So, again, as we worked through from the public comment period, we've had a career-led effort in looking at the comments and trying to understand some of the complex issues that were raised. Many of these issues led us to recommend to the Administrator the benefit of a supplemental to provide clarifications and further discussion of the certain aspects of the rule. The Administrator agreed that it would be important to do that. So we're moving forward, and we'll be looking to get further comment on that rule when it goes out.

Mr. TONKO. Thank you. And many people fear that this rule will endanger the health and safety of Americans. If Americans are sickened as a result of this rule, does EPA have a plan to provide care?

Dr. ORME-ZAVALETA. So, again, EPA is looking to protect public health and the environment.

Mr. TONKO. But Americans are sickened as a result of this rule, do they have a plan to provide care?

Dr. ORME-ZAVALETA. We've got a ways to go to see what the final rule is going to look like. We have lots of information that we are considering. Decisions have not been made what that final rule will look like.

Mr. TONKO. So I assume they don't have a plan. And if Americans are sickened or die as a result of this rule, who will be held accountable?

Dr. ORME-ZAVALETA. Yes, I—you know, it's——

Mr. TONKO. Who would be——

Dr. ORME-ZAVALETA. It's hard to say.

Mr. TONKO [continuing]. Held accountable?

Dr. ORME-ZAVALETA. It's hard to say. Again, we don't know what the final rule is going to look like.

Mr. TONKO. Who's the top political EPA appointee overseeing the drafting of the supplemental proposed rule?

Dr. ORME-ZAVALETA. Well, the Administrator is the top official.

Mr. TONKO. Thank you. With that, Madam Chair, I yield back.

Chairwoman JOHNSON. Thank you very much. Mr. Babin.

Mr. BABIN. Yes, ma'am. Thank you very much, Madam Chair.

Dr. Orme-Zavaleta, thank you for being here today, and I thank you for your professional career. I appreciate it.

I'd like to continue this same line that Dr. Murphy had started a while ago. As several of my colleagues have already mentioned, our discussion here today is overshadowed by the recent New York Times article that provided a long list of comments and a leaked copy of an earlier draft of the supplemental rule.

I have to say that I'm very disappointed that we're allowing the work of one reporter to characterize our discussion here today, particularly when we have yourself, followed by a panel of expert witnesses, to talk about the broader issue of improving scientific transparency.

But since we've decided to make a New York Times article the centerpiece of our discussion, I think it's only fair that we include the EPA's rebuttal to that article, which Dr. Murphy had already brought up. And without objection, if it's not already done, I'd like to enter that into the record if that's OK, Madam Chair.

Chairwoman JOHNSON. Without objection.

Mr. BABIN. Thank you.

I know you've already mentioned it, and I'd like for you to elaborate a little bit more. Do you think that *The New York Times* article accurately portrayed the draft supplemental rule that was leaked?

Dr. ORME-ZAVALETA. So I think the article confused a few aspects.

Mr. BABIN. OK. All right. Thank you. Do you think this Committee would be better served if we, as you suggested in your prepared testimony, received briefings on the supplemental rule once it is published through the appropriate channels instead of wasting our time debating an outdated version?

Dr. ORME-ZAVALETA. So, again, I'm happy to be here today to help answer questions related to the proposed rule, and we're happy to follow up with briefings once the supplemental is publicly available.

Mr. BABIN. OK. Well, will you commit today to work to schedule those briefings as soon as the supplemental rule is published?

Dr. ORME-ZAVALETA. I'll defer to our congressional affairs staff, and they'll follow up.

Mr. BABIN. OK. And do you have any reason to believe that the proposed or draft supplemental rule would somehow make it more difficult for the EPA to carry out its regulatory mission?

Dr. ORME-ZAVALETA. So just to note, the supplemental is a supplement——

Mr. BABIN. Right.

Dr. ORME-ZAVALETA [continuing]. To the proposed rule seeking additional clarifications and modifications to the rule and getting comment back on that.

Mr. BABIN. OK. Well, *The New York Times* article said just the opposite, so will this supplemental make it more difficult to——

Dr. ORME-ZAVALETA. So that's one of the clarifications that we wanted to provide, that this is not a new rule. It is a supplement to what was proposed where we are seeking some clarification of terms and other aspects of the rule and getting further comment back from the public.

Mr. BABIN. Well, when I read *The New York Times* article, it didn't come across like that at all. Madam Chair, I'm going to yield back. That's all I have. Thank you. Thank you very much.

Chairwoman JOHNSON. Thank you very much. Mr. Casten.

Mr. CASTEN. Thank you. Dr. Orme-Zavaleta, thank you so much for coming today and for your decades of service to the EPA.

If my cell phone is any predictor, this is not the Committee hearing that most of the country is watching today. But I want to suggest there's a parallel. Our colleagues over in the Intelligence Committee right now are defending the Constitution from the White House. And I sit here watching this and thinking we are right now defending the enlightenment from the White House. And I'm not being hyperbolic. When we politicize the Constitution, we put our republic at jeopardy, and when we politicize science, we put our species in jeopardy.

You cannot be happy that you're here. You cannot be happy that your leadership has put you in a position to defend an anti-scientific history. But make no mistake, Union of Concerned Sci-

entists has reported that the idea behind this rule came from a 1996 memo from Chris Horner to R.J. Reynolds—Chris Horner, who was part of Trump's transition team at EPA; Chris Horner, who is a tinfoil-hat-wearing climate denier. And he wrote in his memo in 1996, "Because there is virtually no chance of affecting change if the focus is environmental tobacco smoke, our approach is one of addressing process as opposed to scientific substance." He then went through and recommended essentially what you're proposing here today, what your Agency is proposing here today.

Madam Chair, I'd like unanimous consent to enter this memo into the record.

Now, in *The New York Times* report, it said that the supplemental proposed rule is considering applying the policy retroactively so that all past scientific research could be excluded by EPA unless the underlying data is made publicly available. The EPA response to this—which you've been talking about—largely dodges the important points.

So, number one, EPA said in a release that, quote, "The proposal and supplemental will not apply to any regulations already in place." Yes or no, is it within EPA's authority to review and update existing regulations at its own discretion?

Dr. ORME-ZAVALETA. I believe they follow the statutory schedule.

Mr. CASTEN. So it's a yes?

Dr. ORME-ZAVALETA. It's a maybe.

Mr. CASTEN. You have that discretion. Aren't there mandated timelines to update certain existing regulations like those issued under the National Ambient Air Quality Standards?

Dr. ORME-ZAVALETA. I believe the statutes do require a regular schedule for updating.

Mr. CASTEN. OK. So given that EPA can reconsider any regulations it deems necessary and the mandatory reconsiderations—is it safe to say that any existing regulation can be ultimately rewritten within the bounds of this proposed rule should it be finalized?

Dr. ORME-ZAVALETA. Should this rule be finalized, then it will apply prospectively to new rules and regulations.

Mr. CASTEN. But those old rules are going to come up for renewal under what we just talked about, so it's fundamentally disingenuous to assert, as EPA has, that the rule will not be applied retroactively to existing regulations. And——

Dr. ORME-ZAVALETA. It's still applying prospectively.

Mr. CASTEN. But all those rules are coming up for renewal. This——

Dr. ORME-ZAVALETA. And the Agency may decide to update—a lot of it is driven by what new information becomes available.

Mr. CASTEN. And we are asked to trust that people led by science deniers are going to make that decision right. Look, this is painful. And we are sitting at a moment where none of this assault on science happens if people in your shoes stand up. If and when you stand up, we've got your back, but please stand up.

Dr. ORME-ZAVALETA. Thank you.

Mr. CASTEN. Thank you. I yield back.

Chairwoman JOHNSON. Thank you very much. Mr. Balderson.

Mr. BALDERSON. Thank you, Madam Chair. And, Doctor, thank you very much.

Doctor, it's my understanding that the EPA currently has transparency rules in place for internal research in EPA grants. Can you elaborate on what those requirements are today?

Dr. ORME-ZAVALETA. So related to public access, which is different from a transparency rule, but it's public access to information. And, so, yes, that's currently in place where our research and the publications from that research are made publicly available, along with the underlying data for that, that's now extended across the Agency, as well as applying to our external grants community.

Mr. BALDERSON. OK. Thank you. A follow-up, are there policies to ensure the protection of personal or sensitive data within these transparency requirements?

Dr. ORME-ZAVALETA. The Agency does have laws and regulations that do provide for the protection of PII and CBI.

Mr. BALDERSON. OK. Thank you. Is there any reason that non-government-funded research could not also be subject to similar transparency requirements?

Dr. ORME-ZAVALETA. So the public access information applies more broadly. This particular transparency rule applies just to EPA.

Mr. BALDERSON. OK. Thank you. When finalizing the science transparency rule will the EPA ensure the all-important studies underlying significant regulatory actions at the EPA regardless of their source are subject to a transparent review by a qualified scientist?

Dr. ORME-ZAVALETA. So we go through the scientific process, and our information that we develop, the science that we use, we look for external peer review to help ensure the quality of that science. In agency decisionmaking and rulemaking process, it does go through a public notice and comment period.

Mr. BALDERSON. Doctor, thank you for your time. And, Madam Chair, I yield back my remaining time.

Chairwoman JOHNSON. Thank you very much. Mr. Foster.

Mr. FOSTER. Thank you, Madam Chair, and thank you, Dr. Orme-Zavaleta, for everything. You know, I read some interview you had online, and you talked about growing up I think in the Cleveland area.

Dr. ORME-ZAVALETA. I did.

Mr. FOSTER. And I got my Ph.D. in the salt mine under Mentor Harbor, and we'd go swimming in the lake. And you probably know what a Tittabawassee trout is from——

Dr. ORME-ZAVALETA. Actually, I don't.

Mr. FOSTER. You don't, OK. All right. There's a song about it I think having to do with "burn on big river"——

Dr. ORME-ZAVALETA. Oh, yes.

Mr. FOSTER [continuing]. Which you're probably familiar with. Yes.

I thank you for your career.

I'd like some clarification if I could on the prospective nature of the proposed rule. So under the proposed rule change, might it be possible that during a rule update, scientific studies that had previously been accepted as valid scientific input for the original rule might be rejected for the purposes of the rule update?

Dr. ORME-ZAVALETA. So that's also part of the kinds of comments that we received, and that's currently what's being discussed and debated. So we'll have to see how all of this weighs as we work toward finalizing that rule and what that final rule——

Mr. FOSTER. So the answer is possibly yes with the current state of deliberation?

Dr. ORME-ZAVALETA. I think it's one of a number of comments that we're still working through.

Mr. FOSTER. OK. So something as simple as a change in the data retention requirements between the time it was originally published and current data retention requirements might—might—cause the science to be rejected?

Dr. ORME-ZAVALETA. Yes, I don't know about the data retention. That's a little more detailed than I think——

Mr. FOSTER. Yes, well, the general issue that we've been wrestling with, you know, for the last several years is this whole narrative about secret science and honest science and so on, you know, to my mind represents a deliberate blurring between—and of distinctions between science that's irreproducible due to, you know, statistical or procedural errors or science that is not reproducible because it's based on confidential PII or CBI that really shouldn't be made public. Science that's based on natural experiments, things that just happen naturally, volcano eruptions, you know, things like that, and also manmade ones such as, say, the BP blowout that, you know, where very valid science was extracted using an experiment that probably should not be repeated.

And, finally, valid experiments that have been performed and research that's been performed in the past at a time when the data retention requirements were different, you know, I very much appreciate when you read *Science Magazine* these days there's backup information that you can see at the end of the article.

And it's good that we've moved that way, but some of the best science, things like the Harvard Six Cities studies, if that is at risk, then people's lives are at risk. And I think to the extent that you're even involved in the final decisions over this, I urge you to stick up for retaining science, the best available science.

And, you know, as was mentioned, you know, Congress has considered and rejected a lot of these, you know, secret science and honest science proposals for good reasons. Can you understand why we might not be comfortable with having the final call on these being made by an coal lobbyist?

Dr. ORME-ZAVALETA. So, again, I think what you raise I think highlights a number of the comments that we received. There's a lot of confusion about what some of these terms meant, and that's part of the reason that we are looking to a supplemental to provide some clarification, provide some modifications, and seek comment on additional aspects of this.

We're going to go through the rulemaking process. We're currently at the interagency review of the supplement. The information that comes in from that, we will then take into consideration as we work through developing. So these are comments that we are all grappling with right now.

Mr. FOSTER. Yes. Now, would you characterize the formulation of the draft rule, which has been, you know, discussed, as something

that is bottom-up where the scientific staff, the career people in the EPA have come up with the first drafts and then these are looked over and approved by the top? Or would you characterize it as top-down where the political appointees consult with whoever they consult with, come up with a draft, and then you're at best asked to comment on——

Dr. ORME-ZAVALETA. So, again, I was not engaged in the drafting of the proposed rule.

Mr. FOSTER. So that happened at a level above you in the EPA?

Dr. ORME-ZAVALETA. Or outside of me, yes.

Mr. FOSTER. Or outside of you. And so above you in the org chart are all political appointees at this point?

Dr. ORME-ZAVALETA. I report to the Acting Deputy Administrator.

Mr. FOSTER. So everyone above yo—is the people involved in drafting a——

Dr. ORME-ZAVALETA. You know, we'd be happy to follow up if you'd like more information on the development of the proposal. We can follow up with you on that.

Mr. FOSTER. OK. Thank you. I'm out of time and yield back.

Dr. ORME-ZAVALETA. Yes.

Chairwoman JOHNSON. Thank you very much. Mrs. Fletcher.

Mrs. FLETCHER. Thank you, Chairwoman Johnson.

And, Dr. Orme-Zavaleta, thank you for being here again before this Committee.

Many scientific, academic, and public health and nonprofit organizations have formally expressed concern or opposition to the proposed rule, including, among others, the American Heart Association, the American Lung Association, the American Academy of Pediatrics, Children's Environmental Health Network, American Association for the Advancement of Science, the National Academies, the American Medical Association, the Association of American Medical Colleges, which has expressed its concern in writing. And I would like unanimous consent to enter their letter expressing objection into the record.

The list goes on and on and on. And so I want to ask you a few questions about the comments that you've received from these institutions. You've worked at the EPA for 40 years, and over the course of your career I assume that you've encountered these groups or groups like them and worked with them on many occasions. Do you believe that they are good-faith advocates for scientific research and public health?

Dr. ORME-ZAVALETA. I think many of the people that submitted comments, whether they are professional associations or others, all submitted those in good faith.

Mrs. FLETCHER. And we can agree that the organizations with which you're familiar and referencing, they perform worthwhile work in this area?

Dr. ORME-ZAVALETA. For some of those professional associations, yes.

Mrs. FLETCHER. So some of their concerns about the rule, two of the quotations that I've seen repeatedly are that they restrict the use of the best available science, that that was one outcome of the

rule, and that it will adversely affect decisionmaking processes. Are they wrong in that assessment?

Dr. ORME-ZAVALETA. So they raised a number of points, and we are looking at those very closely, very carefully as we consider, you know, the future development, future steps of the rulemaking process.

Mrs. FLETCHER. So later this morning in the next panel the CEO of the Michael J. Fox Foundation will testify about that foundation's concerns regarding the rule. And based on the written testimony that he submitted, he'll say that the rule puts individuals at great risk of having their Parkinson's or other diagnoses exposed if they participate in clinical studies. Now, certainly, that is a concern for my constituents. It's a concern for the researchers. We want to encourage these kinds of studies, and that concern is something that I think Americans share.

And on another issue, you know, as I'm sure you're aware, the EPA may be working on setting a maximum contaminant level for PFAS in the near future, and studies to date have revealed serious concerns and serious health problems associated with these chemicals. But the majority of what we know about PFAS contamination and the adverse health effects comes from studies that rely on personal information and health information of individuals.

So, currently, the scientists don't share that data for ethical and legal reasons.

Dr. ORME-ZAVALETA. Right.

Mrs. FLETCHER. Shouldn't the EPA reconsider the rule that would threaten to expose the personal information and could have a chilling impact both on participation and on research overall?

Dr. ORME-ZAVALETA. Yes, so we appreciate all the comments that we received on this, and we took that very topic to our Science Advisory Board for review. They provided some comments through that consultation process on how the Agency can continue to protect PII, as well as CBI, and how we can use that information in our decisionmaking process. So all of this is now coming in for our consideration as we go forward.

Mrs. FLETCHER. And are those protections for PII and CBI contained in the supplement to the rule?

Dr. ORME-ZAVALETA. So, again, I can't speak to the particulars of what's in the supplement at this point in time. Again, the supplement is something that we're looking to help clarify terms, as well as talk through additional modifications and gaining further input.

Mrs. FLETCHER. So with these principal concerns about participation, about PII, CBI, about getting the best possible science, are you also aware that, in addition to the diverse organizations and the other folks who have weighed in on these issues, that the CBO, working on the *Secret Science Reform Act of 2015*, discussed by my colleague Mr. Tonko earlier, that that would cost EPA approximately $250 million a year for several years going forward? And given the concerns of the scientific community, the concerns about the expense of complying with this rule, what is the likelihood or the possibility that EPA will abandon this rule in its entirety?

Dr. ORME-ZAVALETA. So I don't believe the—so we received a number of comments related to potential costs, and I'm aware that

there's been some earlier conversations. Again, all of that is going to be coming into our deliberations and our discussions as we finalize the rule. I don't believe that the committee's workgroup has gotten to that particular issue just yet, but that's something that will be weighed as we go forward.

Mrs. FLETCHER. Thank you very much. I've gone over my time, so, Madam Chairwoman, I yield back.

Chairwoman JOHNSON. Thank you very much. Ms. Wexton.

Ms. WEXTON. Thank you, Madam Chair. Thank you, Doctor, for joining us again today.

I want to return to the question of the statutory authority that EPA is citing in support of its proposed rule, specifically 5 U.S.C. 301, which we are putting on the board. So that section applies to the head of an executive department or military department may prescribe regulations and so on and so on. So is the EPA an executive department or a military department?

Dr. ORME-ZAVALETA. So EPA is in the executive branch.

Ms. WEXTON. OK.

Dr. ORME-ZAVALETA. It's an independent agency in the executive branch.

Ms. WEXTON. All right. Were you aware that 5 USC 301 also specifically outlines the executive departments that are included under that statute?

Dr. ORME-ZAVALETA. Yes, so similar to the earlier questions, I'm going to have to defer any questions related to the statutory authority because that's beyond my area of expertise, but we can follow up with you on that.

Ms. WEXTON. But we can agree that the EPA is not a military department?

Dr. ORME-ZAVALETA. Not that I am aware of.

Ms. WEXTON. OK. And then do we have the graphic of 101? So these are the executive departments that are specifically outlined as pertaining to 301's requirements. Can you show me where on there we have anything about the EPA?

Dr. ORME-ZAVALETA. So I think you raise a good point, and that's something that we'll consider going forward and we'll have our general counsel review that.

Ms. WEXTON. OK. It's concerning to me that the EPA is using this particular statute to justify this rulemaking and don't even have a shred of other authority in support of it. This is a basic housekeeping rule. It's really intended for internal operations for certain agencies, not for outward-facing big things like this proposed rule. So if they're planning to cite this again, I would suggest that they come up with something better.

Dr. ORME-ZAVALETA. Well, thank you. I appreciate the comment.

Ms. WEXTON. So switching gears just a little bit right now, the proposed rule has a provision that would allow the Administrator to provide case-by-case unilateral exemptions to the rule. Is that correct?

Dr. ORME-ZAVALETA. So that's in the proposed rule, yes.

Ms. WEXTON. OK. Does that cause you any concern at all?

Dr. ORME-ZAVALETA. Well, it's a topic that we heard a number of comments on, and that's something that's currently being discussed further.

Ms. WEXTON. What sort of guardrails or regulations or rules are there for that case-by-case exemptions?

Dr. ORME-ZAVALETA. I don't know of existing ones now, but I will note that in the Agency's rulemaking process, you know, there is a briefing. There are decisions that are made by the EPA Administrator, so the EPA Administrator already makes a number of decisions related to——

Ms. WEXTON. But this exemption provision for the proposed rule would apply only to the EPA Administrator, who would be able to exempt studies and science from the rule. Is that correct?

Dr. ORME-ZAVALETA. That's what's in the proposed rule, yes.

Ms. WEXTON. OK. And the EPA Administrator is a political appointee, is that correct?

Dr. ORME-ZAVALETA. And Senate-confirmed, yes.

Ms. WEXTON. And how long have you served with this EPA? How long have you been——

Dr. ORME-ZAVALETA. Thirty-eight years.

Ms. WEXTON. OK. And in your 38 years at the EPA, have you ever seen any instance where an EPA administrator was given this kind of authority to overrule career staff's decision to consider a particular study during the rulemaking process?

Dr. ORME-ZAVALETA. I haven't been involved in all of those types of decisions with administrators over all that time.

Ms. WEXTON. With the understanding that you have not been involved in every decision that's been made over the last 38 years, can you recall a time that that the Administrator has been allowed to overrule——

Dr. ORME-ZAVALETA. Yes, I can't really speak to that because I haven't been engaged in that.

Ms. WEXTON. But can you cite an example?

Dr. ORME-ZAVALETA. Not that I'm aware of.

Ms. WEXTON. OK. Very good. As a career scientist, how would you feel personally if a political appointee told you that you could arbitrarily consider some scientific research in your work but not other scientific research?

Dr. ORME-ZAVALETA. As a career scientist, I would have a conversation and make the case, but the Administrator makes the policy decision.

Ms. WEXTON. OK. Thank you very much. I have no further questions. I'll yield back.

Chairwoman JOHNSON. Thank you very much. Ms. Sherrill.

Ms. SHERRILL. Thank you. And, Dr. Orme-Zavaleta, our soldiers and their families make great sacrifices on our behalf, and we have a duty to take care of them. Military operations and facilities present unique environmental challenges, as I'm sure you know. And the Department of Defense (DOD) funds a great deal of important public health research relevant to its operations. Are you aware that the DOD was one of the 600,000 public commenters in response to the proposed rule?

Dr. ORME-ZAVALETA. Yes.

Ms. SHERRILL. And are you aware that in its public comment the DOD criticized the fundamental premise of the rule by saying, quote, "We do not believe that failure of the Agency to obtain a

publications underlying data from an author external to the Agency should negate its use," quote?

Dr. ORME-ZAVALETA. So I have not read all 600,000 comments that came in. I'm aware that they submitted comments, but I think those are the types of comments that our workgroup is going through right now.

Ms. SHERRILL. So does it concern you that the DOD thinks the EPA's position is incorrect?

Dr. ORME-ZAVALETA. I think it's one of many comments that we'll be going through. We heard from a wide variety of different sectors, and those are things that we will be looking at seriously going forward.

Ms. SHERRILL. And the DOD also wrote that the EPA should not apply the rule retroactively. Why is the EPA even considering retroactive application in the face of DOD's opposition?

Dr. ORME-ZAVALETA. So, again, to be clear, this rule does not apply retroactively. It applies prospectively to future rulemakings.

Ms. SHERRILL. But it does appear you won't be using some prior studies in future rulemakings, so it will——

Dr. ORME-ZAVALETA. We don't know that at this point.

Ms. SHERRILL. And so the DOD wrote in its comments that, quote, "It appears as if the EPA may have overlooked the advancement of science through open publication as a compelling interest," end quote. Can you walk me through why the EPA sees it fit to disregard the importance of open science, as laid out by the Defense Department in its public comment?

Dr. ORME-ZAVALETA. So I think, again, I don't know the specifics of what DOD raised. I would note that, however, in the rulemaking process, there is an interagency review step of which DOD is one of those agencies that has a chance to review and comment during that time.

Ms. SHERRILL. I would implore you to look carefully and listen carefully to what they say.

Can you explain why it seems that the DOD is concerned with protecting the health and wellness of our Nation's soldiers and families, and yet it appears from some of what we're seeing from this rule that the EPA is not as concerned with that?

Dr. ORME-ZAVALETA. So EPA's mission, again, is to protect public health and the environment, and that applies for civilian and military.

Ms. SHERRILL. So it is a huge concern, I would think, that the DOD has some real concerns with this proposed rule. Dr. Orme-Zavaleta, can you confirm that the EPA will fairly consider any further comments submitted by the DOD about the supplemental proposed rule? Because our soldiers and families really deserve nothing less.

Dr. ORME-ZAVALETA. Yes, we are looking seriously at all the comments that we received, and so additional comments that come in, we are weighing very carefully.

Ms. SHERRILL. Thank you, and I yield back.

Chairwoman JOHNSON. Thank you very much. Ms. Horn.

Ms. HORN. Thank you, Dr. Orme-Zavaleta, for your dedication and your work.

We've had some important questions I think raised today. I want to dig in a little bit more about the processes that are currently in place and the ability to understand and interpret the data. As a scientist, you've no doubt gone through years of training to understand the data that comes in front of you and to be able to make use of it, correct?

Dr. ORME-ZAVALETA. Yes.

Ms. HORN. And would you say that on average regular members of the public could take raw data and correctly interpret that information without proper training or insight?

Dr. ORME-ZAVALETA. So, again, these were similar to some of the comments that we've received in trying to get better clarification of data.

Ms. HORN. So I'm going to take that as a no.

And it's correct to say that the EPA, throughout its history and to this day, possesses time-tested methods that look at the scientific data, that have peer-reviewed processes of other individuals who have experience and expertise in those areas to interpret the data?

Dr. ORME-ZAVALETA. We do rely heavily on independent expert peer review——

Ms. HORN. So the EPA doesn't just take the assertions of a study and put it out without a peer-review process before it does anything with them?

Dr. ORME-ZAVALETA. Many of the studies already go through an independent peer-review process as part of the journal publication, for example, but how EPA might use that information may also go through additional peer review, as well as public comment if it's used in the decisionmaking process.

Ms. HORN. So as a scientist, you've no doubt been through this peer-review process. In your personal experience, have you seen this as effective in assessing the validity of the data?

Dr. ORME-ZAVALETA. We rely on it heavily.

Ms. HORN. And EPA has a number of advisory boards such as SAB and CASAC (Clean Air Scientific Advisory Committee) and other boards that evaluate the data and the science that comes before the EPA to evaluate or to set policies, correct?

Dr. ORME-ZAVALETA. Yes.

Ms. HORN. And this has been used throughout the history of the EPA to address, as you said, public health and environmental issues. These are no doubt critical to our whole communities from our Nation's security, our soldiers, sailors, the water that we drink, the air that we breathe. And would you say that the peer-review process and analysis by these advisory boards are a critical component to providing necessary checks and balances on the validity of the data without endangering the personally identifiable and very important health information that is needed to get to the heart of these problems?

Dr. ORME-ZAVALETA. All right. So peer review is a core tenet of how we ensure good science, and the particular question you've raised about PII and CBI is in fact one that we took to our Science Advisory Board.

Ms. HORN. So, bottom line, we do have processes in place to ensure that the studies that are being conducted are scientifically

valid, and there are checks in the process by individuals who understand the science and the data?

Dr. ORME-ZAVALETA. Yes.

Ms. HORN. OK. Thank you. I yield back.

Chairwoman JOHNSON. Thank you very much. Mr. Lamb.

Mr. LAMB. Thank you, Madam Chairwoman.

Dr. Orme-Zavaleta, are you familiar with the application of cost-benefit analysis to an EPA rulemaking?

Dr. ORME-ZAVALETA. I am familiar with it, but I have not conducted that personally.

Mr. LAMB. Administrator Wheeler emphasizes the importance of cost-benefit analysis as part of his administration, correct?

Dr. ORME-ZAVALETA. I don't know for sure.

Mr. LAMB. On May 13, 2019 of this year he sent an agency-wide memo in which he endorsed a sound, transparent, and consistent approach to evaluating benefits and costs. Do you remember that?

Dr. ORME-ZAVALETA. Right offhand, no.

Mr. LAMB. OK. Was a cost-benefit analysis done for this proposed rule?

Dr. ORME-ZAVALETA. I'm not aware that one was done.

Mr. LAMB. OK. Do you know that it was not done?

Dr. ORME-ZAVALETA. We could follow up with you and provide you that information.

Mr. LAMB. So you don't know whether it was done or not?

Dr. ORME-ZAVALETA. No, because I was not involved in developing the proposed rule.

Mr. LAMB. OK. Do you know if any cost-benefit analysis is planned for the future of this proposed rule or supplemental?

Dr. ORME-ZAVALETA. We will be looking at the number of comments that came in related to cost as we go forward in developing a final rule. So I think that will come into play, but it hasn't been part of the conversation yet.

Mr. LAMB. Do you know if they will do a formal cost-benefit analysis?

Dr. ORME-ZAVALETA. We don't know yet.

Mr. LAMB. You don't know. Will you commit that if one has already been done or if one is done, you will share the cost-benefit analysis with this Committee?

Dr. ORME-ZAVALETA. I will have to follow up with you on that.

Mr. LAMB. OK. Behind you, your assistant is nodding her head yes——

Dr. ORME-ZAVALETA. OK.

Mr. LAMB [continuing]. So can you confirm——

Dr. ORME-ZAVALETA. No, she's not confirming. We're not there yet in those kinds of discussions.

Mr. LAMB. Is there any reason why you would not share a cost-benefit analysis with this Committee?

Dr. ORME-ZAVALETA. If we conduct one and it's going to be part of the final rule, then that will be shared with everyone.

Mr. LAMB. If you conduct one and as part of the final rule, you will share it with this Committee, is that correct? Yes?

Dr. ORME-ZAVALETA. Yes.

Mr. LAMB. OK. Thank you. Have you ever heard of something called the Health Effects Institute (HEI)?

Dr. ORME-ZAVALETA. Yes.

Mr. LAMB. And is it correct to say that the Health Effects Institute is a collaboration equally funded between the motor vehicle industry and the EPA for research purposes?

Dr. ORME-ZAVALETA. Yes, and in fact from EPA both Office of Research and Development and Office of Air and Radiation support the Health Effects Institute.

Mr. LAMB. And in 2000, the Health Effects Institute did a reanalysis of the Harvard Six Cities study and the American Cancer Society study and confirmed the findings of those original studies. Are you aware of that?

Dr. ORME-ZAVALETA. Yes.

Mr. LAMB. So, in other words, the auto industry paid half the cost, along with the EPA, of confirming that those two Six Cities air quality studies were accurate. Is that correct?

Dr. ORME-ZAVALETA. So both the authors of the Harvard Six Cities study and the author of the American Cancer Society study requested—given a lot of the scrutiny and questions placed on their studies, requested that the Health Effects Institute do a reanalysis, and that's how that played out.

Mr. LAMB. And the result of that playing out was that they confirmed the finding of those studies, correct?

Dr. ORME-ZAVALETA. Correct, yes.

Mr. LAMB. So, again, in other words, the auto industry helped to pay for the effort to confirm those two studies, correct?

Dr. ORME-ZAVALETA. Well, they paid for the Health Effects Institute. I can't say exactly what resources were used to support the reanalysis.

Mr. LAMB. OK. Would you agree with Dr. Rice on our next panel that using the HEI to vet results like this is a practical and proven approach to the concerns about transparency specifically without compromising the health data privacy of study participants?

Dr. ORME-ZAVALETA. So the way the HEI approached this is they formed an independent panel that conducted analysis, and then there was a separate peer review of that analysis that was performed.

Mr. LAMB. So the auto industry, through this process, was able to confirm the results of a study without releasing the health data publicly, correct?

Dr. ORME-ZAVALETA. So the auto industry supports HEI.

Mr. LAMB. Which confirmed the results of this study without publicly releasing the health data, correct?

Dr. ORME-ZAVALETA. Yes.

Mr. LAMB. Thank you. Madam Chairwoman, I yield back.

Chairwoman JOHNSON. Thank you very much. That concludes our questioning for this panelist witness. And let me thank you, Dr. Orme-Zavaleta, for coming, and you're dismissed.

Dr. ORME-ZAVALETA. Thank you very much.

Chairwoman JOHNSON. We will have a short recess just to let the second panel be set up.

[Recess.]

Chairwoman JOHNSON. Welcome back at this time. And I'd like to introduce our second panel of witnesses. First, we have Dr. Linda Birnbaum. Dr. Birnbaum served as Director of the National

Institute of Environmental Health Sciences from 2009 to 2019, and she is speaking today as a private citizen.

Dr. Mary Rice is an Assistant Professor of Medicine at Harvard Medical School and a Pulmonary and Critical Care Physician at Beth Israel Deaconess Medical Center in Boston, Massachusetts.

And third, we have Dr. David Allison. Dr. Allison is the Dean of Indiana University's Bloomington School of Public Health. He has served on the Replicability in Science Committee at the National Academies of Sciences, Engineering, and Medicine.

And Dr. Brian Nosek. Dr. Nosek is Professor of Psychology at the University of Virginia and the Co-Founder and Executive Director of the Center for Open Science in Charlottesville, Virginia.

And last but not least Dr. Todd Sherer, the CEO of the Michael J. Fox Foundation for Parkinson's Research.

As with our first panel, you each will have 5 minutes for your spoken testimony. Your written testimony will be included in the record for the hearing. And when all of you have completed your spoken testimony, we will begin the round of questions. Each Member will have 5 minutes to question the panel.

We will begin now with Dr. Linda Birnbaum.

TESTIMONY OF DR. LINDA S. BIRNBAUM, FORMER DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES, 2009–2019

Dr. BIRNBAUM. Good morning, Chairwoman Johnson, Ranking Member Lucas, and distinguished Members of the Committee. I'm Linda Birnbaum, recently retired after 40 years of Federal service. I was Director of NIH's (National Institute of Health's) National Institute of Environmental Health Sciences (NIEHS) and with HHS' (Department of Health and Human Services) National Toxicology Program for the past 10 years. Prior to that, I spent 19 years at EPA for most of it directing the Agency's largest health research division. I've conducted scientific research to better understand how the environment impacts our health and have published over 800 peer-reviewed papers, book chapters, and reports.

I'm a member of the National Academy of Medicine, the recipient of the North Carolina Governor's Award for Science, the former President of the Society of Toxicology, the Vice President of the International Union of Toxicology, Chair of the Toxicology Division of the American Society of Pharmacology and Experimental Therapeutics, and the recipient of multiple honorary degrees and awards.

I've always been involved in the conduct of research, much of which has been used in making policy decisions. My work and that which I have overseen has involved basic biomedical research, toxicology, and public health. I've never been a regulator myself.

My comments today are those of a private citizen and do not reflect the views of NIEHS, NIH, or HHS.

I want to focus on three basic issues. The first is the core values of scientific studies, which involve people. Because it is unethical to intentionally expose people to chemicals of concern, observational human studies compare populations who have different exposures. People provide personal information such as medical information, as well as behaviors in confidence that their own data will not be openly shared.

Human studies require confidentiality to be conducted. It is unethical to reveal individual human data. In many epidemiology studies, scientists and subjects work closely together in design, conduct, interpretation, and communication of the findings. Thus, the second point is that the impact of EPA's proposed transparency rule will not only make it more difficult for human studies to be conducted ethically but in many cases will make it impossible to use any information collected not only prospectively but looking back at the vast treasure trove of existing investigations.

The third point involves EPA's mandate to use the best available science to protect the environment and public health. Scientific knowledge is constantly evolving. While a given experiment may answer one question, it invariably raises others. There is always some uncertainty in science, but that does not mean that decisions cannot be made, which is why it is so important to use all the data.

While I am a toxicologist, that does not mean I prefer using animal data when data from people exists. Nature is inherently conservative, and studies in various animal models can inform us about the potential for human risk. We can investigate, observe the effects mechanistically in animal and cell culture models, and then ask whether the same mechanisms exist in humans. Such approaches all provide biological plausibility to human observational studies.

When we have several epidemiology studies in different populations conducted by various investigators and achieve the same results and they're supporting animal and mechanistic evidence, why would we think that we can't believe the findings? Why would we want to rely solely on 20th-century methodologies in the 21st century? Good laboratory practice only assures that we know what was done, not that the right question was asked.

The same can be said of some guideline studies, which may be inappropriate when you're looking for effects of pharmaceuticals in an individual rather than effects of environmental exposures on a population. Small effects may not be measurable in an individual but may have large impacts on a population. For example, developmental exposure to lead results in the loss of several IQ points in a population, which has significant economic and societal costs, but you can't know whether each of us would be a little smarter if we hadn't been exposed to lead.

Today, we have systematic review of the lead data which confirm that there is no safe level for lead. In fact, the more we look at population data, there is no threshold for many exposures, including arsenic, mercury, and air pollution. Thresholds are often a function of analytical methodology. Why would EPA want to enshrine threshold approaches in regulation?

EPA's proposed transparency rule in fact will block the use of the best science. It will prevent EPA from using the best available science in making policy. In fact, it will practically lead to the elimination of science from decisionmaking. EPA's current proposal would silence science and block its ability to meet its mission of protecting human health and the environment.

Thank you, and I welcome your questions.

[The prepared statement of Dr. Birnbaum follows:]

Oral Statement as Prepared for Delivery by

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S, Retired Former Director of NIEHS and NTP

House Committee on Science, Space, and Technology

Hearing on "Strengthening Transparency or Silencing Science? The Future of Science in EPA Rulemaking"

November 13, 2019

Good morning Chairwoman Johnson, Ranking Member Lucas, and Distinguished members of this Committee. I am Linda Birnbaum, recently retired after 40 years of federal service. I was Director of NIH's National Institute of Environmental Health Sciences and of the HHS' National Toxicology Program the past 10 years. Prior to that I spent 19 years at EPA, for most of it directing the Agency's largest health research division. I have conducted scientific research to better understand how the environment impacts our health, and have published over 800 peer reviewed papers, book chapters, and reports.

I am a member of the National Academy of Medicine, the recipient of the North Carolina Governor's Award for Science, former president of the Society of Toxicology, Vice-president of the International Union of Toxicology, chair of the Toxicology

Division of the American Society of Pharmacology and Experimental Therapeutics, and the recipient of multiple honorary degrees and awards. I have always been involved in the conduct of research, much of which has been used in making policy decisions. My work, and that which I have overseen, has involved basic biomedical research, toxicology, and public health. I have never been a regulator myself.

My comments today are those of a private citizen and do not reflect the views of NIEHS, NIH, or HHS. I want to focus on 3 basic issues. The first is the core values of scientific studies which involve people. Because it is unethical to intentionally expose people to chemicals of concern, observational human studies compare populations who have differing exposures. People provide personal information, such as medical information as well as behaviors, in confidence that their own data will not be openly shared. Human studies require confidentiality to be conducted. It is unethical to reveal individual human data. In many epidemiology studies, scientists and subjects work closely together in design, conduct, interpretation, and communication of the findings. Thus, the second point is that the impact of EPA's proposed transparency rule will make it not only more difficult for human studies to be conducted ethically, but in many cases will make it impossible to use any information collected, not only prospectively, but

looking back at the vast treasure trove of existing investigations.

The third point involves EPA's mandate to use the best available science to protect the environment and public health. Scientific knowledge is constantly evolving. While a given experiment may answer one question, it invariably raises others. There is always some uncertainty in science, but that does not mean that decisions cannot be made, which is why it is so important to use ALL the data. While I am a toxicologist, that does not mean I prefer using animal data when data from people exists! Nature is inherently conservative, and studies in various animal models can inform us about the potential for human risk. We can investigate observed effects mechanistically in animal and cell culture models and then ask whether the same mechanisms exist in humans. Such approaches all provide biological plausibility to human observational studies. When we have several epidemiology studies in different populations conducted by various investigators and achieve the same results, and there is supporting animal and mechanistic evidence, why would we think that we can't believe the findings?

Why would we want to rely solely on 20th century methodologies in the 21st century? Good Laboratory practice only assures that we know what was done, NOT that the right

question was asked. The same can be said of some guideline studies, which may be appropriate when you are looking for effects of pharmaceuticals in an individual, rather than effects of environmental exposures on a population. Small effects may not be measurable in an individual but may have large impacts on a population. For example, developmental exposure to lead results in a loss of several IQ points in a population, which has significant economic and societal costs, but you can't know whether each of us would be a little smarter if we hadn't been exposed to lead. Today we have systematic review of the lead data which confirm that there is no safe level for lead. In fact, the more we look at population data, there is no threshold for many exposures, including arsenic, mercury, and air pollution. Thresholds are often a function of analytical methodology. Why would EPA want to enshrine threshold approaches in regulation?

EPA's proposed transparency rule in fact will block the use of the best science. It will prevent EPA from using the best available science in making policy. In fact, it will practically lead to the elimination of science from decision making. EPA's current proposal would silence science and block its ability to meet its mission of protecting human health and the environment.

Thank you. I welcome your questions.

Short Resume

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S. is the former Director of the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health, and the National Toxicology Program (NTP). As a retiree, she was granted scientist emeritus status. As a board-certified toxicologist, Birnbaum served as a federal scientist for 40 years. Prior to her appointment as NIEHS and NTP Director in 2009, she spent 19 years at the U.S. Environmental Protection Agency (EPA), where she directed the largest division focusing on environmental health research.

Birnbaum has received many awards and recognitions. In 2016, she was awarded the North Carolina Award in Science. She was elected to the Institute of Medicine of the National Academies, one of the highest honors in the fields of medicine and health. She was also elected to the Collegium Ramazzini, an independent, international academy comprised of internationally renowned experts in the fields of occupational and environmental health and received an honorary Doctor of Science from the University of Rochester and a Distinguished Alumna Award from the University of Illinois. She also received an Honorary Doctorate from Ben-Gurion University, Israel and Amity University, India; the Surgeon General's Medallion 2014; and 14 Scientific and Technological Achievement Awards, which reflect the recommendations of EPA's external Science Advisory Board, for specific publications.

Birnbaum is an active member of the scientific community. She was vice president of the International Union of Toxicology, the umbrella organization for toxicology societies in more than 50 countries, and former president of the Society of Toxicology, the largest professional organization of toxicologists in the world. She is the author of more than 800 peer-reviewed publications, book chapters, and reports. Birnbaum's own research focuses on the pharmacokinetic behavior of environmental chemicals, mechanisms of action of toxicants including endocrine disruption, and linking of real-world exposures to health effects. She is also an adjunct professor in the Gillings School of Global Public Health, the Curriculum in Toxicology, and the Department of Environmental Sciences and Engineering at the University of North Carolina at Chapel Hill, as well as in the Integrated Toxicology and Environmental Health Program at Duke University.

A native of New Jersey, Birnbaum received her M.S. and Ph.D. in microbiology from the University of Illinois at Urbana-Champaign.

Chairwoman JOHNSON. Thank you very much. Dr. Rice.

TESTIMONY OF DR. MARY B. RICE,
ASSISTANT PROFESSOR OF MEDICINE,
HARVARD MEDICAL SCHOOL, AND PULMONARY AND
CRITICAL CARE PHYSICIAN,
BETH ISRAEL DEACONESS MEDICAL CENTER

Dr. RICE. Madam Chairwoman, Ranking Member, and Members of the Science Committee, thank you for the opportunity to speak today. I'm a Pulmonary and Critical Care Physician at Beth Israel Deaconess Medical Center at Harvard Med School where I treat patients with lung disease and study the effects of air pollution on lung health.

I am speaking on behalf of the American Thoracic Society (ATS). We are a 16,000-member medical professional organization dedicated to the prevention of lung disease, and we treat patients with illnesses such as asthma, COPD (chronic obstructive pulmonary disease), or lung cancer that are caused or worsened by air pollution. We have serious concerns about the EPA's proposal and what it means for our patients and the health of Americans, especially children and the elderly, who are especially susceptible to pollution.

Our major objection to this proposal is that by excluding studies whose underlying data cannot be shared with the public, it would effectively block EPA from considering critical studies that involve real people living in the real world and exposed to day-to-day levels of pollution. These epidemiology studies provide the most relevant information to protect the health of the American public. They have repeatedly shown that pollution is linked to premature death in older adults due to heart attacks and respiratory causes, to worse lung function and asthma attacks among kids and adults.

There are multiple mechanisms for data-sharing and resolution of controversy in research, but this proposal is not about improving transparency. It is a strategy to block sound science. I'll explain how this proposal introduces a process barrier.

Before a health study can begin, investigators must complete a rigorous review by an institutional review board to ensure that the risks of participating in the study are as low as possible, including risks to privacy. Study participants sign a consent form that details how their private data will be protected. Researchers cannot share publicly data about people's medical problems, hospitalizations, or deaths or the addresses of their homes and schools. So under this rule, EPA would disregard such studies in its rulemaking because the demand for public data sharing cannot be met.

Ignoring medical research in regulatory decisionmaking is the opposite of progress, and it's not in the interest of human health. As a doctor, I would do my patients a disservice if I ignored a huge chunk of the scientific literature in making my medical decisions. And the same would be true for EPA if it ignored evidence in making decisions about toxins in our environment.

It's naive to argue that de-identification will fully protect the privacy of study participants in today's era of big data. For example, a recent study in California took the HIPAA (*Health Insurance Portability and Accountability Act*)-compliant de-identified data

from an air pollution study and, using publicly available databases and programs, the investigators re-identified one in four study participants. Now, imagine the long-term consequences of leaking private health and address information as a result of this proposal. Would you be willing to enroll yourself or your child in a study about toxins in the water, air, or food if you knew EPA would take your data and share it with the world?

Second, I want to emphasize that this process barrier is a familiar and sneaky strategy to discredit science that was pushed by big tobacco in the 1990s. As mentioned earlier, there's an internal memo that I've included with my testimony from 1996 by tobacco lawyer Chris Horner that lays out a detailed strategy for how the tobacco industry can discredit scientific findings that it doesn't like.

Mr. Horner advised big tobacco to focus on process as opposed to scientific substance because attacking the substance of the science that secondhand smoke is bad for health would be a public relations nightmare. He advised big tobacco to lobby for the construction of, quote, "explicit procedural hurdles the EPA must follow in issuing scientific reports." The memo used the same terms of, quote, "transparency" and, quote, "sound science" that the EPA is now using in its proposal.

The American Thoracic Society is not fooled. This proposal is not about transparency; it's about discrediting or ignoring science about the harmful effects of toxic exposures to our kids and all adults.

And one final point, this proposal gives broad discretion to the EPA Administrator to, quote, "exempt significant regulatory decisions on a case-by-case basis." And the ATS is concerned that this grants excessive authority to the Administrator, without accountability to the public to cherry-pick studies that support political objectives and ignores studies, no matter how robust, that have inconvenient results. This flies in the face of any transparent scientific process.

Our patients with lung disease and all Americans depend on the EPA to make well-informed decisions based on the best available evidence to set environmental standards that protect their health.

On behalf of the ATS, I implore this Committee and Congress to prevent EPA from adopting process proposals that block peer-reviewed research from being considered in its rulemaking, and I look forward to your questions. Thank you.

[The prepared statement of Dr. Rice follows:]

American Thoracic Society
American Journal of Respiratory and Critical Care Medicine | American Journal of Respiratory Cell and Molecular Biology | Annals of the American Thoracic Society

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Comments of the American Thoracic Society
Before the House Science Committee
Regarding EPA's Proposed Strengthening Transparency in Regulatory Science Rule
Presented by
Mary B. Rice MD MPH
November 13, 2019

Mr. Chairman, Ranking member and members of the House Science Committee, thank you for the opportunity to speak at today's hearing.. I am a pulmonary and critical care physician and assistant professor of medicine at Harvard Medical School, where I treat patients with lung disease, and investigate the effects of air pollution on lung health. I am speaking today on behalf of the American Thoracic Society (ATS). We are a 16,000-member medical professional organization of physicians, researchers, nurses, respiratory therapists and allied health professionals dedicated to the prevention, detection, treatment, cure and research of respiratory disease and critical illness. Our members treat patients whose illnesses were caused or worsened by air pollution, including patients with lung disease like asthma, cystic fibrosis or COPD, and critical illnesses like pneumonia. Our members are also engaged in basic, human, clinical and epidemiological research studies on the health effects of air pollution. We have serious concerns about the EPA's proposed rule called "Strengthening Transparency in Regulatory Science," and what it means for our patients who are especially susceptible to the harmful effects of air pollution.

The proposed rule requires that the EPA make publicly available the underlying data from "pivotal regulatory science" studies that the agency relies on to establish major regulatory policy - including standards, exposure thresholds, and dose-response relationships. **Our major objection to this rule is that by excluding studies whose underlying data cannot be shared in a public database (e.g. due to study participant privacy concerns), this rule would effectively block the use of most epidemiological research studies from EPA rule-making.** Instead of promoting transparency in regulatory science, this rule would decrease transparency, by giving the EPA administrator unchecked authority to pick and choose which research studies will inform policies that affect the

health of the U.S. population. The ATS strongly favors transparency in research, and I will outline some of the ways in which the NIH and scientific community are promoting transparency and replication of research while protecting the privacy of research participants. Our key take-away points about this obstructionist and potentially harmful EPA rule are summarized below:

1. **Under the rule, EPA would disregard studies of how pollution affects the health of children and adults**

This rule introduces a barrier that will exclude from EPA consideration any studies whose underlying data cannot be shared with the public. While studies that expose laboratory animals to pollution may be able to meet this demand, many studies of how pollution exposure affects risk of death and disease among real people (i.e. epidemiological studies) will not be able to meet the demand of public data-sharing. Sharing data about diagnoses, hospitalization or death, and address information about the home, school and work locations of study participants is not always feasible, because the privacy of study participants must be protected. Before a health study of children or adults can even begin, investigators must complete a rigorous review by an Institutional Review Board to ensure that the risks to study participants, including risks to privacy, are minimized. As part of its review, the Institutional Review Board carefully scrutinizes the consent form that study participants sign before joining a study, to ensure the form details how participants' private data might be shared, and what safeguards will remain in place to protect their privacy after study completion. This new rule would prevent most research about health effects of pollution in the real world from informing EPA policy, because the underlying data about the participants of these health studies cannot be shared with the public.

Ignoring medical research in regulatory decision-making is the opposite of progress, and is not in the interest of human health. As a doctor, I would do my patients a disservice if I ignored the best available evidence to guide my decisions. Medical guidelines are based on the weight of the evidence, which emerges from multiple peer-reviewed scientific studies, not just one study. It would be malpractice for a doctor to apply such a "transparency" standard, as proposed for the EPA, to the care of patients, because it would involve ignoring large portions of the scientific literature. Such a standard would lead to misinformed treatment decisions, like offering drugs that have been found to be unsafe, and may deny patients the best treatments that modern medicine offers today. Patients would suffer if the medical community ignored scientific evidence to guide therapy. The same would be true if the EPA ignored evidence in making decisions about air quality and other environmental standards that affect the health of children and adults living in the United States.

2. **The proposed rule could jeopardize confidential information about study participants**

The proposed rule states that the EPA will apply the tools and methods developed by other Federal agencies to de-identify private information. The rule cites a Department of Health and Human Services (HHS) document as an example of how data can be de-identified to protect

confidential patient information.[1] However, the very HHS guidance that EPA references notes that de-identification does not fully protect patient information, stating:

"Both methods, even when properly applied, yield de-identified data that retains some risk of identification. Although the risk is very small, it is not zero, and there is a possibility that de-identified data could be linked back to the identity of the patient to which it corresponds."

I have included the full print out of the HHS guidance – with the above text highlighted – with my statement. In environmental health research, which often involves information about location, it may be especially easy to re-identify study participants. A recent (2017) study by Sweeney and colleagues took the HIPAA-compliant de-identified data from an air pollution epidemiology study, and using other publicly available data sets and commercially available computer programs, successfully re-identified 25% of study participants.[2] Even the Centers for Medicare and Medicaid Services requires researchers who use Medicare information to report only summary information across large numbers of people to ensure that individual people cannot be identified. A recent publication in *Nature Communications* strongly challenges the "de-identification release-and-forget" approach, finding that nearly 99.98% of Americans could be re-identified with just 15 demographic variables.[3]

EPA's proposal to make the underlying data of policy-relevant studies fully available to the public in de-identified form risks disseminating the sensitive information about health problems, deaths and addresses of study participants. The long-term consequences of such a data breach could be devastating, not only for the study participants whose private health information is leaked, but also for the future of environmental health research. Imagine how such a breach would affect anyone's willingness to participate in an environmental health research study in the future.

3. Multiple mechanisms and safeguards promote research transparency and data-sharing

The ATS supports efforts by the NIH to fund and promote transparency in health research, including environmental health research. Major funding sources including the National Institutes of Health (NIH) and the U.S. EPA require scientists to establish a data sharing plan as part of the scientific granting process. Major journals that publish research on how pollution affects health, including *Lancet, the Journal of the American Medical Association*, the *New England Journal of Medicine*, and others require researchers to specify a mechanism for sharing data as part of their manuscript submission. To be clear, these data sharing plans are intended to facilitate data sharing within the scientific community – i.e. from one scientist to another—to facilitate replication of findings, or pooling of data from multiple studies. The receiving scientist must demonstrate that he/she has skills, resources and safeguards to appropriately use and protect the data. When research data is shared, a data use agreement is usually signed by both institutions to guarantee those safeguards are in place.

In addition, there are multiple data repositories for NIH-funded research in which de-identified data is deposited under NIH policy. For these NIH-designed data repositories, the informed

consent signed by study participants when they joined the study determines if the data is appropriate for the NIH repository, and whether the data should be available through unrestricted (public) or controlled access (e.g. for scientists with safeguards in place).

The proposed EPA rule does not fund a mechanism for improving scientific transparency. Rather, it creates an obstructive mechanism *(a process barrier)* by which environmental health research, especially epidemiologic research that cannot be fully de-identified or publicly shared, can be excluded by EPA in its rulemaking.

4. An independent EPA-funded resource already exists to resolve scientific disputes

The Health Effects Institute (HEI) is a research group funded equally by the motor vehicle industry and the U.S. EPA that has played a key role in resolving disputes about pivotal environmental health research that informs EPA regulation. For example, in July of 2000, the HEI conducted a re-analysis of two early air pollution studies: the Harvard Six Cities Study and the American Cancer Society Study, on the link between particulate matter pollution and mortality. The re-analysis was conducted by a team of independent scientists, and overseen by a broad board of stakeholders, and confirmed the findings of the original studies.[4] In addition, to assess differences in industry versus academic/NCI analyses regarding risk estimates for diesel exhaust as a carcinogen, HEI held a public workshop and convened an independent panel of scientists. HEI then issued a report verifying the original findings in that scientific controversy, too.[5] These past interventions by HEI to independently verify the data analysis for studies on controversial scientific issues provide a generalizable model to address the challenge of privacy vs. transparency in evaluating scientific research directly relevant to the regulatory process. Using the HEI to vet such key results is a practical and proven approach to address concerns raised about transparency, without compromising health data privacy of study participants.

5. The rule follows a familiar script for how industry can discredit sound scientific findings

What EPA is proposing comes straight out of the playbook of the tobacco industry and its attempts to discredit research findings that link environmental tobacco smoke exposure to health problems. I have included an internal tobacco industry memo,[6] authored by tobacco lawyer Chris Horner in 1996, that describes in detail the steps that can be taken to discredit scientific information. These steps included the construction of "explicit procedural hurdles the Agency must follow" and to address "process as opposed to scientific substance." The memo used the same terms of "transparency," "sound science" and calls for "reproducible" science - the language that the EPA is now using in its proposed rule. The goal of this strategy, as described by Mr. Horner, was to help RJ Reynolds avoid having to "undo the (EPA) Agency's work" "after-the-fact." Mr. Horner served on the EPA transition team.

Soon after the date of that memo to RJ Reynolds, congressional efforts were underway to mandate the release of environmental health research data to the public. I have enclosed a manuscript by ATS member Dr. George Thurston,[7] published in 1998 and still as relevant

today as it was 20 years ago, in which he articulates the risks of public release of environmental health data, and provides historical examples of what can happen when vested interests analyze health data to achieve corporate aims. In one example, consultants for the RJ Reynolds Company used a Georgia state law to access raw research data to discredit study findings by Dr. Paul Fischer, which concluded that the use of cartoon characters (such as "Joe Camel") appealed to children. RJ Reynolds even went as far as to request the telephone numbers of children who participated in the study. While Dr. Fischer's research was later validated by others (and RJ Reynolds later admitted targeting children in advertising), Dr. Fischer abandoned his research career as a result of the attacks he endured. The EPA rule would deliver sensitive environmental health research data straight to the potentially misleading manipulations of vested interests. Special interest groups, who may not like the conclusions of health studies about health risks of pollution and chemicals, will be free to report their alternative findings without peer review, and without having to demonstrate they have the skills and resources to appropriately analyze and interpret the data in an unbiased manner.

6. The proposed rule gives unchecked discretion to the EPA Administrator.

The proposed rule includes a provision allowing the Administrator to "exempt significant regulatory decisions on a case-by-case basis." The ATS is concerned that delegating the discretionary authority solely to the Administrator would grant excessive authority to one person without accountability to the public. Allowing the Administrator to pick research in this way is secretive, and flies in the face of any transparent ethical process.

Conclusion

In summary, this rule does not improve on existing measures to enhance the transparency of environmental health research, and instead would function as a roadblock against the use of epidemiologic research in EPA rule-making. This misguided rule, if implemented, would lead EPA to make decisions based on incomplete information. Our patients with lung disease, and all Americans, depend on the EPA to make well-informed decisions—based on the best available evidence—to set environmental standards that protect their health.

On behalf of the ATS, I greatly appreciate the Committee's attention to this important scientific issue. I would strongly urge this Committee and Congress to ensure that EPA uses the weight of the evidence in its policy-setting decisions, and to prevent EPA from adopting process rules that block peer-reviewed research from being considered. I look forward to answering your questions.

Mary B. Rice, MD MPH
Chair, ATS Environmental Health Policy Committee

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Mary B. Rice MD
Assistant Professor of Medicine
Harvard Medical School

Dr. Rice has a longstanding interest in environmental exposures and respiratory health. She graduated from Harvard College in 1999 with a degree in environmental science and public policy. After working in New York City as a consultant and completing premedical studies, she spent a year pursuing research and public policy analysis at the Columbia University Center for Children's Environmental Health, where she studied air pollution, genetic susceptibility, and pulmonary outcomes in a birth cohort of children in New York City. As a medical student at Harvard Medical School, she joined Students for Environmental Awareness in Medicine, a student-run nonprofit. She led the organization as a second year student and organized a conference on health and the environment in Washington DC, and met with senators and staff about air pollution and health. She also developed a small community-based participatory research project in collaboration with Tufts and Boston University to study the prevalence of asthma and environmental triggers in the low-income community of Dorchester. As a resident, she worked with Dr. David Christiani of Massachusetts General Hospital, investigating the effects of particulate matter exposure on lipid levels in a cohort of welders, which resulted in a first author publication in the *Journal of Occupational and Environmental Medicine*. She then pursued clinical and research training in pulmonary and critical care medicine at Harvard Medical School, with the goal of understanding how respiratory health is affected by environmental exposures.

As a pulmonary fellow, she selected as a primary research mentor Dr. Murray Mittleman, a physician epidemiologist at Beth Israel Deaconess Medical Center and the Harvard School of Public Health with expertise in epidemiologic methods and environmental epidemiology. Under Dr. Mittleman's mentorship, Dr. Rice completed coursework for a Master's Degree in Public Health at the Harvard School of Public Health (graduation March 2015). She successfully obtained an F32 NRSA career development award from the National Institute for Environmental Health Sciences to study air pollution exposure and lung function in the Framingham Heart Study. This research has resulted in important scientific findings. In particular, Dr. Rice and colleagues found that previous-day exposure to criteria air pollutants, within current EPA standards, was associated with lower lung function in the Framingham Heart Study. Secondly, Rice and colleagues found that long-term estimates of traffic and particulate air pollution exposure are associated with accelerated lung function decline, of a magnitude similar to the effect of former smoking. These findings resulted in two first author manuscripts in the *American Journal of Respiratory and Critical Care Medicine* and a first place award in the 9th Annual Respiratory Disease Young Investigators' Forum.

Dr. Rice is a member of the faculty of Harvard Medical School and Beth Israel Deaconess Medical Center and was promoted to the position of Instructor in Medicine in July, 2014. She is board certified in internal medicine, pulmonary disease and critical care medicine. She spends 75% of her effort investigating associations between measures of long-term exposure to ambient air pollution and pulmonary structural abnormalities in generally healthy adults and has proposed new research to study associations between measures of daily pollution exposure and lung function and respiratory symptoms in adults with chronic obstructive pulmonary disease (COPD). As a clinician, Dr. Rice cares for ambulatory patients in her general pulmonary clinic and for hospitalized patients on the wards and in the intensive care unit of Beth Israel Deaconess Medical Center.

Ms. BONAMICI [presiding]. Thank you for your testimony.
I now recognize Dr. Allison for 5 minutes for your testimony.

**TESTIMONY OF DR. DAVID ALLISON,
DEAN, SCHOOL OF PUBLIC HEALTH,
INDIANA UNIVERSITY-BLOOMINGTON, AND MEMBER,
"REPRODUCIBILITY AND REPLICABILITY IN SCIENCE"
COMMITTEE, THE NATIONAL ACADEMIES OF SCIENCES,
ENGINEERING, AND MEDICINE**

Dr. ALLISON. OK. Good morning, Ms. Bonamici, Ranking Member Lucas, and Members of the Committee. Thank you for the opportunity to speak with you today. My name is David Allison, and I have the privilege of serving as the Dean of the School of Public Health at Indiana University Bloomington, although today I am not speaking on behalf of Indiana University but as a member of the National Academies' Committee on Reproducibility and Replicability in Science. I've dedicated my career to the pursuit of knowledge through rigorous science and its truthful communication.

My written testimony provides background on the National Academies' Committee, a copy of the executive summary of the committee's report, and an expanded version of my remarks here.

Science is a method to discover and share knowledge about the world. In science, three things are vital: The data, the methods used to collect the data which give them their probative value, and the logic connecting the data and methods to conclusions. These are the substrates of science.

The data, methods, and logic used to inform conclusions need to be thoroughly and transparently described so that others may understand what was done and thereby judge the probative value of the data for the conclusions. As we all heard from our middle school mathematics teachers, show all your work. That is, it is not enough to provide an answer. One must show us how one got the answer. Transparency has value.

I will now address the questions posed by you and conclude my testimony with my own perspectives on the EPA proposed rule. The first question posed to me was what is the definition of reproducibility? The Academies' study defined reproducibility as obtaining consistent results using the same input data, computational steps, methods and codes, and conditions of analysis.

Another important concept is scientific rigor. Rigor can be defined as the diligent application of scientific procedures that, based on principles and theories of science, would be expected in probability to offer successively ever-better approximations to the truth.

The remaining questions on my invitation to testify focused on the risks of both a strict interpretation of the proposed EPA rule and the establishment of reproducibility standard within its regulatory process. And they ask how rigor and reproducibility are related.

Were reproducibility to become the sole and essential criteria for inclusion of data, some sound research would likely be excluded from EPA environmental and public health regulations. Reproducibility by itself is neither necessary nor sufficient for determining the validity of a study. In general, a rule that strongly encourages

and incentivizes making science transparent and reproducible would be good. In contrast, a rule which made transparency and reproducibility jointly necessary or jointly sufficient for the admissibility of a study could result in the exclusion of high-quality studies that, for legitimate reasons, cannot be made fully transparent and reproducible.

At the other extreme, studies may be transparent and reproducible but contain flaws leading to incorrect conclusions. Transparency contributes to rigor, but additional aspects of rigor are vitally important, including appropriateness of study design, sampling procedures, measurements, and statistical analyses.

The 2018 proposed EPA rule allows for exceptions. What is unclear is how exceptions will be adjudicated and whether the adjudication process will lead to the exclusion of rigorous studies, potential bias in terms of which studies and data sets are used in rulemaking, and ultimately diminish public trust.

Finally, it is not obvious that a rule addressing the admissibility of studies in rulemaking would serve EPA's goals of promoting transparency and rigor in science better than would a statement of principles on the valuing and weighting of evidence, especially with so many likely and necessary exceptions built into the rule.

In summation, the National Academies' Study Committee and I, as an individual scientist, are strong proponents of reproducibility and replicability of transparency and science and, more importantly, of the utmost rigor in the execution of and the unvarnished truthful communication of scientific research. To the extent that EPA can enact procedures that promote these practices, that is all to the good. Yet there must be flexibility to allow for research lacking complete transparency or reproducibility but otherwise shown to be rigorous to inform rulemaking.

Just as other scientific communities and government regulatory bodies relying on scientific information must do, I advocate that we consider all relevant scientific information, while providing the most weight to the best information. As scientists drawing conclusions about whether propositions have been demonstrated to be true, we might withhold a conclusion unless research meeting some specified condition is available. But as a society engaged in prudent decisionmaking, we must make our decisions on the best information available. Thank you.

[The prepared statement of Dr. Allison follows:]

INVITED TESTIMONY BEFORE THE U.S. HOUSE OF REPRESENTATIVES' COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY HEARING "STRENGTHENING TRANSPARENCY OR SILENCING SCIENCE? THE FUTURE OF SCIENCE IN EPA RULEMAKING"

Statement of

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and

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The National Academies of Sciences, Engineering, and Medicine

before the

U.S. House Of Representatives' Committee on Science, Space, and Technology

November 13, 2019

My name is David B. Allison. I currently serve as the dean of the School of Public Health at Indiana University – Bloomington, although on this occasion I am speaking as a member of the Committee on Reproducibility and Replicability in Science and on behalf of the National Academies of Sciences, Engineering, and Medicine (the National Academies) and not Indiana University. I have been asked by The U.S. House of Representatives' Committee on Science, Space, and Technology to testify at their hearing titled, *"Strengthening Transparency or Silencing Science? The Future of Science in EPA Rulemaking"* on November 13, 2019. I understand from the invitation that "The purpose of the hearing is to assess the EPA's proposed rule *Strengthening Transparency in Regulatory Science."*

In my testimony, I have been asked to address the following topics:

- The definition of reproducibility, as determined by the Committee on Reproducibility and Replicability in Science of the National Academies;
- The potential consequences of EPA's goal to establish a reproducibility standard within its regulatory process by requiring that the underlying data of scientific studies be made available;
- Whether it is appropriate to determine the rigor or regulatory applicability of a study based solely on its reproducibility; and
- Whether a reproducibility requirement could increase the risk that sound science could be excluded from EPA environmental and public health regulations.

These topics will be addressed in addition to several other points. In this testimony, I will provide:

1. A brief background on the Committee on Reproducibility and Replicability in Science and my involvement in it.
2. Some overview remarks about science found in the "Reproducibility and Replicability in Science" report as well as my own personal perspectives that serve as context for this discussion.
3. Responses to the topics posed by the House Science committee.
4. A copy of the Executive Summary of the "Reproducibility and Replicability in Science" report.

My testimony ends with a summary of its main points which are my own personal perspectives.

1. **A brief background on the Committee on Reproducibility and Replicability in Science and my involvement in it.**

   The American Innovation and Competitiveness Act of 2017 directed the National Science Foundation to engage the National Academies in a study to assess reproducibility and replicability in scientific and engineering research and to provide findings and recommendations for improving rigor and transparency in scientific research. The National Academies appointed a committee of experts to carry out this evaluation, representing a wide range of expertise and backgrounds: methodology and statistics, history and philosophy of science, science communication, behavioral and social sciences (including experts in the social and behavioral factors that influence the reproducibility and replicability of research results), earth and life sciences, physical sciences, computational science, engineering, academic leadership, journal editors, and industry expertise in quality control. In addition, individuals with expertise pertaining to reproducibility and replicability of research results across a variety of fields were selected. Dr. Harvey Fineberg, President of the Gordon and Betty Moore Foundation and a past president of the Institute of Medicine—now the National Academy of Medicine—served as the

chair of the Committee. The Committee's report is available for download without charge at: https://www.nap.edu/catalog/25303/reproducibility-and-replicability-in-science.

I was asked to serve as a committee member based on my work as a scientist and my long-term interest in issues related to reproducibility, replicability, and rigor in science such as my involvement in organizing and participation in the 2017 National Academy of Sciences Colloquium which was focused on these issues. My research interests include obesity and nutrition, quantitative genetics, clinical trials, statistical and research methodology, and research rigor and integrity. I have authored more than 600 scientific publications and edited five books. A member of the National Academy of Medicine of the National Academies, I am also an elected fellow of the American Association for the Advancement of Science, the American Statistical Association, the American Psychological Association, the New York Academy of Medicine, the Gerontological Society of America, the Academy of Behavioral Medicine Research, and other academic societies. I have devoted my career to the rigorous pursuit of knowledge through science. It is an honor to represent the Committee on Reproducibility and Replicability in Science and to discuss the content of its report and my perspectives on these topics with the U.S. House Committee on Science.

2. **Science as a shared communal process for objectively determining the truth of propositions about the world.**

Science is a method by which society tries to discover and share knowledge about the state of the world. It is fundamentally a communal process in which communicating the research process and findings, helping others to understand the knowledge obtained, and subjecting conclusions and the bases for them to public questioning and scrutiny are all essential components. What makes science special both in its claims to have access to objective knowledge about the world as well as in its communal process involves the methods by which scientific knowledge is generated. In particular, "in science, three things matter: the data, the methods used to collect the data (which give them their probative value), and the logic connecting the data and methods to conclusions."[1] These are the substrates of science.

Because of the critical role of methods in this process, it is an essential tenet of science that the methods used to collect or produce data and to analyze them be as thoroughly and transparently described as possible so that others may understand what was done and thereby judge the probative value of the data. Thus, transparency is critical to one of the three fundamental elements of science as I have described. As the Committee states in its report (p. 32), *"When research is communicated with clear, specific, and complete accounting of the materials and methods used, the results found, and the uncertainty associated with the results, other scientists can know how to interpret the results. The communal enterprise of science allows scientists to build on others' work, develop the necessary skills to conduct high quality studies, and check results and confirm, dispute, or refine them."* In short, observability of

[1] https://www.pnas.org/content/115/11/2563

methods and observability of data, which might both be considered under the rubric of "transparency", support the objectivity and communal validation process of science.

That is, as scientists or individuals consuming and judging the validity, value, and utility of science, we need to know more than one's answer, we need to know how one got that answer. The phrase so many of us heard from our middle school math teachers "show your work" is an apt description. Only by seeing the process of the work done to produce an answer in science can we judge that answer. This observability requires transparency. This observability and transparency in turn makes reproducibility possible.

Reproducibility is a word that is used in multiple different ways in the scientific and general communities. Most recently, as I will state in Section 4, the term reproducibility was defined in the Reproducibility and Replicability in Science report as follows (p. 46) "*reproducibility is obtaining consistent results using the same input data, computational steps, methods, and code, and conditions of analysis. This definition is synonymous with 'computational reproducibility'.*" Notably, reproducibility is neither a necessary nor sufficient condition for a particular scientific project to be judged as valid for supporting any conclusions drawn from it. It is a valuable aspect of science, but only one aspect of science that is valuable, and it is not clear that reproducibility should merit a privileged position as the sole arbiter of whether a particular study or data set should be admitted into a discussion of evidence.

It is worth noting that the Committee on Reproducibility and Replicability in Science did not consider the EPA proposed rule in its tasking and, since the proposed rule was released during Committee deliberations, the Committee's report was not publicly available while EPA's proposed rule was underdevelopment.

The proposed EPA rule does not necessarily state that reproducibility *per se* or even that transparency will be the sole arbiter of the admission of evidence into the policy making process, but it might be construed as implying this. Part of the challenge with the proposed rule is the substantial number of terms including *reproducibility, transparency, independent validation*, and others which are not all explicitly defined. This leads to ambiguity in how the rule may be interpreted and utilized. Rulemaking is arguably not served by ambiguity nor is science itself. Though some ambiguity is inherent in all language, we should strive to be precise in terms. Therefore, if some variant of the proposed EPA rule were to go forward, the public interest would likely be served by defining all terms as precisely as possible, by including factors other than reproducibility (at least as the Committee's report has defined it) as key factors in determining how to evaluate evidence, as well as potentially making other modifications.

From my perspective, it is important to consider what the ultimate goals of science and policy making are in considering what those other modifications might be. The ultimate goal of science is to uncover and communicate truths about the state of the world. The ultimate goal of policy making is to serve the interests of the public. Science is a valuable input to policy making decisions but can never be fully dispositive of policy-making decisions which also must take into account moral, social, economic, political, and other factors. But the evaluation of the science *per se* should be based only on the science and not on these other factors.

Science can inform us about the plausible truth of propositions. These propositions can relate to things such as how much of a substance is in the environment, whether the amount of a substance in the environment has increased or decreased, what may have caused exposure to various substances, what the effects of exposure to various substances at various times in various doses are in humans, etc. Reproducibility is of interest because it potentially helps us to evaluate the extent to which a study supports the truth of some proposition and, in the long run, buttresses the entire enterprise of science and thereby ensures that we are better able to pursue truth through science. As the Committee report states (p. 33): *"Science is engaged in a continuous process of refinement to uncover ever closer approximations to the truth."* In the report, Conclusion 2-1 states (p.33):

> *"CONCLUSION 2-1: The scientific enterprise depends on the ability of the scientific community to scrutinize scientific claims and to gain confidence over time in results and inferences that have stood up to repeated testing. Reporting of uncertainties in scientific results is a central tenet of the scientific process. It is incumbent on scientists to convey the appropriate degree of uncertainty in reporting their claims."*

The degree of certainty about the truth of any proposition in science comes from many sources including but not limited to reproducibility. The overall rigor of the science such as the quality of the measurement instruments used, the extent to which the findings have been replicated (as opposed to simply reproduced), the degree of transparency and reporting of the science, the extent to which it has been thoroughly peer reviewed, the extent to which results fit with a larger body of data available to the scientific community, are all factors that can come into play in judging the extent to which we have a scientific basis for believing that any particular proposition is true. Collectively, all of these things might be called "rigor." My colleagues and I on the Committee wrote (p.52):

> *"Rigor is defined as 'the strict application of the scientific method to ensure robust and unbiased experimental design' (National Institutes of Health, 2018e). Rigor does not guarantee that a study will be replicated, but conducting a study with rigor—with a well-thought-out plan and strict adherence to methodological best practices—makes it more likely. One of the assumptions of the scientific process is that rigorously conducted studies 'and accurate reporting of the results will enable the soundest decisions' and that a series of rigorous studies aimed at the same research question 'will offer successively ever-better approximations to the truth' (Wood et al., 2019, p. 311)."*[2]

From my personal perspective, it may not be apt for a governmental rule to define the admissibility of evidence into a discussion on consideration of a policy that can and should be informed by science solely on the basis of reproducibility. I have stated that one reason for this

[2] See National Institutes of Health. (2018e). Rigor and Reproducibility in NIH Applications: Resource Chart. Available: https://grants.nih.gov/grants/RigorandReproducibilityChart508.pdf and Wood, A.C., Wren, J.D., and Allison, D.B. (2019). The Need for Greater Rigor in Childhood Nutrition and Obesity Research. JAMA Pediatrics, 173(4), 311-312. doi:10.1001/jamapediatrics.2019.0015.

is that reproducibility is neither a necessary nor a sufficient condition for a scientific study or data set to be valid or useful. This is so for many reasons.

First, a study can be reproducible and transparent and yet completely invalid. If a second analyst repeats the entire process of the first analyst applied to the same data, including the first analyst's mistakes or to a data set that is fundamentally flawed and inappropriate, an answer may be reproduced, the process may be transparent, and yet the answer may be worthless and invalid.

Additionally, a scientific project may not be reproducible because the available information is insufficient to allow someone to reproduce it. The original raw data may not be available or for many reasons may not be able to be made public. The original investigators may not have sufficiently documented their steps to allow a full evaluation of exactly what was done permitting an exact reproduction. These are certainly limitations and should be noted. And yet, limitations are not necessarily the same as invalidating factors that should exclude information from further inquiry. A general tenet of scientific evaluation is that one should consider all of the available evidence. One may weigh the individual elements of evidence differentially, but it is uncommon to exclude particular evidence from consideration because it contains some limitations. Virtually all empirical evidence is imperfect and has some limitations. It is vital that in the scientific process those limitations are noted and some of those limitations may preclude firm conclusion-making. Yet the evidence should still be weighed and considered.

In considering the rationale for this approach, the fundamental distinction between the idea of conclusion-making and decision-making is called for. Scientific conclusion-making may depend on certain key types of data. Scientific conclusion-making may depend upon scientific evidence which supports a sufficient degree of certainty that rules out alternative explanations that would compete with a proposition being accepted as true to some reasonable degree of certainty. For example, in biomedical research, and many other domains, scientists will often not be prepared to state unequivocally that it has been demonstrated by scientific methods that '*x causes y*' unless there has been a randomized controlled experiment in which experimental units (e.g., people in medical trial) have been randomly assigned to different levels of *x* (e.g., to take a drug vs. a placebo or to eat diet A vs. diet B). Yet, in medicine, nutrition, public health, and other applied domains we are often called upon to make recommendations to individual patients, citizens, or society at large and often must do so in the absence of data that would be sufficient to allow us to draw a firm scientific conclusion that *x causes y*. We may have to make our recommendation simply by saying that *it seems likely that x causes y* even though it has not been *demonstrated that x causes y*. When we make a recommendation that somebody should *act as though x causes y* even though we have not demonstrated scientifically that x causes y, we are involved in decision-making not conclusion-making. The scientific conclusion can remain unclear while we still proceed with a recommendation. In all cases that recommendation should be made with honesty, letting those to whom we communicate it know that we have not yet demonstrated that x causes y only that it seems a reasonable and plausible proposition given the available information.

This distinction was put eloquently by Sir Austin Braford Hill in 1965 who considered issues such as whether smoking caused lung cancer. He recognized that there were not randomized

controlled trials demonstrating unequivocally that smoking causes lung cancer but that the evidence for an association between smoking and lung cancer was extremely strong and, combined with much other information in the scientific domain, has led virtually all scientists to accept the proposition that smoking causes lung cancer as true beyond any reasonable doubt.[3] In discussing the thought process involved in this, Sir Austin Bradford Hill stated *"in passing from association to causation I believe in 'real life', we shall have to consider what flows from that decision. On scientific grounds, we should do no such thing. The evidence is there to be judged on its merits and the judgment (in that sense) should be utterly independent of what hangs upon it – or who hangs because of it."*[4]

Similarly, in a recent New York Times' article considering the controversy around the health effects of red meat,[5] I was quoted as describing the distinction between evidence for conclusion-making versus evidence for decision-making, stating *"The standards of evidence for the former are scientific matters and should not depend on extra scientific considerations. The standards of evidence for the latter are matters of personal judgment or in some cases legislation. People should be aware of the uncertainty and make their decisions based on that awareness."*

This recognition of the difference between decision-making for applied purposes, the fundamental aspect of policy making, and conclusion-making for scientific purposes underlies the very credible approaches taken by multiple other government organizations with respect to their consideration of evidence around key questions. For example, in their discussion of what constitutes adequate evidence for making their decisions about such things as drug approvals, the U.S. Food and Drug Administration has stated (p. 5):[6]

> *"The need for independent substantiation has often been referred to as the need for replication of the finding. Replication may not be the best term, however, as it may imply that precise repetition of the same experiment in other patients by other investigators is the only means to substantiate a conclusion. Precise replication of a trial is only one of a number of possible means of obtaining independent substantiation of a clinical finding and, at times, can be less than optimal as it could leave the conclusions vulnerable to any systematic biases inherent to the particular study design. Results that are obtained from studies that are of different design and independent in execution, perhaps evaluating different populations, endpoints, or dosage forms, may provide support for a conclusion of effectiveness that is as convincing as, or more convincing than, a repetition of the same study."*
>
> . . . (p.17) *"However, situations often arise in which studies that evaluate the efficacy of a drug product lack the full documentation described above (for example, full patient records may not be available) or in which the study was conducted with less monitoring than is ordinarily seen in commercially*

[3] https://www.americanscientist.org/article/reasonable-versus-unreasonable-doubt
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1898525/
[5] https://www.nytimes.com/2019/09/30/health/red-meat-questions-answers.html
[6] https://www.fda.gov/media/71655/download

> *sponsored trials. Such situations are more common for supplemental indications because postapproval studies are more likely to be conducted by parties other than the drug sponsor and those parties may employ less extensive monitoring and data-gathering procedures than a sponsor. Under certain circumstances, it is possible for sponsors to rely on such studies to support effectiveness claims, despite less than usual documentation or monitoring."*

Similarly, the "Reference Manual on Scientific Evidence" produced by the National Research Council of the National Academies and the Federal Judicial Center states (p.330):[7]

> *"A party that offers data to be used in statistical work, including multiple regression analysis, should be encouraged to provide the following to the other parties: (a) a hard copy of the data when available and manageable in size, along with the underlying sources; (b) computer disks or tapes on which the data are recorded; (c) complete documentation of the disks or tapes; (d) computer programs that were used to generate the data (in hard copy if necessary, but preferably on a computer disk or tape, or both); and (e) documentation of such computer programs. The documentation should be sufficiently complete and clear so that the opposing expert can reproduce all of the statistical work."*

Yet, also states (Preface, p. xiv):

> *"In the final analysis, a judge does not have the option of suspending judgment until more information is available, but must decide after considering the best available science."*

In the academic community, we have a system called GRADE.

> *"GRADE (Grading of Recommendations, Assessment, Development and Evaluations) is a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations.[1-3] It is the most widely adopted tool for grading the quality of evidence and for making recommendations with over 100 organisations worldwide officially endorsing GRADE."*[8]

In using systems like GRADE, while limitations of individual studies are noted, *"...the credibility and trustworthiness of **the totality of evidence*** [emphasis added] *across studies in relation to a specific research question"*[9] is key. This reliance on the totality of evidence via GRADE is also a hallmark of the process for generating dietary recommendations used by Federal Agencies.[10] Thus, GRADE is used to help evaluate evidence that can potentially support decisions about public health recommendations. Importantly, GRADE defines principles for standards of evidence and helps evaluate individual pieces of evidence so that they may be properly weighed in an analysis. In contrast, GRADE does not specifically state that certain types of evidence will

[7] https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf
[8] https://bestpractice.bmj.com/info/toolkit/learn-ebm/what-is-grade/
[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6001464/
[10] https://www.ncbi.nlm.nih.gov/books/NBK465019/

simply be excluded from discussion, but rather outlines which types of evidence should be given greater value and lead to more confident conclusions versus less confident conclusions.

All of this leads one to ask whether the public interest would be well-served by modifying the current proposed EPA rule to increase clarity around definitions and procedures for its implementation. Or would the public interest be better-served by a more thorough and expansive statement of principles as to what constitutes good scientific evidence, about ideals of scientific evidence which include, but are not limited to, reproducibility and transparency, and suggestions for how to weigh and evaluate evidence both for drawing scientific conclusions and for making prudent decisions. A statement of such broad principles may serve the interests of the public and of science by promoting openness in science, good quality science, rational policy making, and transparency in both science and government, more so than does a rule which serves to exclude certain information from consideration.

3. Executive Summary of the "Reproducibility and Replicability in Science" of the National Academies.

The executive summary of the "Reproducibility and Replicability in Science" report of the National Academies appears as Appendix A to this document.

4. Responses to Specific Questions.

a) The definition of reproducibility, as determined by the Committee on Reproducibility and Replicability in Science of the National Academies.

The term reproducibility is defined in Conclusion 3-1 in the Committee's report, "Reproducibility and Replicability in Science" (p. 46):

> *Reproducibility* is obtaining consistent results using the same input data, computational steps, methods, and code, and conditions of analysis. This definition is synonymous with "computational reproducibility". . .

The Committee's definition of replicability is also important. The same section of the report defines:

> *"Replicability* to mean obtaining consistent results across studies aimed at answering the same scientific question, each of which has obtained its own data."

b) The potential consequences of EPA's goal to establish a reproducibility standard within its regulatory process by requiring that the underlying data of scientific studies be made available.

In my opinion, the answer to this depends upon exactly how the rule is implemented and modified. If reproducibility were to become the sole arbiter of whether information, a study, or a data set were included in policy making considerations, I believe the effects would be deleterious for the reasons I have stated above. Some high-quality information that, for any number of reasons, cannot be made fully reproducible and transparent would be excluded. Moreover, the rule might lead to the mistaken conclusion that information that was judged to

be admissible because it met a transparency or reproducibility standard was valid information, and as I have indicated above there can be much that is reproducible and transparent but is nonetheless invalid or otherwise flawed.

The likely quality of the outcomes as a result of the proposed rule would also depend upon the extent to which the request that underlying data be transparent and the studies be reproducible be implemented flexibly and in an unbiased manner or inflexibly or in a biased manner. Were a rule to be implemented that provided strong encouragement and incentives for making science reproducible and transparent, that would be good. In contrast, if such a rule became *dicto simpliciter* and a sole arbiter of whether information could be included, that would be bad. Certainly, the current EPA rule contains many situations in which exceptions can be made. That is wise. Yet what is unclear to me is whether the rule is necessary at all and, if it is valuable, how these exceptions will be adjudicated and whether the process of making them will lead to excessive use of time, excessive exclusion of studies, and potential bias in terms of which studies and datasets ultimately are allowed to be included.

c) Whether it is appropriate to determine the rigor or regulatory applicability of a study based solely on its reproducibility.

No, from my perspective, it would not be appropriate to determine the rigor or the regulatory applicability of a study based solely on its reproducibility as reproducibility is defined in the National Academies' report for the reasons I have stated above. In short, reproducibility is neither a necessary nor a sufficient condition to determine the validity of a study for in turn determining the truth of a proposition.

d) Whether a reproducibility requirement could increase the risk that sound science could be excluded from EPA environmental and public health regulations.

It is not clear to me that the currently proposed rule definitively proposes a reproducibility requirement as the sole arbiter or a *sine qua non* for which studies and datasets can enter into policy making because the proposed rule only addresses certain aspects of policy making and it allows for exceptions. Yet, for the reasons I have described above, I do think there is some danger that if reproducibility is poorly defined and more importantly if it becomes the sole and essential criterion for inclusions of data, then yes, such a requirement could risk that sound science would be excluded from EPA environmental and public health regulations.

5. Summation.

In summation, the National Academies Committee and I as both a member and an individual scientist are a strong proponents of reproducibility and replicability, of transparency in science, and more importantly and more broadly of the utmost rigor in the execution of science and in the unvarnished truthful communication of scientific information among scientists and to society at large. I personally believe that any effort that serves to promote the goals of reproducibility, transparency, scientific rigor, and truthful communication in and about science should be supported. To the extent that EPA can enact guidance, statements, policies, and procedures that promote these practices, that is all to the good. Yet there must be flexibility

such that we may consider and speak openly about data even when those data have limitations including, but not limited to, incomplete transparency or reproducibility of some datasets and studies. Just as other scientific communities and other government regulatory bodies relying on scientific information must do, in this realm, I advocate that we consider *all* the information, while providing the most weight to the best information.

Appendix A

The Executive Summary from "Reproducibility and Replicability in Science" is copied below. The full report may be downloaded without charge at: https://www.nap.edu/catalog/25303/reproducibility-and-replicability-in-science

EXECUTIVE SUMMARY

When scientists cannot confirm the results from a published study, to some it is an indication of a problem, and to others, it is a natural part of the scientific process that can lead to new discoveries. As directed by Congress, the National Science Foundation (NSF) tasked this committee to define what it means to reproduce or replicate a study, to explore issues related to reproducibility and replicability across science and engineering, and to assess any impact of these issues on the public's trust in science.

Various scientific disciplines define and use the terms "reproducibility" and "replicability" in different and sometimes contradictory ways. After considering the state of current usage, the committee adopted definitions that are intended to apply across all fields of science and help untangle the complex issues associated with reproducibility and replicability. Thinking about these topics across fields of science is uneven and evolving rapidly, and the report's proposed steps for improvement are intended to serve as a roadmap for the continuing journey toward scientific progress.

We define *reproducibility* to mean computational reproducibility—obtaining consistent computational results using the same input data, computational steps, methods, and code, and conditions of analysis; and *replicability* to mean obtaining consistent results across studies aimed at answering the same scientific question, each of which has obtained its own data. In short, reproducibility involves the original data and code; replicability involves new data collection and similar methods used by previous studies. A third concept, *generalizability,* refers to the extent that results of a study apply in other contexts or populations that differ from the original one.[11] A single scientific study may entail one or more of these concepts.

Our definition of reproducibility focuses on computation because of its large and increasing role in scientific research. Science is now conducted using computers and shared databases in ways that were unthinkable even at the turn of the 21st century. Fields of science focused solely on computation have emerged or expanded. However, the training of scientists in best computational research practices has not kept pace, which likely contributes to a surprisingly low rate of computational reproducibility across studies. Reproducibility is strongly associated with transparency; a study's data and code have to be available in order for others to reproduce and confirm results. Proprietary and non-public data and code add challenges to meeting transparency goals. In addition, many decisions related to data selection or parameter setting for code are made throughout a study and can affect the results. Although newly developed tools can be used to capture these decisions and include them as part of the digital record, these tools are not used by the majority of scientists. Archives to store digital artifacts linked to published results are inconsistently maintained across journals, academic and federal institutions, and

[11] The definition of generalizability used by the NSF (Bollen, et al., 2015).

disciplines, making it difficult for scientists to identify archives that can curate, store, and make available their digital artifacts for other researchers.

To help remedy these problems, the NSF should, in harmony with other funders, endorse or create code and data repositories for long-term preservation of digital artifacts. In line with its expressed goal of "harnessing the data revolution," NSF should consider funding tools, training, and activities to promote computational reproducibility. Journal editors should consider ways to ensure reproducibility for publications that make claims based on computations, to the extent ethically and legally possible.

While one expects in many cases near bitwise agreement in reproducibility, the replicability of study results is more nuanced. Non-replicability occurs for a number of reasons that do not necessarily reflect that something is wrong. Some occurrences of non-replicability may be helpful to science—discovering previously unknown effects or sources of variability—while others, ranging from simple mistakes to methodological errors to bias and fraud, are not helpful. It is easy to say that potentially helpful sources should be capitalized on, while unhelpful sources must be minimized. But when a result is not replicated, further investigation is required to determine whether the sources of that non-replicability are of the helpful or unhelpful variety or some of both. This requires time and resources and is often not a trivial undertaking.

A variety of standards are used in assessing replicability, and the choice of standards can affect the assessment outcome. We identified a set of assessment criteria that apply across sciences highlighting the need to adequately report uncertainties in results. Importantly, the assessment of replicability may not result in a binary pass/fail answer; rather, the answer may best be expressed as the degree to which one result replicates another.

One type of scientific research tool, statistical inference, has had an outsized role in replicability discussions due to the frequent misuse of statistics such as the *p*-value and threshold for determining "statistical significance." Inappropriate reliance on statistical significance can lead to biases in research reporting and publication; although publication and research bias are not restricted to studies involving statistical inference. A variety of ongoing efforts is aimed at minimizing these biases and other unhelpful sources of non-replicability.

Researchers should take care to estimate and explain the uncertainty inherent in their results, to make proper use of statistical methods, and to describe their methods and data in a clear, accurate, and complete way. Academic institutions, journals, scientific and professional associations, conference organizers and funders can take a range of steps to improve replicability of research. We propose a set of criteria to help determine when testing replicability may be warranted. It is important for everyone involved in science to endeavor to maintain public trust in science based on a proper understanding of the contributions and limitations of scientific results.

A predominant focus on the replicability of individual studies is an inefficient way to assure the reliability of scientific knowledge. Rather, reviews of cumulative evidence on a subject, to assess both the overall effect size and generalizability, is often a more useful way to gain confidence in the state of scientific knowledge.

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DAVID B. ALLISON is dean of the School of Public Health and distinguished professor and provost professor at Indiana University, Bloomington. Previously, he was associate dean for research and science in the School of Health Professions at the University of Alabama at Birmingham. Dr. Allison's research interests include obesity and nutrition, quantitative genetics, clinical trials, statistical and research methodology, and research rigor and integrity. He has authored more than 600 scientific publications and edited five books. A member of the National Academy of Medicine of the National Academies, he is also an elected fellow of the American Association for the Advancement of Science, American Statistical Association, American Psychological Association, New York Academy of Medicine, Gerontological Society of America, Academy of Behavioral Medicine Research, and other academic societies. He was inducted into the Johns Hopkins University Society of Scholars in 2013 and has received many awards, including the National Science Foundation–administered and White House Conferred 2006 Presidential Award for Excellence in Science, Mathematics, and Engineering Mentoring; Centrum Award from the American Society of Nutrition; TOPS Research Achievement Award from the Obesity Society; Alabama Academy of Science's Wright A. Gardner Award; U.S. Department of Agriculture's W.O. Atwater Award and Lectureship; and the 2018 American Statistical Association's Statistical Advocate of the Year Award. Professor Allison is known for his commitments to mentoring and diversity in science and rigorous research and unvarnished reporting of research findings.

Ms. BONAMICI. Thank you for your testimony.
I now recognize Dr. Nosek for 5 minutes for your testimony.

TESTIMONY OF DR. BRIAN NOSEK,
CO-FOUNDER AND EXECUTIVE DIRECTOR,
CENTER FOR OPEN SCIENCE

Dr. NOSEK. Chairwoman Johnson, Ranking Member Lucas, and Members of the Committee, thank you for this opportunity to discuss the role of transparency and reproducibility for maximizing the return on research investments.

In 2013 Jeff Spies and I launched the Center for Open Science or COS out of my lab at the University of Virginia as a nonprofit technology and culture-change organization. COS has a mission to increase transparency, integrity, and reproducibility of research. To advance that mission, we maintain the free and open-source, open-science framework, a cloud-based collaborative management service used by more than 180,000 researchers to improve the rigor and transparency of their research.

COS is also working to change the incentives landscape in academic science with a policy framework that promotes transparency called the TOP (Transparency and Openness Promotion) Guidelines and initiatives that promote the visibility of open practices and shift publication criteria toward rewarding asking important questions and using rigorous methodologies rather than demanding exciting results.

Finally, COS conducts meta-science, research on the research process, to identify inefficiencies in discovery and to evaluate whether the intervention is to reduce those inefficiencies are effective. Lack of transparency creates friction in the pace of discovery and reduces the return on investment of research dollars. We can increase the returns by promoting greater transparency of a variety of research outputs.

Ideally, you would have transparency of my research plans, what I thought I was doing in advance, so that you can compare the studies that ended up published with the studies that I did that were not published and what my plans were to do at the outset versus what I discovered after the fact. Transparency of my materials would allow others to examine how it is I got to the conclusions that I got to and then re-use those materials for other purposes. Transparency of my data will make it easier for others to replicate or extend or evaluate the rigor of the conclusions that I draw, and transparency of the outcomes makes sure that all of our research investments are available in terms of what we learned from these investments in science.

There is a maturing infrastructure of tools and services that make it possible for researchers to do these behaviors. There's also a growing awareness and shifting norms within the research community about the importance of transparency. For example, the TOP Guidelines policy framework has been adopted by more than 1,000 scientific journals for authors and by some funders for their grantees. There is more work to do, but your continuing support for these efforts could have salutary effects on the research culture.

Ultimately, COS believes that the biggest opportunity for reducing friction in the research process is setting the default to open,

open plans, open materials, open data, and open outcomes. Flipping the default from closed to open will foster decisionmaking frameworks for the exceptions when other interests outweigh the goal of transparency.

Two common occasions in which competing principles can dominate are protecting intellectual property and protecting participant confidentiality for sensitive human subjects research. Sensible policies for managing these competing interests will facilitate the culture shift that's already underway.

There are also important considerations for how best to use scientific evidence in policymaking. The EPA rule that prompted this hearing had the positive qualities of identifying transparency and reproducibility but had the negative quality of suggesting that evidence failing to meet those principles should not be used. It is important to use the best available evidence for rulemaking. There will always be occasions in which the best available evidence is not fully transparent or has unknown reproducibility, and there are many potential solutions for assuring credibility of findings when underlying data cannot be fully transparent.

There are many factors that affect the quality of research, the certainty of its conclusions, and its generalizability to the policy context. The goal should not be transparency or bust. The goal should be explicitly representing the uncertainty of evidence to help you as policymakers make better decisions. There are in fact federally funded research efforts underway to assist with this if you'd like to discuss that during Q&A.

Thank you for your continuing support of science and for the opportunity to speak with you today.

[The prepared statement of Dr. Nosek follows:]

Testimony of

Brian A. Nosek, Ph.D.

Executive Director
Center for Open Science

Professor
Department of Psychology
University of Virginia

Before the

Committee on Science, Space, and Technology
U.S. House of Representatives

November 13, 2019

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

Chairwoman Johnson, Ranking Member Lucas, and Members of the Committee, on behalf of myself and the Center for Open Science, thank you for the opportunity to discuss the role of promoting transparency and reproducibility for maximizing the return on research investments, and responsible management of research transparency with competing interests of privacy protections for sensitive data.

The bottom line summary of my remarks is:

1. **Making open the default** for research plans, data, materials, code, and outcomes will reduce friction in discovery and maximize return on research investments
2. **Extending existing policy frameworks about transparency and openness** across federal agencies will help improve research efficiency. These frameworks can help decision-makers navigate situations in which principles of security and privacy are in conflict with principles of transparency and openness.
3. **Rulemaking should be informed by the best available evidence**. Sometimes the best available evidence is based on data that cannot be transparent, has high uncertainty, or has unknown reproducibility. Developing tools that clarify uncertainty will improve policymaking and shape research priorities.

I joined the faculty at the University of Virginia in the Department of Psychology in 2002. My substantive areas of expertise are research methodology, implicit bias, and the gap between values and practices. In 2013, Jeff Spies and I launched the Center for Open Science (COS) out of my lab as a non-profit technology and culture change organization. COS has a mission to increase transparency, integrity, and reproducibility of research. To advance that mission, COS

maintains the free and open source Open Science Framework (http://osf.io/), a cloud-based collaborative management service used by more than 180,000 researchers to improve the rigor and transparency of their research plans, data, materials, code, and outcomes. COS is working to change the incentives landscape in academic science to prioritize accuracy and rigor. COS works with publishers, funders, institutions, and scientific societies to nudge incentives with a policy framework that promotes transparency and reproducibility called the TOP Guidelines (http://cos.io/top/), and initiatives that promote visibility of open practices (http://cos.io/badges/) and shift publication criteria toward rewarding asking important questions and using rigorous methodologies to investigate them (http://cos.io/rr/). Finally, COS conducts metascience--research on the research process--to identify inefficiencies in the process of discovery and to evaluate whether interventions to reduce those inefficiencies are effective.

Lack of transparency creates friction in the pace of discovery and reduces the return on investment of research dollars. For example, in a large-scale replication project of cancer biology research, we initiated replications of 197 experiments and found that the original papers had enough information to design a complete replication protocol for none of them. Moreover, we were able to access the raw data for just 3 of the 197 experiments in public repositories without engaging the original authors. Return on research investments could increase dramatically by promoting greater transparency of a variety of research outputs:

- Transparency and Openness of Materials -- the protocols, materials, and code that generated my research findings -- will make it easier for others to replicate my findings, and build on my research.
- Transparency and Openness of Data will make it easier for others to test the robustness of my findings and to reuse my data for new questions or combine it with related data for more precise assessments of the totality of evidence.
- Transparency and Openness of Research Plans -- registration of the study design, hypotheses, and analysis plans before the results are known -- will make it easier to discover findings that are never published, particularly negative results that are often ignored, and make clear the difference between confirmatory investigations in which hypotheses are being tested and exploratory investigations in which hypotheses are being generated. Mistaking exploratory analyses as confirmatory tests increases bias and is a threat to the credibility of research claims.
- Transparency and Openness of Research Outcomes will make it easier to find all relevant evidence about a research question, and make it easier for researchers, policymakers, and the tax paying public to examine and use the scientific evidence that we all paid to produce.

There is a mature infrastructure of tools and services, like the Open Science Framework and many other repositories, that make it possible for researchers to do these behaviors. There is also growing awareness within the research community about the importance and value for these transparency promoting behaviors. For example, the TOP Guidelines policy framework has been adopted by more than 1,000 scientific journals for authors, and some funders are likewise adapting their policies for grantees. Following the Holdren memo during the Obama

administration, and with continuing interest in promoting rigor and transparency from OSTP in the present administration, many federal agencies have taken steps toward improving policies supporting transparency and reproducibility of research. There is more work to do, but your continuing support for those efforts could have salutary effects on the research culture. Ultimately, COS believes that the biggest opportunity for reducing friction in research progress is **setting the default to open** -- open plans, open materials, open data, and open outcomes.

Flipping the default from closed to open will foster regulatory framework for the exceptions--when other interests outweigh the goal of transparency. Two common occasions in which competing principles can outweigh the principles of openness and transparency are protecting intellectual property and protecting participant confidentiality for sensitive human subjects research. Sensible policies for managing these competing interests will facilitate the culture shift that is already underway in the private sector and with proactive steps by federal agencies such as NIH and NSF.

Also, federal investment in the services and repositories that support research transparency will ensure persistence and accessibility of that content for researchers, policymakers, and the public. Publicly funded research is a public good, and the infrastructure storing and preserving it should be a public good as well.

Finally, there are a variety of technological and methodological innovations that could address goals of transparency and security simultaneously. For example, data enclaves can provide secure storage of sensitive data and workflows for ethical management of reanalysis and reuse without sacrificing that security. Also, there are emerging methodologies that improve privacy by perturbing the characteristics of the underlying data just enough to make it effectively impossible to identify individual data points but still preserve the overall structure of the data for accurate analysis and inference. Supporting such technologies will make it easier to address the otherwise competing principles of transparency and security.

There are important considerations for how best to use scientific evidence in policy making. The EPA rule that prompted this hearing had the positive qualities of identifying the importance of transparency and reproducibility of research, but had the negative quality of suggesting that evidence failing to meet these principles should not be used in policymaking. This approach would degrade the quality of policymaking.

In policymaking, it is important to use the **best available evidence** for rulemaking. There will always be occasions in which the best available evidence is not fully transparent or has unknown reproducibility. Using the best available evidence does not mean using it blindly or overconfidently. There are many factors that affect the quality of research, the certainty of its conclusions, and its generalizability to the policy context. Explicitly representing the uncertainty of evidence will help policymakers make better decisions. When the evidence is more uncertain, policymakers could ensure that implementation of the policy includes mechanisms to evaluate its success. And, by knowing the uncertainty of evidence, policymakers could direct

resources to supporting research to address those certainty gaps and improve the overall evidence base. For example, DARPA's SCORE program is investigating whether machine algorithms could automatically assess the credibility of research claims. If successful, this could provide an initial filter to inform the translation of research evidence into practice, and prioritization of research funding to topics of national and research interest. Your continuing support for programs like DARPA's is a worthwhile for the long-term objective of having evidence-based social and economic policymaking. [Disclosure: COS is funded by DARPA as part of the SCORE program.]

Public investment in science leads to solutions, cures, and unexpected advancements that benefit the national interest. Making open the default for research process, data, materials, and outcomes would transform science, dramatically increase the return on investment from publicly funded research, and accelerate progress. Thank you for your continuing support of science and for the opportunity to speak with you today.

Brian Nosek is co-Founder and Executive Director of the Center for Open Science (http://cos.io/) that operates the OSF (http://osf.io/)--a collaborative management service for registering studies and archiving and sharing research materials and data. COS is enabling open and reproducible research practices worldwide. Brian is also a Professor in the Department of Psychology at the University of Virginia. He received his Ph.D. from Yale University in 2002. He co-founded Project Implicit (http://projectimplicit.net/), a multi-university collaboration for research and education investigating implicit cognition--thoughts and feelings that occur outside of awareness or control. Brian investigates the gap between values and practices, such as when behavior is influenced by factors other than one's intentions and goals. Research applications of this interest include implicit bias, decision-making, attitudes, ideology, morality, innovation, barriers to change, open science, and reproducibility. In 2015, he was named one of Nature's 10 and to the Chronicle for Higher Education Influence list.

Ms. BONAMICI. Thank you for your testimony.

I now recognize Dr. Sherer for 5 minutes for your testimony.

TESTIMONY OF DR. TODD SHERER,
CEO, THE MICHAEL J. FOX FOUNDATION
FOR PARKINSON'S RESEARCH

Dr. SHERER. Thank you, Madam Chairwoman, Ranking Member Lucas, my Representative Congresswoman Sherrill, and the other esteemed Members of the Committee. Thank you again for the opportunity to testify today.

My name is Todd Sherer, and I'm a Ph.D.-trained neuroscientist and CEO of the Michael J. Fox Foundation for Parkinson's Research. Parkinson's disease is estimated to affect 1 million people in the United States, severely impacting quality-of-life for patients and their loved ones. This disease costs the U.S. Government and American families $52 billion each year, $25 billion of which comes from Medicare and Social Security. Our foundation strives to partner effectively with the government to leverage Federal research investments and help get more good ideas into clinical testing.

It would be impossible to overstate the importance of increasing the flow of patients into these clinical studies. Encouraging research participation by more patients and families is a major focus for us. Since we were founded, we have funded more than $900 million in research to accelerate progress toward a cure. As Federal research funders do more, we can do more, and together we can accelerate real results to those living with this disease.

Before I joined the foundation, I was a bench neuroscientist focused on the underlying causes of Parkinson's disease. Parkinson's is a neurodegenerative disorder. Symptoms include the more recognized movement aspects such as tremor and slowness but also memory and thinking problems, mood disorders, and sleep issues. There are no treatments to slow or stop the progression of the disease.

Because the symptoms can develop slowly, people in the early stages of Parkinson's still go to work, engage with family and friends, and remain leaders in their communities. These individuals also want to participate in clinical studies toward better treatments and a cure. They have every right to keep their diagnosis private and still participate in research.

But the EPA's proposed rule puts these individuals at great risk of having their Parkinson's diagnosis exposed. Such exposure could result in unfair job loss snowballing into a loss of income, insurance, and other life-altering consequences. It is vital that we protect patients' right to privacy.

I do want to be clear, the Michael J. Fox Foundation believes that transparency is critical in research. Open data-sharing among the scientific community is a core value of our foundation to speed discovery and replication and to deepen the public's trust in findings. With the consent of its 1,500 patient and control volunteers, our Parkinson's progression markers initiative makes all de-identified data available to the research community. Scientists around the world have downloaded this data nearly 5 million times and used it in more than 150 peer-reviewed published papers with the goal of improving the diagnosis and treatment of Parkinson's.

Similarly, we encourage the thousands of researchers who've received grants from us to make data available based on the nature of the study and the feasibility of de-identification. Stripping data of personally identifiable information is critical in protecting privacy. There must be a balance between research transparency and protecting patient confidentiality. Major scientific journals follow a similar practice and only require data to made confidentially available to other researchers to reproduce or extend analyses.

If the proposed rule were enacted, there are thousands of studies that would be excluded from the EPA's evaluation when it comes to determining standards, policies, and programs that keep us all safe. For example, epidemiological and population-based studies form the bedrock of knowledge for determining the environment's impact on human health. Data collected through these types of studies cannot always be adequately deidentified and therefore should be protected and not publicly shared.

Under the EPA's proposed rule, findings from these studies could not be used by the Agency as it sets national environmental standards, but census data and epidemiological studies are critical to understanding the causes of Parkinson's disease. We believe most if not all Parkinson's cases are due to a combination of genetic and environmental factors.

I want to share a story, with his permission, from Kevin Kwok of California. Kevin is 58 years old and was diagnosed with Parkinson's when he was 46. He spent his college summers hauling toxic waste drums at a well-known global chemical company and cleaning the insides of chemical reactors. Even with protective outerwear and following OSHA (Occupational Safety and Health Administration) safety guidelines, he had direct contact with chemical reagents every day for months. While we can't say with certainty that the job had a direct impact on Kevin's diagnosis, with more research, we may know in the future how these exposures contributed to his disease.

Kevin is an avid research participant and hopes that his contributions can inform not only the science of Parkinson's but also the legislation that impacts people living with the disease who are at risk. For example, in addition to stories like Kevin's, there are dozens of studies linking Parkinson's disease to pesticide exposure, many of which would be not admissible under this proposed rule.

The proposed rule will force EPA to make decisions based on less information, which compromises its core mission. Please ensure the EPA continues to balance the need for scientific integrity and transparency with its duty to protect the health of Americans. Thank you for the opportunity.

[The prepared statement of Dr. Sherer follows:]



November 13, 2019

United States House of Representatives
Committee on Science, Space and Technology
The Honorable Eddie Bernice Johnson, Chairwoman
The Honorable Frank Lucas, Ranking Member
Washington, DC 20515

Dear Chairwoman Johnson and Ranking Member Lucas:

Thank you for taking the time to hold today's hearing on the U.S. Environmental Protection Agency's (EPA) "Strengthening Transparency in Regulatory Science" proposed rule.

As the world's largest nonprofit funder of Parkinson's disease (PD) research, The Michael J. Fox Foundation (MJFF) is dedicated to accelerating a cure for Parkinson's and improved therapies for those living with the disease today. In funding more than $900 million in research to date — including on toxicity of environmental exposures — the Foundation has fundamentally altered the trajectory of progress toward a cure. It is estimated that one million people in the United States have PD, which costs the U.S. government and American families $52 billion every year.

Before I comment on the proposed rule, let me be clear: The Michael J. Fox Foundation believes transparency is critical in scientific research. Our Foundation supports a general policy of open data sharing among the scientific community and believes this practice speeds discovery and replication and deepens the public's trust in findings. In addition, access to underlying raw data and initial analysis allows scientists to check each other's work and can help catch errors or overlooked factors.

Our Parkinson's Progression Markers Initiative study makes all de-identified data available to the research community, which has downloaded data from the study nearly 5 million times and used it in more than 150 published papers. We encourage our funded researchers to make data available based on the nature of the study and, very importantly, the feasibility of adequate de-identification. Stripping data of personally identifiable information is vital in protecting a study participant's privacy. There must be a balance between research transparency and protecting patient confidentiality.

As overall justification for the proposed rule, the EPA claims it is following the accepted practice of many science organizations, including many scientific journals. However, we believe this is a misleading claim. Major journals in the field only require data be made confidentially available to other researchers for the purposes of reproducing or extending analysis. No major journal requires scientists to publish raw data to the public in all cases. In a joint statement in response to the proposed rule, the editors-in-chief of *Science, Nature, Cell, Proceedings of the National Academy of Sciences,* and the *Public Library of Science* stated that the proposed rule will



exclude important studies from consideration in the rulemaking process and adversely impact the decision-making process.[1]

The types of studies most vulnerable to exclusion — epidemiological studies that investigate how, when and where disease occurs in populations — form the bedrock of knowledge for determining the environment's impact on human health. Exclusion of these studies from EPA review stands to affect every decision made at the agency from National Ambient Air Quality Standards to chemical registration and regulation in consumer products and pesticides. The EPA already requires studies to be peer-reviewed — a gold standard of science — to verify and validate research. The effect of this rule, overall, will be to restrict EPA's access to science rather than make it more transparent. Our specific concerns are outlined below.

Thank you for the opportunity to testify.

De-identified does not mean unidentifiable

As stated in the proposed rule, the agency aims to ensure that "more of ... the science ... is available to the public for validation," while also "reduce[ing] the risk of unauthorized disclosure and re-identification."[2] There are many studies where it is impossible to de-identify data to a level where both the data is usable and the privacy of participants in the study is properly protected. Environmental exposure data often must be specific to a house, street or neighborhood. For example, a 2009 study showed that consuming water from a private well located in an area with historical pesticide use was associated with an increased risk of Parkinson's disease.[3] Due to the nature of wells — typically serving a limited number of people within a very small radius — the detail needed to perform the study renders proper de-identification impossible. Simply knowing that a person lives near a particular well, coupled with a demographic detail such as their age, gender or race could expose the identity of a person with Parkinson's.

Individuals with Parkinson's often do not publicly disclose their disease when first given a diagnosis. Many of them also want to participate in clinical studies toward better treatments and a cure for themselves and for future generations. The EPA's rule puts these individuals at great risk of having their Parkinson's or other diagnoses exposed. Such exposure could, for example, result in unfair job loss, which then causes loss of income, insurance, and other supports necessary to maintain quality of life.

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[1] Jeremy Berg, et.al, Joint Statement on EPA Proposed Rule and Public Availability of Data, Science Magazine, May 4, 2018, at 501.

[2] Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768 (proposed Apr. 30, 2018) (to be codified at 40 C.F.R. pt. 30).

[3] Nicole Gatto, et al., Well Water Consumption and Parkinson's Disease in Rural California, Envtl. Health Persp., Dec. 2009, at 1912-1918.



Rule forces unneeded expense on the public
Even if there was an acceptable way to mask personal data while maintaining enough information to comply with the rule, costs of such anonymizing are unnecessary and expensive. When Texas Congressman Lamar Smith's *Honest and Open New EPA Science Treatment Act of 2017 (Honest Act)*[4] — a bill with content very similar to the currently proposed rule — was under consideration, the Congressional Budget Office estimated it could cost up to several million dollars a year to comply.[5] This money could be better spent on a number of priorities such as more research into the causes of disease.

Chilling impacts to science
If the EPA's rule takes effect, it could introduce selection bias that may slow studies and alter results, and thereby affect regulatory decisions. Large-scale population studies rely on many people — often numbering in the thousands — to reveal sensitive or private information. These studies may have difficulty recruiting or retaining volunteers if the researchers are required to make de-identified data publicly available, as some may be more hesitant to share their information. Those who are willing to participate may be different from others, which could introduce confounding variables and bias that may question the study's results.

The proposed rule stands to affect every program and statute that the EPA administers. Here we highlight the three most directly relevant to the EPA's role in regulating environmental exposures with potential to cause Parkinson's disease.

Parkinson's disease research in pesticide determinations
All pesticides distributed or sold in the United States must first be registered by the EPA and reregistered every 15 years[6]. In order to be registered, the *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)* requires the applicant show that its proposed pesticide does not cause unreasonable risk to human health or the environment.[7] The applicant typically provides studies that comply with the EPA's testing guidelines along with its application materials. The EPA reviews the data provided and performs some of its own work, including human health and ecological risk assessments, on a chemical.[8] Additionally, under the *Food Quality Protection Act*, which amended FIFRA, the EPA must

[4] H.R. 1430, 115th Cong. (2017)
[5] Cong. Budget Office, HONEST Act Cost Estimate (2017).
[6] Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1513, 1514-35 (1996)
[7] Envtl. Prot. Agency, FIFRA and Federal Facilities (2018), https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities
[8] Envtl. Prot. Agency, Human Health Risk Assessment (2016), https://www.epa.gov/risk/human-health-risk-assessment



find a pesticide poses a "reasonable certainty of no harm" before it can be registered for use on food or feed[9].

For example, the herbicide paraquat is currently undergoing reregistration review. As part of that process, the EPA is looking at studies relevant to the chemical's health concerns, including the connection with Parkinson's disease.[10] Over the past few decades, studies consistently show a correlation between exposure to pesticides and Parkinson's disease, but that full breadth of data may not be reviewable by the EPA under the current proposal. For example, a meta-review examined 40 studies and concluded, "epidemiologic studies suggest a relatively consistent association between exposure to pesticides and an increased risk of developing [Parkinson's disease], despite differences in study design, case ascertainment and definition, control selection, and pesticide exposure assessment." Many of these studies would be excluded from consideration under the proposed rule as they (i) gathered personally identifiable data that precludes data sharing, (ii) did not obtain consent for data sharing, or (iii) were foreign studies that do not comply with U.S. data protection regulations.

In addition, relevant studies have design characteristics that make them vulnerable to non-compliance and exclusion. Specifically, two studies of California's Central Valley found years of exposure to a combination of herbicides paraquat and maneb increased the risk of Parkinson's disease later in life. Another study found that Central Valley residents under age 60 who lived near fields where the pesticides paraquat and maneb were used between 1974 and 1999 had a Parkinson's rate many times higher than other residents in the region. Parkinson's is rare enough such that, in many communities, data that would need to be disclosed, such as behavioral factors (e.g., occupation, tobacco or alcohol use, how long a study participant has lived in the area), will render individuals easily identifiable. To protect patient privacy, scientists may not want to make even de-identified data public.[11] Without these and similarly designed studies, the EPA is likely to miss relevant information in its review.

Parkinson's disease research in TSCA determinations

The *Toxic Substances Control Act (TSCA)* is the EPA's primary authority for regulating non-pesticide chemicals. Under TSCA, the EPA can secure information on new and existing chemicals and regulate chemicals it determines pose an unreasonable risk to public health or the environment.[12] All studies used would be subject to the proposed rule.

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[9] Food Quality Protection Act of 1996, Pub. L. No. 104-170 § 408(b)(2)(A)(ii), 110 Stat. at 1516 (1996).
[10] Paraquat Dichloride Human Health Mitigation Decision, 82 Fed. Reg. 118 (Envtl. Prot. Agency Jan. 1, 2017) (notice of availability).
[11] Nat'l Inst. of Health, HIPPA Privacy Rule (2007), https://privacyruleandresearch.nih.gov/pr_08.asp
[12] Envtl. Prot. Agency, Summary of the Toxic Substances Control Act (2017), https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act



In late 2016, the EPA moved to ban toxic chemical trichloroethylene (TCE) due to health risks, including a risk of Parkinson's disease,[13] though this action is still pending[14]. The original recommendation was based on hundreds of studies, many of which would not be considered under the proposed rule.

For example, one study sent questionnaires to 134 people who had formerly worked on a site with heavy and long-term exposure to TCE. Fourteen had signs of Parkinson's disease, and an additional thirteen showed mild features of the condition — far more than expected, given the population.[15] Another asked twin pairs about exposure to solvents including TCE and showed a significant association between TCE exposure and Parkinson's disease risk.[16]

In these relatively small studies, a distinctive characteristic — people who all worked together and twins, respectively — combined with the most basic additional medical information could render the participants identifiable. Both TCE studies are highly cited, and the findings have been replicated. To exclude this evidence that TCE exposure is a risk factor for Parkinson's disease does not serve the best health interests of the American public.

Furthermore, the proposed rule does not comply with the letter of TSCA. TSCA and other statutes administered by the EPA requires the agency use the "best available science"[17] and none require the agency access to raw data. TSCA additionally requires that the EPA consider all information that is reasonably available to the administrator.[18] As drafted, the proposed rule violates these statutes because it would force the agency to ignore some of the best information available.

Parkinson's disease research and the Clean Air Act

The Clean Air Act authorizes the EPA to establish National Ambient Air Quality Standards (NAAQS) to protect public health and to regulate emissions of hazardous air pollutants. The EPA works with local governments to reduce air pollution and uses scientific studies

[13] Press Release, Envtl. Prot. Agency, EPA Moves to Ban Certain Aerosol Degreasers and Dry Cleaning Spot Removers as the First Major Regulatory Action under Chemical Reform Law (Dec. 7, 2016) (on file with the author).
[14] Unified Agenda of Regulatory and Deregulatory Actions, Trichloroethylene 83 Fed. Reg. 1935, 1937. (Jan. 12, 2018)
[15] D.M Gash, et al., Trichlorethylene in Parkinsonism and Complex I Mitochondrial Neurotoxicity, Annals of Neurology, Feb. 2008, at 184-192.
[16] Samuel M. Goldman, et al., Solvent Exposures and Parkinson's Disease Risk in Twins, Annals of Neurology, June 2012, at 776-784.
[17] Frank R. Lautenberg Chemical Safety for the 21st Century Act Pub. L. No 114-182 (codified as amended at 15 USC §2625 (h)) available at: http://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim
[18] Id. at §2625 (k).



that could be impacted by the proposed rule to revise its national air quality standards and NAAQS on a regular basis.[19]

Very little is currently known about air pollution and its impacts on the brain. Recent studies have linked particulate exposures to Parkinson's disease including a large study done in Denmark. This study included several thousand people with and without a current diagnosis of Parkinson's disease. Using extremely specific (within 5-50 meters of the front door) geo-coding to estimate participant's exposure to contaminants, the study estimated that ambient air pollution from traffic increased risk of developing Parkinson's disease by nine percent.[20] Researchers found an increased risk of Parkinson's disease after exposure to particulate matter in studies from Taiwan[21] and South Korea[22] as well.

In addition to challenges in usefulness of data if enough information is redacted to protect privacy, these studies face a hurdle because they were performed internationally. In the Danish study, participants are protected by European Union (EU) law. Going forward, an EU study's compliance with the proposed rule will need to be reconciled with the new General Data Protection Regulation,[23] which is seen as more restrictive than the United States' *Health Insurance Portability and Accountability Act of 1996 (HIPAA)*[24]. Many studies that involve people located in the EU will have a difficult time both complying with the new directive and providing enough information to the EPA to be considered.

Studies from other countries are useful in evaluating U.S. policies. People in other countries are exposed to chemicals at different rates than in the United States, which can show threats not yet discoverable in our country. For example, average particulate matter concentrations in South Korea and China are several times higher than in the United States,[25] making relatively subtle effects stand out more easily. Studies done in other countries can help researchers determine whether an effect is dependent on dose or length of exposure. The inability to review and use international research in determinations will virtually guarantee the EPA is missing major findings and important data.

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[19] Envtl. Prot. Agency, Clean Air Act Overview (2017), https://www.epa.gov/clean-air-act-overview
[20] Beate Ritz, et al., Traffic-Related Air Pollution and Parkinson's in Denmark, Envtl. Health Persp., Mar. 2016, at 351-356.
[21] Chiu-Ying Chen, et al., Long Term Exposure to Air Pollution and the Incidence of Parkinson's Disease: A Nested Case-Control Study, PLOSOne, Aug. 15, 2017, at 1-14.
[22] Hyewon Lee, et al., Short-term Air Pollution Exposure Aggravates Parkinson's Disease in Population-based Cohort, Scientific Reports, Mar. 16, 2017, at 1-14.
[23] Council Directive 2016/679 2016 O.J. (L119) 1, 88 (EC).
[24] Int'l Ass'n of Privacy Prof'l, GDPR Matchup: The Health Insurance Portability and Accountability Act (2018), https://iapp.org/news/a/gdpr-match-up-the-health-insurance-portability-and-accountability-act/
[25] Katherine Ellen Foley, Every Country has Terrible Air Pollution, but these are the World's Worst, Quartz Media, Sep. 28, 2016, https://qz.com/794542/air-pollution-map-by-country-fine-particulate-matter/



In addition to its threat to patient privacy or inclusion of informative studies, this proposed rule also grants too much power to one individual. As written, the proposal grants the EPA administrator broad authority to exclude individual studies. This could have wide-reaching impact depending on the preference of the administrator at the time and allows the administrator to overrule scientists regarding their own research. Allowing politically appointed officials to make decisions about whether a study qualifies for an exception is dangerous. The administrator already has broad authority to decide what action to take on an item. It should not have the power to hide evidence that does not support the action.

The EPA should consider all relevant, peer-reviewed data when making decisions that impact Americans' health, and the proposed rule's exceptions process clearly undermines this goal. If the proposed rule takes effect the EPA should, at least, require that exceptions decisions are made by experts in the area of research. For example, a panel of non-partisan, unaffiliated expert scientists could make recommendations on exceptions.

Overall, the proposed rule will force the EPA to make decisions based on less information, which will compromise its mission to protect human health. As a non-profit organization dedicated to improving the lives of people with a chronic illness, we put patients and families at the heart of everything we do and expect nothing less of the federal government. Decisions made at the EPA impact hundreds of millions of people. Please ensure that the agency continues to balance the need for scientific integrity and transparency with its duty to the protect the country's welfare.

Thank you for the opportunity to testify.

Sincerely,

Todd Sherer
Chief Executive Officer
The Michael J. Fox Foundation for Parkinson's Research
New York, NY and Washington, DC



Todd Sherer, PhD, is the Chief Executive Officer of The Michael J. Fox Foundation for Parkinson's Research. Trained as a neuroscientist, he is responsible for the Foundation's overall scientific and fundraising direction to speed treatment breakthroughs and a cure for Parkinson's disease. Dr. Sherer has played a major role in efforts to increase the pharmaceutical industry's investment in Parkinson's drug development and to engage the patient community in clinical research participation. After a postdoctoral fellowship at Emory University investigating the role of environmental factors in Parkinson's, he joined the Foundation's staff in 2004 and was named Chief Executive Officer in 2011.

Ms. BONAMICI. Thank you for your testimony.

At this point we will begin our first round of questions, and I recognize myself for 5 minutes for my questions.

It's an honor to hear from such a distinguished panel of scientists. And this rule has inspired a lot of attention in the scientific community. And I'd like each panelist to answer very briefly, basically yes or no, do you support the "Strengthening Transparency and Regulatory Science" rule as written?

Dr. BIRNBAUM. No.

Dr. RICE. No.

Dr. ALLISON. More information and clarification is needed.

Dr. NOSEK. Not as written.

Dr. SHERER. No.

Ms. BONAMICI. Thank you very much. The EPA's proposed rule, which we've discussed in this Committee, the essence of it many times, undermines scientific integrity, jeopardizes bedrock public health and environmental standards, and endangers the EPA's ability to protect the American people. It's particularly troubling that the proposed rule appears to be inconsistent with the EPA's statutory obligation to use the best available science, as required in the *Toxic Substances Control Act*, the *Safe Drinking Water Act*, the *Clean Water Act*. And if finalized in its current form, the proposed rule would preclude the use of a range of scientific research that has long been used to safeguard the public.

There's also tremendous uncertainty about how this proposed rule and supplemental would be applied and to what it would be applied, and regardless of how that question is ultimately answered, we know that the rule will severely undermine public health and environmental protections.

I want to start with Dr. Birnbaum. In your testimony, you discuss the evolving nature of science and the importance of using all data. If finalized in its current form, how would application of the proposed rule affect the scientific foundation of the EPA's regulatory decisionmaking?

Dr. BIRNBAUM. So all the available data would mean all the epidemiology studies if there are any clinical studies—and occasionally with air pollution work we've had some clinical studies done. It would include animal studies. It would include mechanistic studies. And the requirement for public availability of all the underlying human data would preclude the use of most of the epidemiological and clinical studies, which would mean that we would be forced to make our decisions based upon animal data only.

Now, the animal data, the question is how much of that will be freely available as well because if some of the data is, say, conducted using chemicals which may have CBI information, that would not be able to be shared. So you lead to constriction of the databases that you can use to make your decision.

Ms. BONAMICI. Thank you very much.

Dr. Allison, the National Academies have issued numerous reports to advise the EPA on opportunities to improve transparency on the collection and analysis of data. And I think everyone here supports transparency. Most recently, these reports have included reproducibility and replicability in science, open science by design, and fostering integrity in research. Does the proposed rule respond

to impediments that reproducibility, as outlined in the Academies' Reproducibility and Replicability in Science report?

Dr. ALLISON. The proposed rule has some provisions in it that respond to some of the issues in the reproducibility and replicability report, but I am not clear that it would take into account all of the comments on it. Clearly, more information in the proposed rule would be necessary to understand how it would be implemented and whether it would successfully accommodate the issues.

Ms. BONAMICI. Thank you. And I mentioned earlier today that I'm sending a letter requesting that the National Academies of Sciences, as an authoritative and independent nonpartisan scientific organization, work with the EPA to review the proposed rule. Last year, the presidents of the National Academies submitted public comments for the proposed rule and warned that it could pose a threat to the credibility of regulatory science at the EPA. The Academies urged the EPA to seek objective expert guidance on the rule and offered their own assistance in reviewing it.

So as a member of the National Academy of Medicine—is that Dr. Rice? Dr. Birnbaum. As a member of the National Academy of Medicine, do you agree that the uncertainties in the proposed rule require the independent expert advice of the National Academies?

Dr. BIRNBAUM. I think it's always useful to get the Academies' advice, but I think there is enough information out there that some of the problems with the rule require it to be redrafted. It would be good if they saw sought outside advice in doing that.

Ms. BONAMICI. Right. And, Dr. Allison, you as well I understand are a member of National Academy of Medicine. Do you agree that the uncertainties in the proposed rule require independent expert advice of the National Academies?

Dr. ALLISON. The National Academies were established by the U.S. Government for the purpose of providing advice to other organizations on scientific matters and are pleased to do so when called upon.

Ms. BONAMICI. Thank you very much. And I see my time is expired. I just want to close with an appreciation for Dr. Sherer. As someone with a family member with Parkinson's, I appreciate your being here, but I also understand the sensitivity of sometimes people do not want to disclose their diagnosis but they still want to get the help and participate in studies, so your points are well taken.

And I yield back, and I now recognize Mr. Lucas for 5 minutes for your questions.

Mr. LUCAS. Thank you, Madam Chair.

Dr. Nosek, in your prepared testimony you stated that the EPA rule had the positive qualities of identifying the importance of transparency and reproducibility of research but had the negative quality of suggesting that evidence failing to meet these principles should not be used in policymaking. I appreciate your effort to provide constructive input on this policy, as well as your work to better institutionalize transparency in the research community. Given your expertise, can you provide additional insights into what you would like to see in any science transparency policy both at the EPA and governmentwide to make it more practical for all policymakers and researchers?

Dr. NOSEK. Yes. Thank you for that question. So as I noted in the statements, a general hope for policymaking is that openness is the default assumption, is that part of the value and opportunity that we have, given the modern ability to share information very widely, is to provide tools and resources and services to make much more of the research process itself, not just the end conclusions, more available to all.

In terms of implementation issues related to that policy, to the extent that there could be provisions that address the issues that have been raised by the whole panel on managing privacy, this would be a significant advantage for the applicability of the rule to maximize the availability and use of research evidence. So, for example, data enclaves that manage the preservation of data but still the privacy of that data for independent others to confirm its validity is a means of potentially promoting the credibility and overall reproducibility of findings while simultaneously managing that with privacy concerns.

Mr. LUCAS. Your research involves developing technology solutions to help researchers incorporate transparent mechanisms as they conduct their research. One example is the open science framework (OSF), an online data management tool that allows scientists to store their data privately as they conduct their research but then allows them to easily make the entire project publicly accessible once their work is completed. The OSF also allows individual researchers to set the parameters of disclosing data, establishing tiered and more limited access to data that may require additional controls such as personal, sensitive information. How could a Federal agency use OSF or similar technology to improve data transparency?

Dr. NOSEK. So some opportunities for using OSF and the many other tools and services that support similar aims would be building into grant requirements what the provisions are for the preservation of the research planning, the materials, the data, and the outcomes that were produced from that work and under what conditions that data must be preserved over a period of time and which parts of it can be made publicly accessible to the maximum extent possible.

So many agencies that provide funding for Federal research already have been making advances for data management plans being an important part of the proposal process for grants. NIH just released some new plans for their data management planning, for example. Continuing to support those efforts would be very useful.

Mr. LUCAS. So along that line, a similar-tiered access approach could be useful in ensuring appropriate data protections for all Federal research?

Dr. NOSEK. Yes.

Mr. LUCAS. With that, Mr. Chairman, I yield back.

Mr. CASTEN [presiding]. Mr. Tonko, you are recognized for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair.

I have here a letter, Mr. Chairman, that was sent to the Committee by esteemed organizations, including the Environmental Defense Fund, the Union of Concerned Scientists, Earth Justice, the

Natural Resources Defense Council, the Environmental Protection Network, and the Clean Air Task Force, all requesting that this rule not move forward.

The letter states that the rule has been criticized by, quote, "leading scientific organizations and public health organizations with the editors of the Nation's leading scientific journals; Presidents of the National Academies of Sciences, Engineering, and Medicine; the President of Harvard University; nearly 100 leading Harvard scientists and medical experts; EPA's own Science Advisory Board, and other scientific experts have all voiced concerns about the proposed rule."

The letter concludes, and I quote, "For the sake of the air and water, the EPA has been tasked with protecting and the millions of human lives that rely on these resources, EPA must not finalize this proposal," close quote.

I share these concerns and move to enter the letter into the record.

Mr. CASTEN. Without objection.

Mr. TONKO. Thank you. In terms of public health, what consequences should we be most worried about if this rule moves forward, to anyone on the panel? Yes. Doctor?

Dr. RICE. Thank you for that question. Let me give an example. So the EPA right now is looking at the National Ambient Air Quality Standard for particulate matter, and as part of that review, they just released their policy assessment. They looked at hundreds of studies about the health effects of particulate matter. And where the data are particularly robust is that long-term exposure of particulate matter is associated with premature mortality. There are many studies that have shown that. So just for this particular policy assessment, the EPA focused on 21 studies looking at particulate matter and total mortality, 14 on premature cardiovascular death, 10 on lung cancer, 7 on respiratory premature death.

If this proposed rule were implemented now, the EPA would not be able to use those studies in deciding what level of particulate matter is safe because the studies could not meet the requirements for public data release. And so the EPA would be setting a health standard that affects the health of the entire country, all of us, on exposure that is clearly associated with mortality and just ignoring that science. And we are very concerned about what the long-term ramifications would be of setting standards without looking at the science.

Mr. TONKO. Thank you, Dr. Rice.

Anyone else on the panel? Yes.

Dr. ALLISON. I think it's really the health of science that's the key question here, and I think that anything which serves to restrict access to useful information on the basis of a simplistic notion of looking at one indicator of the value of research is unwise and undermines the health of science and rationality in general. We need to consider the many aspects that provide science its probative value, not only reproducibility and transparency.

Mr. TONKO. So that being said, to the panel again, the entire panel, how would this rule then affect the health of future generations?

Dr. BIRNBAUM. So many of the exposures that we experience have effects on susceptible populations. And one of the most susceptible populations are the unborn and young children. And the effects that occur developmentally, the exposures that occur developmentally not only may have immediate effects but can have effects that will last the rest of your life. So the effects here could affect an entire generation.

Mr. TONKO. Thank you, Dr. Birnbaum.

Anyone else that wants to take a stab at answering how it would affect future generations? Dr. Rice?

Dr. RICE. Yes, I, too, would echo that my greatest concern is our children, my own children. I have three kids. I have one of them who has respiratory problems. It is clear that—and I'm an air pollution scientist, so that's a pollutant I focus on. But air pollution exposure makes kids sicker and increases their——

Mr. TONKO. In what ways? Addressing what types of diseases?

Dr. RICE. So asthma attacks——

Mr. TONKO. OK.

Dr. RICE [continuing]. So children who have asthma are more likely to end up in the hospital or to use medications for their asthma. Studies in California and across the country have shown that exposure to pollution makes kids' lung function trajectory slow down, and they don't attain the level—the same level of peak lung function in adulthood that they might have if they were exposed to lower levels of pollution. So these are critical windows of exposure. And so exposure to our children today matters for the health that they attain for the rest of their lives.

Mr. TONKO. So if this rule isn't supported by public health groups or scientific societies, then it forces us to ask why did the Administration go down this path?

Dr. RICE. I can't answer that question, but in my oral testimony and my written testimony I want to draw attention to the fact that there's a history here and that there's a long precedent of using the terms transparency and reproducibility in science as a barrier for using science that's inconvenient.

So let me give just one example. Back in the 1990s R.J. Reynolds used a law in Georgia to get the raw data from a study that a pediatrician that looking at Joe Camel, the cartoon character, and how it appealed to kids, and they recognized that he was associated with tobacco smoking more than they knew that Mickey Mouse was associated with Disney. And that wasn't the only study showing that. The *Journal of the American Medical Association* released multiple studies showing that that kind of marketing appealed to kids. So it wasn't really that controversial. But then when they got the raw data, they attacked the scientists, and they attacked the conclusions that he drew. And I worry that those are some of the motivations behind this effort.

Mr. TONKO. Yes, it's tragic. With that, I yield back, Mr. Chair.

Mr. CASTEN. Mr. Baird, you're recognized for 5 minutes.

Mr. BAIRD. Thank you, Mr. Chair.

And, Ranking Member Lucas, I appreciate the opportunity to ask questions. I really appreciate the opportunity to have comments from such a distinguished group of witnesses. That's very helpful

and insightful for our Committee and the work that we're trying to do.

I only have a certain amount of time, so, Dr. Allison, you're the one that I'm going to ask a couple of questions of. First off, though, I just wonder if you're aware that if you'd have just gone 2 more hours north when you came to Indiana from Alabama you'd have been at Purdue University.

You know, in your testimony and all the work that you've done, what, over 600 scientific publications, you've edited five books, you serve as a member of the Committee on Reproducibility and Replicability from the National Academy of Sciences, so I think it's very appropriate to have you here to talk about the things that we're interested in today.

And so my first question is that in your testimony you mentioned that perhaps a thorough statement of raw principles like what constitutes good scientific evidence and how to effectively weigh and evaluate evidence for drawing conclusions could be more useful than a single rulemaking transparency. Could you elaborate on that?

Dr. ALLISON. Certainly. Let me say that these are my own opinions are not necessarily those of the committee that I was here to represent today since the committee didn't address the EPA rule per se.

But it seems to me that EPA, to construct a simplistic rule that says information will be available or usable only if it's reproducible and transparent puts too much weight on one factor. It may allow things in that shouldn't come in, and it may exclude things that shouldn't be excluded, whereas there are other factors that need to be involved. It becomes reasonable only to the extent that exceptions are allowed. But those exceptions will likely be extensive and frequently necessary. Questions have already been raised about exactly how would those exceptions be made, and would the process of making those exceptions foster trust or distrust or optimal approaches?

Better yet it seems to me would be to say multiple factors are important to weigh, including but not limited to reproducibility and transparency, replicability, generalizability of findings, and importantly, overall research rigor. This can be assessed on a case-by-case basis so that the overall evidence can be weighed, all evidence can be considered, but then ultimately decisions are based upon the weight of the evidence. This is the typical practice in much of science, as I wrote extensively in my written remarks about this, and is a practice generally used by other organizations, for example, like FDA (Food and Drug Administration).

Mr. BAIRD. I found it especially interesting you mentioned that scientific research, you know, involves data and methods and logic in how you got there, but the application of rigor in the methods, I found that extremely useful and extremely relevant to making sound scientific decisions. So any further thoughts on that issue on rigor?

Dr. ALLISON. Certainly. We know that a great deal of science varies tremendously in the degree of rigor. Some studies have stronger value than others in helping us determine the truth of propositions. We can only evaluate the strength of those studies to the extent

that we really know what was done. So knowing what was done is very important, and that's partly where transparency comes in.

So transparency is vital. We do want to promote it in all of science. As Dr. Nosek said, we are, as an entire scientific community, working on this, taking ever greater steps to make more and more science transparent. But, as Dr. Rice and others have pointed out, there will always be certain aspects of science that are not fully transparent for any number of reasons. These could include protection of patient privacy, fulfillment of the contract of informed consent, simple loss of information, and we should not make a dicto simpliciter out of the notion that we will only consider information that's transparent.

Mr. BAIRD. Thank you. I've got a whole notebook here. I could spend the rest of the day with you, but they tell me I've got 5 minutes, so thank all of you for being here, and I yield back.

Mr. CASTEN. Thank you. And I now recognize myself for 5 minutes.

Dr. Allison, are you familiar with the phrase p-hacking?

Dr. ALLISON. Sadly, yes.

Mr. CASTEN. Could you give us just a simple overview of what that means for the Committee and how that can be used to draw bad conclusions from good data sets?

Dr. ALLISON. Certainly. P-hacking is a term that it broadly includes multiple practices in which one adaptively analyzes data with the intent of producing a particular result in terms of a p-value, a p-value being a particular statistic that tells one about what we refer to as the statistical significance of the data, very, very loosely speaking, getting a finding. And one can continually reanalyze the data, one can analyze only males and only females separately. One can analyze only young and old. One can throw out an outlier, include an outlier, and transform the data until eventually one gets the result one wants. And so the practice of p-hacking undermines the replicability and validity of analyses.

Mr. CASTEN. So that is a brilliant job of summarizing at least 3 weeks of my college statistics class. I appreciate it.

So in the supplemental rule that the EPA released, they said that their intent is to, quote, "reanalyze data," which they defined as "to analyze exactly the same data to see if the same result emerges from the analysis by using the same programs and statistical methodologies that were originally used to analyze the data." To my way of thinking, that sounds like a recipe for p-hacking. Would you share that concern?

Dr. ALLISON. Again, these are my own comments, but I would not describe it as a recipe, but I would describe it as an opportunity. And I think that this is again where the issue of more information is needed. One would hope that in fact with respect to transparency, then if EPA is going to go down that road, it might want to propose additional plans whereby they engaged the services of Dr. Nosek or other people who do these sorts of things so that their plans also became transparent and so that their reanalysis plans became shots they called prior to looking at and analyzing the data. That might be something in an ideal world. Whether that would always be practicable is unclear. Of course, there would need to be exceptions but it would be helpful.

Mr. CASTEN. Thank you for that clarification. I really was thinking in the context of because the reanalysis would only apply to results where the data was there, we are limiting this that we have. And so, you know, accepting your very good comments that reproducibility cannot be the sole basis of good science, it would seem to me that reanalysis, as they're describing, is not even synonymous precisely with reproducibility. Yes or no, do you agree with that?

Dr. ALLISON. If reproducibility is defined as the National Academies of Science Committee that I served on defines it, then reanalysis is at most reproducibility if it runs the exact same analysis as was initially run.

Mr. CASTEN. OK. Dr. Rice, I've got another easy one for you.

Dr. RICE. I had a follow-up comment on that——

Mr. CASTEN. Well, let me—because we're tight on time——

Dr. RICE. OK.

Mr. CASTEN [continuing]. I'm sure as a medical doctor you're familiar with pre-existing conditions.

Dr. RICE. Absolutely.

Mr. CASTEN. Purely as an individual, not any associations you're with, do you have complete confidence that Congress will never remove the protections to people with pre-existing conditions?

Dr. RICE. I can't comment on that issue specifically, but I can talk about the kinds of conditions that we collect and research. You asked about——

Mr. CASTEN. Well, I asked the question because if we have a concern that our data may not always be kept private and that it may limit our ability to get insurance, get medical coverage——

Dr. RICE. Yes. Oh, I see where you're asking.

Mr. CASTEN [continuing]. Is it reasonable to assume that the average American may not want their health data to be in a publicly searchable database?

Dr. RICE. Well, that I agree with. I think that the average American probably does not want their data about their mental health, their alcohol use, their tobacco behavior, their income on a public database that could potentially be hacked. And for environmental health data, it may be especially easy to figure out who people are because it has to do where people are located.

So, for example, in my research we adjust for community-level confounders, things like census-tracked income, census-tracked education level, things that are associated with where the person lives. And so if you had 10 or 15 of those variables which are data sets, too, you could pretty easily figure out where that person is located. So I think that's a real——

Mr. CASTEN. I always hate interrupting because our time is so short here, but if you could just with a limited time left——

Dr. RICE. Yes.

Mr. CASTEN [continuing]. In the supplemental rule that was revealed, EPA says that studies will be weighted not by scientific metrics but by the public availability of data and models. So can you just speak to what that weighting would do to the quality of data and, ultimately the ethics of——

Dr. RICE. Yes.

Mr. CASTEN [continuing]. Data collection, given what you just discussed?

Dr. RICE. Certainly. That concerns me because environmental health research, we really need to adjust for those kinds of confounders that I just mentioned. Personal-level characteristics are really important so that we do the biostatistics right. So that would actually create a bias against research that really characterizes their study participants really well so that you can account for confounding. Those are the kinds of studies that are least likely to be able to meet this requirement.

Mr. CASTEN. Thank you. And I have used up my time.

Mr. Foster.

Mr. FOSTER. Thank you, Mr. Chair. And I'd also actually like to start out by thanking the Ranking Member Lucas and the minority staff for the existence of Dr. Nosek on this panel. You know, for someone who's lived through the previous 5 years on this panel, seeing an entire panel, minority and majority, all with the dedication to getting the best science as the basis of public policy, it's thrilling.

Now, to me, the privacy and PII are some of the toughest problems in everything that we're wrestling with here. So, first, what is the state-of-the-art on patient consent forms and data anonymization? Is there at least going forward a pretty good, you know, recipe for how you perform public health studies without making too many compromises?

Dr. BIRNBAUM. So it's very difficult to completely protect privacy if you make the data fully available.

Mr. FOSTER. Yes. But, for example, you know, does a typical consent form for a specific study allow that data to be used in a subsequent real scientific study——

Dr. BIRNBAUM. Yes, so the types of terminology that goes into an IRB (institutional review board) protocol, a consent form, is that all attempts to maintain confidentiality will be—but you can't assure confidentiality.

Dr. SHERER. Yes, just to jump in because I referenced one of the studies that we are supporting, there are ways to handle this in the consent process. And I think we have to be clear we don't just focus on what the scientists want to do. These are the volunteers that are participating and being transparent to them on what's happening with their data and that their data will be used for further research. And obviously there's always the risks, but people should be aware of the risks if they're participating.

And one of the concerns that we have is that you can wind up biasing people who are involved in projects who don't want to participate if you put too much criteria on it, and then you don't have a full data set.

Mr. FOSTER. Right. And presumably, if you ask them to consent to having their data used for multiple potentially unknown future studies, that's a much bigger ask than one specific study. You'll get drop-off that may or may not bias your patients and——

Dr. SHERER. Yes, I think people are—you know, you have a pyramid of people who are willing to be involved at different levels, and it's just a matter of being transparent. I think in the case of some of the studies being discussed here that are using census data

or medical record data, you're a lot further from that direct consent, and you have to be very careful about how that data is ultimately going to be shared.

Mr. FOSTER. Now, in terms of data anonymization, I guess Dr. Rice mentioned the problem that if you just do a first-order anonymization, it can be undone with access to other data sets. This is something we're wrestling with on my other committee. I chair a task force on artificial intelligence, and we are wrestling with the fact that artificial intelligence works better with big data sets, you know, like big sets of medical records. And what you want to do is give access to lots of researchers, very large data sets. And one of our witnesses was promoting a technology that goes by the name of homomorphic encryption, which allows you to publish an encrypted data set and ask very detailed statistical questions about that without actually having access to it.

And I guess, Dr. Nosek, is that an approach your familiar with?

Dr. NOSEK. I am familiar with the general approach, not the particulars of that one, but yes, this is a very interesting set of emerging technologies. Alfred P. Sloan Foundation has supported a number of efforts in this regard that perturb the data in such a way that you can't identify any individual data point, but it still maintains the overall structure of the data so you can draw confident conclusions.

Mr. FOSTER. Yes, because it seems like that's something where some effort in that direction could really be transformative to—your ability to make fewer compromises in this pyramid of people willing to come into this.

Dr. SHERER. Just to add, particularly in a chronic disease like Parkinson's disease where it's a late onset, people are older in their life, one additional concern is that some of the data collection may have started decades ago, and you can't really go back in time to re-consent and re-set up the rules about that data. So I think one of the concerns is you'd still want to be able to use that data if you're changing the rules going forward on what is required with sharing. You can't go back 30 years when you started collecting the data.

Mr. FOSTER. Well, yes, over Veterans Day weekend there was a veteran with Parkinson's probably from Agent Orange. And the questions of the—just the validity of the data that was collected, and I guess there's automatic consent in the military, yes, there was another comment.

Dr. RICE. Yes. Oh, I just wanted to describe the process by which—when a study participant enrolls in a study, we have to specify exactly how we're going to use their data and what protections are going to be in place to protect that data. So really the same point that—studies that have already completed, these participants have already signed those consent forms, and those consent forms specified how the data could be used, so this would really impose a major limit on the kind of research that could be used by the EPA.

Mr. FOSTER. Now, going forward, do you believe there's a satisfactory set of options for there, or is that still a work in progress in trying to maximize acceptance of participation on the study versus, you know, ability of it to be used?

Dr. BIRNBAUM. So what is done frequently now—and this started a number of years ago—is you would basically give people two or three choices, you know, I don't want my data used for anything else, my data can be used for everything, you have to come back and ask me. And those are kind of the three basic options that exist. And going forward, that can be done. And there are some studies for the past couple of years where that has already been done. But if you go back before a couple years ago, people were pretty much consented to do exactly one thing.

Mr. FOSTER. Right. And then you have to track down that patient, which has got to be a nightmare in many circumstances.

And so maybe I'll just close with a pitch for the repeal of the unique patient identifier ban that the medical world has been living under, which is something we successfully passed through the House this summer and is awaiting action on the Senate, could be transformative to the ability of researchers to actually, you know, go through and do things like re-contacting patients.

Anyway, thank you, and yield back my time.

Mr. CASTEN. Thank you.

Before we bring today's hearing to a close, I really want to thank all our witnesses for coming before the Committee today and taking the time. Thank you very much.

The record will remain open for 2 weeks for additional statements from the Members and for any additional questions the Committee may ask of the witnesses.

The witnesses are excused, and the hearing is now adjourned.

[Whereupon, at 12:36 p.m., the Committee was adjourned.]

Appendix I

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Dr. Jennifer Orme-Zavaleta

[Despite repeated requests by the Committee over a period of ten months, EPA declined to submit any responses to the Questions for the Record put forth by Committee Members.]

Responses by Dr. Mary B. Rice

1) In the draft of the supplemental rule published by the New York Times, EPA wrote that its intent is to "reanalyze" data, which they define as to "analyze exactly the same data to see if the same result emerges from the analysis by using the same programs and statistical methodologies that were originally used to analyze the data."

   This sounds like a recipe for "p-hacking." Do you share that concern?

Representative Casten and Members of the House Science Committee:

Thank you for submitting this question for the record. I am concerning about the potential for "p-hacking." The practice of "p-hacking" refers to analyzing the same data multiple ways until a desired result is achieved, such as a statistically significant finding with a p value less than 0.05. This practice of "p-hacking" is scientifically unsound, because it boils down to tinkering with data to achieve a desired conclusion, rather than answering the scientific question at hand. The misguided practice of "p-hacking" is avoided whenever scientists establish an analysis plan and statistical methodology that is most appropriate for answering a particular scientific question *before* analyzing the data. For research funded by federal grants, scientists describe their hypothesis and statistical plan in a grant proposal prior to initiation of data analysis. Regardless of funding source, research involving human subjects must undergo Institutional Review Board (ethics) approvals, which also require a written analysis plan prior to starting data analysis.

When the "exactly same data" is reanalyzed by "using the same programs and statistical methodologies," the same result should emerge. This is not p-hacking, just double checking work. However, the published Supplemental Rule states that the statistical methodologies employed by EPA (or other stakeholders) for reanalysis could be different, yet the results are expected to be the same. The rule states: "A person doing a reanalysis of data may use the same programs and statistical methodologies that were originally used to analyze the data **or may use alternative methodologies,** but the point is to analyze exactly the same data to see if the same result emerges from the analysis." Reanalysis using "alternative methodologies" should not necessarily deliver the same results as the original study. Even in cases when alternative methodologies do provide the same results, these results need to be interpreted differently given that an alternative methodology was employed.

Other text in the Supplemental Rule sounds very much like "p-hacking." The rule indicates that data reanalysis will be completed by "stakeholders," who will have the opportunity to "reanalyze the data and models and explore the sensitivity of the conclusions to alternative assumptions while accessing only the data and aspects of the models that they need." There is a lack of clarity over who the "stakeholders" involved in this analysis may be. The suggestion that they may cherry pick data to force into models that support "alternative assumptions" (essentially "hacking" the data to achieve desired alternative results) goes directly against the scientific process and certainly looks at least superficially like exactly the sort of bias the EPA is hoping to avoid with this rule.

Responses by Dr. Todd Sherer

THE MICHAEL J. FOX FOUNDATION
FOR PARKINSON'S RESEARCH

December 11, 2019

The Honorable Paul Tonko
2369 Rayburn House Office Building
Washington, DC 20515

Dear Representative Tonko:

Thank you for your questions in response to my testimony at the Committee of Science, Space, and Technology. The answers are below. Please do not hesitate to reach out directly to me or my colleague, Brittany Meyer (bmeyer@michaeljfox.org) for additional information.

You asked why EPA pesticide determinations under FIFRA are important for people with Parkinson's disease and the impact of the transparency rule on those determinations. All pesticides distributed or sold in the United States must first be registered by the EPA and reregistered every 15 years. In order to be registered, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires the applicant show that its proposed pesticide does not cause "unreasonable risk to human health or the environment." The applicant typically provides studies that comply with the EPA's testing guidelines along with its application materials. The EPA reviews the data provided and performs some of its own work, including human health and ecological risk assessments, on a chemical. Additionally, under the Food Quality Protection Act, which amended FIFRA, the EPA must find a pesticide poses a "reasonable certainty of no harm" before it can be registered for use on food or feed.

The Michael J. Fox Foundation is concerned that the proposed rule could change the quantity and quality of science used when determining whether a pesticide poses "reasonable certainty of no harm," because such studies are likely to be epidemiological in nature and require consent that is unobtainable in order to comply with the rule. In addition, the administrator is given wide discretion to determine whether studies are exempt from the rule, which could easily skew which studies are considered and conclusions based on review of those studies.

For example, the herbicide paraquat is currently undergoing reregistration review. As part of that process, the EPA is looking at studies relevant to the chemical's health effects, including the connection with Parkinson's disease. Over the past few decades, studies consistently show a correlation between exposure to pesticides and Parkinson's disease, but that full breadth of data may not be reviewable by the EPA under the current proposal. For example, a meta-review examined 40 studies and concluded, "epidemiologic studies suggest a relatively consistent association between exposure to pesticides and an increased risk of developing [Parkinson's disease], despite differences in study design, case ascertainment and definition, control selection, and pesticide exposure assessment." Many of these studies would be excluded from consideration under the proposed rule.

In addition, relevant studies have design characteristics that make them vulnerable to non-compliance and exclusion. Specifically, two studies of California's Central Valley found years of exposure to a combination of herbicides paraquat and maneb increased the risk of Parkinson's later in life. Another study found that Central Valley residents under age 60 who lived near fields where the pesticides paraquat and maneb were used between 1974 and 1999 had a Parkinson's rate many times higher than



other residents in the region. Parkinson's is rare enough that in many communities' data that would need to be disclosed, such as behavioral factors (e.g., occupation, tobacco or alcohol use, how long they've lived in the area), will render individuals easily identifiable. To protect patient privacy, scientists may not want to make even de-identified data public. Without these and similarly designed studies, the EPA is likely to miss relevant information in its review.

You asked why EPA's actions under TSCA are important for Parkinson's disease and the impact of the transparency rule on those determinations. The Toxic Substances Control Act (TSCA) is the EPA's primary authority for regulating non-pesticide chemicals. Under TSCA, the EPA can secure information on new and existing chemicals and regulate chemicals it determines pose an unreasonable risk to public health or the environment. All studies used would be subject to the proposed rule. Like concerns regarding FIFRA, The Michael J. Fox Foundation is concerned that the proposed rule could alter the science considered when deciding whether a chemical poses an unreasonable risk to public health or the environment.

For example, in late 2016, the EPA moved to ban toxic chemical trichloroethylene (TCE) due to health risks, including a risk of Parkinson's disease, though this action is still pending. The original recommendation was based on hundreds of studies, many of which would not be considered under the proposed rule.

One study sent questionnaires to 134 people who had formerly worked on a site with heavy and long-term exposure to TCE. Fourteen had signs of Parkinson's disease, and an additional thirteen showed mild features of the condition, far more than expected given the population. Another asked twin pairs about exposure to solvents including TCE; the study showed a significant association between TCE exposure and Parkinson's disease risk.

In these relatively small studies, a distinctive characteristic — people who all worked together and twins, respectively — combined with the most basic additional medical information could render the participants identifiable. Both TCE studies are highly cited, and the findings have been replicated. To exclude this evidence that TCE exposure is a risk factor for Parkinson's disease is illogical and does not serve the best health interests of the American public.

Furthermore, the proposed rule does not comply with the letter of TSCA. TSCA and other statutes administered by the EPA requires the agency use the "best available science." None require the agency to access the raw data. TSCA additionally requires that the EPA consider all information that is reasonably available to the administrator. As drafted, the proposed rule violates these statutes because it would force the agency to ignore some of the best information available.

You asked about the connection between Parkinson's disease and air pollution and the impact of the rule on future studies. The Clean Air Act authorizes the EPA to establish National Ambient Air Quality Standards to protect public health and to regulate emissions of hazardous air pollutants. The EPA works with local governments to reduce air pollution and uses scientific studies that could be impacted by the proposed rule to revise its national air quality standards on a regular basis.

Very little is currently known about air pollution and its impacts on the brain, but studies are ongoing. As the science progresses, it is very likely that future studies may be excluded under the rule and could



prevent the EPA from making informed decisions with the best available science. In addition to concerns about obtaining consent and required deidentification procedures, the emerging science is further complicated in this area because much of it is done outside of the United States. Strict data protection laws in other regions may make it difficult for studies to meet the open data standard for consideration by the EPA.

For example, a Danish study estimated that ambient air pollution from traffic increased risk of developing Parkinson's disease by nine percent. As Denmark is part of the European Union, it must comply with the strict General Data Protection Regulation. That regulation would make it difficult for it to also meet the EPA's proposed rule and be considered in the agency's review of air pollution's health effects.

Studies coming from other countries are vital to health determinations in the Unites States because people in other countries are exposed to chemicals at different rates than in the U.S. The ability to compare exposure to health outcomes can be enlightening. For example, average particulate matter concentrations in South Korea and China are several times higher than in the United States, allowing relatively subtle effects to stand out more easily. Studies done in other countries can also help researchers tease out whether an effect is dose- or length-of-exposure-dependent. The inability to review and use international research in determinations will virtually guarantee EPA is missing major findings and important data.

Again, thank you very much for taking the time to learn about the issue and for reaching out.

Sincerely,

Todd Sherer

Todd Sherer

Appendix II

Additional Material for the Record

LETTER SUBMITTED BY REPRESENTATIVE EDDIE BERNICE JOHNSON

November 13, 2019

United States House of Representatives
Committee on Science, Space and Technology
The Honorable Eddie Bernice Johnson, Chairwoman
The Honorable Frank Lucas, Ranking Member
Washington, DC 20515

Dear Chairwoman Johnson and Ranking Member Lucas:

Thank you for taking the time to hold today's hearing on the U.S. Environmental Protection Agency's (EPA) "Strengthening Transparency in Regulatory Science" proposed rule. As 62 public health, medical, academic, and scientific groups representing millions of Americans, we write to reiterate our ongoing concern over the rule. We hope this oversight hearing will shed further light on the rule's detrimental impacts on EPA's policymaking abilities.

We strongly oppose EPA's efforts to restrict the use of the best available science in its policymaking. Please request that EPA ensure research is protected, and ensure this rule does not move forward.

We support the goal of improving the transparency of science and access to data. When feasible, scientists should strive for appropriate public access to data to maximize utility and trust in the scientific process. However, there are many credible scientific studies where the exposure of raw data to the public is infeasible or would reveal confidential patient or research participant information. The National Academy of Sciences has long opposed such action, stating "[s]ince unrestricted access can cause harm to individuals and also conflicts directly with respect for individual autonomy, it is not an appropriate policy."[i]

The research EPA relies on to make determinations is already transparent in most cases. Many scientific journals and research agencies now have policies governing the sharing of data among researchers and with appropriate access by the public at large. This would also put EPA at odds with the approaches in place at the Centers for Disease Control and Prevention, the National Institutes of Health, and the Food and Drug Administration.

If EPA excludes studies because the data cannot be made public, people may be exposed to real harm. The result would be decisions affecting millions based on inadequate information that fails to include well-supported studies by expert scientists. These efforts will not improve the quality of science used by EPA nor allow the agency to fulfill its mandate of protecting human health and the environment.

For the sake of the country's health, EPA must not restrict this research.

Sincerely:

Allergy & Asthma Network
Alliance for Aging Research
American Academy of Pediatrics
American Autoimmune Related Diseases Association
American Brain Coalition
American College of Physicians
American Geophysical Union
American Geriatrics Society
American Heart Association
American Institute of Biological Sciences
American Lung Association
American Parkinson Disease Association
American Physiological Society
American Public Health Association

American Society for Investigative Pathology
American Sociological Association
American Thoracic Society
Association of American Universities
Association of Public Health Laboratories
Association of Schools and Programs of Public Health
Asthma and Allergy Foundation of America
Autism Speaks
Big Cities Health Coalition
Bridge the Gap - SYNGAP Education and Research Foundation
Center for Open Science
Center for Reproductive Rights
Children's Environmental Health Network
Cornell University
Council on Governmental Relations
Endocrine Society
Geological Society of America
Harvard University
Health Care Without Harm
Healthy Schools Network
Huntington Breast Cancer Action Coalition, Inc.
International Essential Tremor Foundation
International Society for Environmental Epidemiology
Medical Advocates for Healthy Air
Medical Society Consortium on Climate and Health
National Association of County and City Health Officials
National Center for Environmental Health Strategies
National Eczema Association
National Multiple Sclerosis Society
Parkinson's Foundation
Physicians for Social Responsibility
Princeton University
Society for the Study of Evolution
Society for the Study of Reproduction
Society of Toxicology
Stony Brook University
The Association of Public and Land-Grant Universities
The Michael J. Fox Foundation for Parkinson's Research
The University of California System
Union of Concerned Scientists
University of California, Berkeley
University of California, Los Angeles
University of California, Merced
University of California, Riverside
University of California, San Francisco
University of California, Santa Cruz
University of Florida
University of Washington

[1] National Research Council. 2000. *Improving Access to and Confidentiality of Research Data: Report of a Workshop*. Washington, DC: The National Academies Press. https://doi.org/10.17226/9958

ARTICLE SUBMITTED BY REPRESENTATIVE SUZANNE BONAMICI

The New York Times

E.P.A. to Limit Science Used to Write Public Health Rules



By Lisa Friedman

Nov. 11, 2019

Want climate news in your inbox? Sign up here for ***Climate Fwd:****, our email newsletter.*

WASHINGTON — The Trump administration is preparing to significantly limit the scientific and medical research that the government can use to determine public health regulations, overriding protests from scientists and physicians who say the new rule would undermine the scientific underpinnings of government policymaking.

A new draft of the Environmental Protection Agency proposal, titled Strengthening Transparency in Regulatory Science, would require that scientists disclose all of their raw data, including confidential medical records, before the agency could consider an academic study's conclusions. E.P.A. officials called the plan a step toward transparency and said the disclosure of raw data would allow conclusions to be verified independently.

"We are committed to the highest quality science," Andrew Wheeler, the E.P.A. administrator, told a congressional committee in September. "Good science is science that can be replicated and independently validated, science that can hold up to scrutiny. That is why we're moving forward to ensure that the science supporting agency decisions is transparent and available for evaluation by the public and stakeholders."

The measure would make it more difficult to enact new clean air and water rules because many studies detailing the links between pollution and disease rely on personal health information gathered under confidentiality agreements. And, unlike a version of the proposal that surfaced in early 2018, this one could apply retroactively to public health regulations already in place.

"This means the E.P.A. can justify rolling back rules or failing to update rules based on the best information to protect public health and the environment, which means more dirty air and more premature deaths," said Paul Billings, senior vice president for advocacy at the American Lung Association.

Public health experts warned that studies that have been used for decades — to show, for example, that mercury from power plants impairs brain development, or that lead in paint dust is tied to behavioral disorders in children — might be inadmissible when existing regulations come up for renewal.

For instance, a groundbreaking 1993 Harvard University project that definitively linked polluted air to premature deaths, currently the foundation of the nation's air-quality laws, could become inadmissible. When gathering data for their research, known as the Six Cities study, scientists signed confidentiality agreements to track the private medical and occupational histories of more than 22,000 people in six cities. They combined that personal data with home air-quality data to study the link between chronic exposure to air pollution and mortality.

But the fossil fuel industry and some Republican lawmakers have long criticized the analysis and a similar study by the American Cancer Society, saying the underlying data sets of both were never made public, preventing independent analysis of the conclusions.

The change is part of a broader administration effort to weaken the scientific underpinnings of policymaking. Senior administration officials have tried to water down the testimony of government scientists, publicly chastised scientists who have dissented from President Trump's positions and blocked government researchers from traveling to conferences to present their work.

In this case, the administration is taking aim at public health studies conducted outside the government that could justify tightening regulations on smog in the air, mercury in water, lead in paint and other potential threats to human health.

Scott Pruitt, the former administrator of the E.P.A., had made publication of underlying scientific data a top priority and tried to rush a proposal through the regulatory system in 2018. Mr. Pruitt resigned that July, and his successor, Mr. Wheeler, delayed the transparency rule and suggested the E.P.A. needed time to address the chorus of opposition from environmental and public health groups.

But a draft of the revised regulation headed for White House review and obtained by The New York Times shows that the administration intends to widen its scope, not narrow it.

The previous version of the regulation would have applied only to a certain type of research, "dose-response" studies in which levels of toxicity are studied in animals or humans. The new proposal would require access to the raw data for virtually every study that the E.P.A. considers.

"E.P.A. is proposing a broader applicability," the new regulation states, saying that open data should not be limited to certain types of studies.

Most significantly, the new proposal would apply retroactively. A separate internal E.P.A. memo viewed by The New York Times shows that the agency had considered, but ultimately rejected, an option that might have allowed foundational studies like Harvard's Six Cities study to continue to be used.

An E.P.A. spokeswoman said in an emailed statement, "The agency does not discuss draft, deliberative documents or actions still under internal and interagency review."

On Wednesday, the House Committee on Science, Space and Technology will hold a hearing on the E.P.A.'s efforts. A top pulmonary specialist and a representative of the country's largest nonprofit funder of research on Parkinson's disease, the Michael J. Fox Foundation, are expected to testify that the E.P.A.'s proposed rule would eliminate the use of valuable research showing the dangers of pollution to human health.

Mr. Pruitt's original proposal drew nearly 600,000 comments, the vast majority of them in opposition. Among them were leading public health groups and some of the country's top scientific organizations like the American Association for the Advancement of Science.

The National Association of Pediatric Nurse Practitioners said it was "deeply concerned" that the rule would lead to the exclusion of studies, "ultimately resulting in weaker environmental and health protections and greater risks to children's health." The National Center for Science Education said ruling out studies that do not use open data "would send a deeply misleading message, ignoring the thoughtful processes that scientists use to ensure that all relevant evidence is considered." The Medical Library Association and the Association of Academic Health Science Libraries said the proposal "contradicts our core values."

Industry groups said the rule would ensure greater public understanding of the science behind regulations that cost consumers money.

"Transparency, reproducibility and application of current scientific knowledge are paramount to providing the foundation required for sound regulations," the American Chemistry Council wrote to the E.P.A. in support of the plan.

The new version does not appear to have taken any of the opposition into consideration. At a meeting of the agency's independent science advisory board this summer, Mr. Wheeler said he was "a little shocked" at the amount of opposition to the proposal, but he was committed to finalizing it. Beyond retroactivity, the latest version stipulates that all data and models used in studies under consideration at the E.P.A. would have to be made available to the agency so it can reanalyze research itself. The politically appointed agency administrator would have wide-ranging discretion over which studies to accept or reject.

"It was hard to imagine that they could have made this worse, but they did," said Michael Halpern, deputy director for the Center for Science and Democracy at the Union of Concerned Scientists, a nonprofit advocacy group. He added, "This is a wholesale politicization of the process."

Academics are not typically required to turn over private data when submitting studies for peer review by other specialists in the field, or for publication in scientific journals, the traditional ways scientific research is evaluated. If academics were to turn over the raw data to be made available for public review, the E.P.A. would have to spend hundreds of millions of dollars to redact private information, according to one federal estimate.

The Six Cities study and a 1995 American Cancer Society analysis of 1.2 million people that confirmed the Harvard findings appear to be the inspiration of the regulation.

The proposal gives the public 30 days to offer comments on the changes to the E.P.A.'s plan. Agency officials have said they hope to finalize the measure in 2020.

"The original goal was to stop E.P.A. from relying on these two studies unless the data is made public," said Steven J. Milloy, a member of Mr. Trump's E.P.A. transition team who runs Junkscience.org, a website that questions established climate change science and contends particulate matter in smog does not harm human health.

He dismissed concerns that the new rule could be used to unravel existing regulations, but he said he did expect it to prevent pollution rules from getting tougher.

"The reality is, standards are not going to be tightened as long as there's a Republican in office," he said.

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NEWS RELEASE SUBMITTED BY REPRESENTATIVES SUZANNE BONAMICI AND BRIAN BABIN

An official website of the United States government.

Close

We've made some changes to EPA.gov. If the information you are looking for is not here, you may be able to find it on the EPA Web Archive or the January 19, 2017 Web Snapshot.

EPA United States Environmental Protection Agency

News Releases from Headquarters

The New York Times' Several Glaring Inaccuracies "That's Fit To Print"

11/12/2019

Contact Information:
EPA Press Office (press@epa.gov)

WASHINGTON — Late yesterday, the New York Times published a story ***EPA to Limit Science Used to Write Public Health Rules***, that has numerous errors and is based on leaked preliminary, draft documents that are not accurate and do not include the final text submitted to the Office of Management and Budget (OMB) for interagency review.

On Friday, Nov. 8, the U.S. Environmental Protection Agency (EPA) delivered to OMB a draft supplemental federal register notice (FRN) to clarify, modify and supplement certain provisions included in the 2018 proposed "Strengthening Transparency in Regulatory Science" rule. The 2018 proposed rule solicited comment on all aspects of the proposed rule. This supplemental FRN solicits comment only on the changes and additions to the proposed regulatory text discussed in this supplemental notice. The agency still intends to issue a final rule in 2020. This final rule will take into account the comments received in response to both the 2018 proposed rule and this supplemental FRN as well as those submitted by the Science Advisory Board.

EPA recognizes that when it develops significant regulations using public resources, including regulations for which the public is likely to bear the cost of compliance, EPA should ensure that the data and models underlying scientific studies that are pivotal to the regulatory action are available for review and reanalysis. The "Strengthening Transparency in Regulatory Science" rulemaking is designed to increase transparency in the preparation, identification and use of science in rulemaking. When final, this action will ensure that the regulatory science underlying EPA's actions are made available in a manner sufficient for independent validation.

EPA has not finalized this proposal but responds to the claims alleged as they are not an accurate account of where the proposal stands. **How the New York Times got it wrong:**

The reporter incorrectly reports that "unlike a proposal that surfaced in early 2018, this one could apply retroactively to public health regulations already in place." **This is completely false.** The proposal and supplemental will not apply to any regulations already in place.

The reporter again says the proposal would apply retroactively to existing regulations, **which is completely false.** The supplemental (and the original proposal) allow studies like the Harvard Six City study to be used. The agency has not rejected or otherwise eliminated that option in anyway in its original proposal or supplemental. In fact, the supplemental makes it even clearer that such studies must be properly considered and takes comment from the public on this issue.

Additionally, they report that this "would require scientists to disclose all of their raw data, including confidential medical records." **This is not true.** In the originally proposed regulation and in the leaked supplemental, EPA maintains protecting confidential personal information just as other federal health agencies regularly do. The reporter clearly does not understand the terms in the context of science transparency.

The story continues with more false information. The reporter writes: "The measure would make it more difficult to inact new clean air and water rules…" **This is just wrong.** The reality is that the supplemental addresses this concern and clarifies points that were not entirely made clear in the original proposal. If the reporter had truly read the *outdated* leaked draft she would have read a discussion of how scientists across the country have already approved methods to gain access to a study's underlying data that contains personal information without revealing the identity of the individuals.

The article continues with more misleading and false information. The reporter writes: "The change is part of a broader administration effort to weaken the scientific underpinnings of policymaking." **Science transparency does not weaken science, quite the contrary**. By requiring transparency, scientists will be required to publish hypothesis and experimental data for other scientists to review and discuss, requiring the science to withstand skepticism and peer review.

In fact, EPA currently has transparency rules in place for its intramural research and extramural grants. **Non-government funded research should also be subject to transparency requirements.** When finalized, the science transparency rule will ensure that all important studies underlying significant regulatory actions at the EPA, regardless of their source, are subject to a transparent review by qualified scientists.

The article continues with inaccurate information. The reporter writes: "The new version does not appear to have taken any of the opposition into consideration." **This is just bad reporting. It is completely misleading, and lacks the understanding of the rule making process.** A supplemental to a proposed rule is not a 'new' rule and is not intended to address comments to a proposal. The public will have the ability to comment on the supplemental just as they did for the proposal. The final rule will address all comments.

Additionally, the reporter incorrectly states that: "The politically appointed agency administrator would have wide-ranging discretion over which studies to accept or reject." **This is completely false.** The rule requires transparency but gives the EPA Administrator the discretion to use studies when information is not available. However, this should be the exception instead of the way of EPA doing business.

The reporter again inaccurately reports on the meaning of "raw data." The supplemental seeks public comment on any changes to the scope. Once again, **the reporter confuses the situation by using "raw data," which is clarified in the supplemental.**

In the first paragraph, they report that "the new rule would…" **This is not a new rule.** What was submitted to OMB is a supplemental to the 2018 proposed rule. In the next paragraph, they continue to misreport by calling this a "new draft." Again, this is not a new rule, this is supplemental to the 2018 proposal.

And finally, the reporter writes: "Academics are not typically required to turn over private data when submitting studies for peer review…" The scientific community is increasingly interested in increasing transparency in research. Several academic journals, including the Public Library of Science and the Annals of Internal Medicine already have a publication condition requiring authors to make their data available upon request and many institutions, including Yale and Harvard universities, are making strides in creating publicly accessible repositories of research and clinical data.

LAST UPDATED ON NOVEMBER 12, 2019

LETTERS SUBMITTED BY REPRESENTATIVE LIZZIE FLETCHER

AAAS

November 11, 2019

The Honorable Eddie Bernice Johnson
Chairwoman, House Science, Space & Technology Committee
2321 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Lucas
Ranking Member, House Science, Space & Technology Committee
2321 Rayburn House Office Building
Washington, DC 20515

Dear Chairwoman Johnson and Ranking Member Lucas:

The American Association for the Advancement of Science (AAAS) appreciates that the committee has scheduled a November 13 hearing to discuss the role of science in decision-making at the Environmental Protection Agency (EPA). When EPA issued its proposed rule, *Strengthening Transparency in Regulatory Science*, AAAS submitted public comments[i] articulating our concerns. In sum, AAAS strongly believes that the proposed rule would undermine EPA's ability to use the best available science in its policymaking process and ultimately restrict the use of science in its decisions.

As the publisher of the world's preeminent peer-reviewed scientific journal *Science*, we are committed to upholding the values of scientific peer review and to ensuring, to the maximum extent possible, the quality of information in support of the conduct of research and the dissemination of research results. In response to the EPA's proposed rule, the editors of several peer-reviewed journals, including *Science*, issued a rare joint statement noting that journal editorial standards of scientific journals "recognize the array of workflows across scientific fields and make the case for data sharing at different levels of stringency; in not every case can all data be fully shared." It further warned EPA that it "does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather it is paramount that the full suite of relevant science vetted through peer review...inform the landscape of decision making."[ii]

The complexity surrounding access to scientific data utilized in regulations and policies deserves a thoughtful and rigorous discussion among the entities and stakeholders that comprise the public and private scientific community. EPA's initial proposed rule, if enacted, would set a dangerous precedent and a flawed standard that peer-reviewed scientific research data that is not publicly available is not rigorous enough for use in decision-making. This would be detrimental to the use of vetted evidence in public policy.

Requiring raw data to be made publicly available before a study can be utilized, or retroactively applying such a standard in decision-making, risks cutting off foundational research that has informed EPA's work for decades. AAAS believes that prior studies should be exempt, as many foundational studies regarding air quality and asthma and exposure to mercury and lead were conducted decades ago. It would be difficult and potentially impossible to make all the

Executive Office
AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE
1200 New York Avenue, NW • Washington, DC 20005 USA • Tel: 202 326 6640 • aaas.org

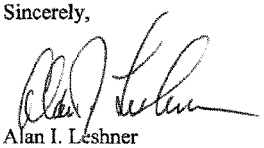
underlying data fully accessible. Most of these studies have been reanalyzed, reassessed and/or reproduced by other institutions and countries. Applying a transparency rule to science retroactively would narrow the scope of scientific research available to the agency in its decision-making.

Another concern focuses on whether the proper checks and balances with appropriate oversight bodies are in place when determining what scientific information would be reanalyzed or reproduced by the agency. For example, AAAS recognizes that independent peer review is important, however, it was not clearly articulated who may serve as an independent peer reviewer and who makes the determination. Would a scientific advisory committee or a political appointee determine who may serve as an independent reviewer? In the proposed rule, the EPA Administrator had been named as the sole authority to grant exceptions in the proposed transparency rule. Since the agency addresses a wide range of scientific disciplines that intersect with the environment and public health, this exemption could eliminate the important role that relevant scientific advisors should play in the decision-making process.

The nation's judicial system also has recognized the importance of EPA having access to as much scientific information as possible to protect public health and the environment. In 2002, the D.C. Circuit Court argued that it would be "impractical and unnecessary" for the EPA to require that all underlying data be made public.[iii]

AAAS continues to urge EPA to consider carefully and deliberately, in concert with the scientific community and other stakeholder communities, any policy changes that could diminish the necessary role of scientific evidence in helping to make decisions that impact the health of all Americans.

Sincerely,



Alan I. Leshner
Interim CEO and Executive Publisher

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[i] https://www.aaas.org/sites/default/files/s3fs-public/Comment%20on%20Proposed%20Rulemaking%20titled%20%E2%80%9CStrengthening%20Transparency%20in%20Regulatory%20Science%2C%E2%80%9D%20Docket%20ID%20No.%20EPA-HQ-OA-2018-0259.pdf

[ii] Berg, J., Campbell, P., Kiermer, V., Raikhel, N., Sweet, D. Joint statement on EPA proposed rule and public availability of data. *Science*. 2018 May 4:360(6388). http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

[iii] https://law.justia.com/cases/federal/appellate-courts/F3/283/355/484491



Association of American Medical Colleges
655 K Street, NW, Suite 100, Washington, DC 20001-2399
T 202 828 0400
aamc.org

November 13, 2019

The Honorable Eddie Bernice Johnson, Chair
The Honorable Frank Lucas, Ranking Member
Committee on Science, Space, and Technology
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairwoman Johnson and Ranking Member Lucas:

The Association of American Medical Colleges (AAMC) is pleased to submit the following July 2018 letter for the record to accompany the House Science, Space, and Technology Committee's November 13 hearing, "Strengthening Transparency or Silencing Science? The Future of Science in Environmental Protection Agency (EPA) Rulemaking."

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The attached letter was submitted by the AAMC and other members of the higher education community in response to the EPA's April 2018 proposed rule, "Strengthening Transparency in Regulatory Science," which seeks to limit the science the agency could consider in rulemaking to research for which all underlying data are publicly available. While EPA Administrator Andrew Wheeler at a September 19 hearing before the committee stated that the agency intends to issue a supplemental proposal to the April 2018 proposed rule, we wish to reinforce the previous comments from the AAMC and its peer institutions, and encourage the EPA to rescind the proposed rule and work with the scientific community on the development of an evidence-based policy that promotes the use of the best science in protecting human health.

The AAMC appreciates the opportunity to submit this letter to reiterate the importance of the use of scientific evidence in agency rulemaking and looks forward to continuing to work with the committee and agencies to ensure that the best available and most relevant scientific findings are used in rulemaking activities to promote the health of all Americans.

Sincerely,

Karen D Fisher

Karen Fisher, JD
Chief Public Policy Officer



July 11, 2018

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Submitted electronically at www.regulations.gov

Re: Docket Number EPA-HQ-OA-2018-0259-0025, Strengthening Transparency in Regulatory Science

The Association of American Medical Colleges (AAMC), Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), and Council on Governmental Relations (COGR), collectively the "Associations," write in response to the proposed rule issued by the Environmental Protection Agency (EPA), published in the Federal Register on April 30, 2018. The member institutions of AAMC, AAU, APLU, and COGR are the primary performers of federally funded research.

In this notice of proposed rulemaking (NPRM), the EPA has set forth a process that limits the science it will consider in critical rulemaking activities to those studies for which all underlying data are publicly available for analysis. Rather than foster the laudable goals of increasing transparency and enhancing the validity and reproducibility of scientific findings, this proposed rule would effectively prevent the EPA from evaluating the *best available* evidence when developing regulations specifically aimed at protecting human health. **While our Associations strongly support transparency, reproducibility, and open science, we have never suggested that scientific research lacks merit or value if the data, for legitimate reasons, cannot be made publicly available or reproduced.** We are particularly concerned when such rationale becomes the justification for ignoring scientific evidence that can save lives. **The Associations, therefore, urge the EPA to withdraw this proposed rule.**

The proposed rule does not advance the type of sound, evidence-based policymaking that is essential for every agency, and particularly important for the EPA, whose activities and regulations have a profound impact on air, land, and water quality, and thus the health of all Americans. **This proposal thwarts the promise of evidence-based policymaking, squarely contradicting the requirement that the EPA use the "best available science"[1] to make its regulatory decisions.** Basing decision-making on only those

[1] Exec. Order No. 13563, 3 C.F.R. 3821 (2011) and Exec. Order No. 13783, 3 C.F.R. 16093 (2017).

studies with publicly available data would drastically curtail the use of key information and studies in the policymaking process and ignore the entire body of scientific evidence built up over years of inquiry.

The NPRM indicates that it "takes into consideration the policies and recommendations of third party organizations who advocated for open science." However, while encouraging greater access to research data and suggesting incentives or necessary infrastructure enhancements to enable data sharing, **most of the cited reports and policies from respected organizations listed do not recommend or support the premise that research should be disregarded if the data are not publicly available.** The recommendations from one such report from the National Academies of Science, Engineering, and Medicine, "*Optimizing the Nation's Investment in Academic Research*,"[2] were incorporated into the 21st Century Cures Act and discuss the potential burdens of data sharing policies, but do not suggest that a policy such as the one being proposed by the EPA would be beneficial.

The NPRM further asserts that the policies are "informed by the policies recently adopted by some major scientific journals," specifically citing the journals *PLOS ONE*, *Science*, and *Nature*. A commentary by the editors in chief of those journals in response to this NPRM refutes this characterization and rejects such a stringent approach, stating, "It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."[3]

There are legitimate, reasonable and ethical reasons that scientific data may not be available to the public. This should not invalidate the research or its findings, and should not prevent the research from being used in important EPA rulemaking. In cases where it is not appropriate for data to be made publicly available, there are other mechanisms intrinsic to the scientific process for substantiating the relevance and validity of research results. Large-scale health and environmental studies generally involve sensitive data from human subjects, which may not be fully de-identifiable. In addition, many individuals agree to participate in these research studies through an informed consent process that ensures their data will not be shared in any form. The assurances provided to research subjects are reviewed, along with the entirety of each proposed study, by an institutional review board (IRB) charged with ensuring the ethical treatment of human subjects and their data. As a highly relevant example, data from the landmark "Six Cities" study[4] that established a link between air pollution and human mortality, could not be made

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[2] National Academies of Sciences, Engineering, and Medicine. 2016. *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*. Washington, DC: The National Academies Press. https://doi.org/10.17226/21824.

[3] Berg, J., Campbell, P., Kiermer, V., Raikhel, N., Sweet, D. Joint statement on EPA proposed rule and public availability of data. Science. 2018 May 4:360(6388). http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

[4] Dockery, D.W., Pope, C.A., Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris, Jr., B.G., Speizer, F.E. An Association between Air Pollution and Mortality in Six U.S. Cities. N Engl J Med. 1993 329:1753-1759. https://www.nejm.org/doi/full/10.1056/NEJM199312093292401.

publicly available for a number of reasons, including promises that were made to the study participants at time of enrollment. Notably, the outcomes of this particular study have been validated in a number of scientifically rigorous ways and by several independent studies. Nowhere does the NPRM suggest that other mechanisms could be used to give the EPA confidence that the findings should be considered in rulemaking. Such mechanisms include comparing outcomes of several trials from different groups that reach the same conclusions, and vetting the science through expert scientific panels specially convened for this purpose. These mechanisms are especially important for studies conducted in the past, for which the underlying datasets may be wholly unsuitable or unavailable for public review.

In some instances, this proposed rule will directly conflict with Executive Order 13556[5] and the accompanying National Archives and Records Administration implementing directive[6], which place limitations on the release of specific non-classified information involving privacy, security, proprietary business interests, and law enforcement investigations. We would particularly question if controlled unclassified information (CUI) categories limiting the release of information relating to health, genetic information, proprietary business information, pesticide producers and railroad safety analysis records[7] might prevent valid scientific studies based upon these CUI categories from being released and as a result, prevent the best possible scientific evidence from being used to develop regulations aimed at protecting public health and safety.

Even for those studies where the researchers are not specifically prohibited by an IRB or other restrictions from making the data publicly available, **de-identification to maintain privacy is not simply a matter of redacting names from documents, but a complex and resource-intensive process**. Scientific data may be prepared for and shared with other scientists for many reasons, including the development of new hypotheses, new analyses to seek novel patterns or test current suppositions, or for purposes of reproducing or confirming aspects of a particular study, and also to avoid duplication of efforts and accelerating discovery. Weighing the merit of these approaches, the privacy considerations, and the resources needed to accomplish meaningful data sharing is what drives these decisions today, and should continue to be considerations going forward. Policy should be informed by science, but science is not always undertaken for purposes of informing regulatory decisions.

Even the strongest and most sincere supporters of the open science movement have recognized that there is value in research for which underlying data are not made publicly available and acknowledge an imperative to leverage all science to develop policies and regulations.[8] The goals of open science are not advanced through this proposal, which does not provide incentives, funding, or infrastructure for increasing access to data, but simply allows the Agency to disregard important, ethical, well-designed and executed studies.

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[5] Exec. Order No. 13556, 3 C.F.R. 68675 (2010).
[6] 32 C.F.R. pt. 2002 (2016).
[7] National Archives CUI Categories (2018). *Available at:* https://www.archives.gov/cui/registry/category-list.
[8] Ioannidis, J.P.A. All science should inform policy and regulation. PLOS Medicine. 2018 15(5): e1002576. https://doi.org/10.1371/journal.pmed.1002576.

The trend toward data transparency championed by the Associations and by foundations and science agencies around the world is predicated on the view that **peer-reviewed, published studies already have presumptive scientific merit.** In fact, the EPA itself is bound through a recent Executive Order to develop regulations through "transparent processes that employ the best available peer-reviewed science."[9] The proposed rule presumes that peer-reviewed, otherwise credible scientific studies do not merit consideration in the agency's decision making, unless data supporting the study are made publicly available within the agency's specifications. This presumption is not in keeping with the spirit of data transparency as understood by the scientific community. Science does not depend on the public availability of underlying data to indicate quality and reliability of evidence, and public availability of research data is not a proxy for the reproducibility of science. **The Associations urge the EPA to promptly rescind this proposed rule, and to engage with the scientific community to discuss how evidence-based policy should be developed to protect human health and the environment.**[10]

Sincerely,

Darrell G. Kirch	Mary Sue Coleman	Peter McPherson	Anthony P. DeCrappeo
President and CEO, AAMC	President, AAU	President, APLU	President, COGR

The Association of American Medical Colleges (AAMC) is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems; and more than 80 academic societies. The Association of American Universities (AAU) is an association of 60 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization with a membership of 237 public research universities, land-grant institutions, state university systems, and affiliated organizations in the U.S., Canada, and Mexico, that is dedicated to strengthening and advancing the work of public universities. The Council on Governmental Relations (COGR) is an association of over 190 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

[9] Exec. Order No. 13783, 3 C.F.R. 16093 (2017).
[10] United States Environmental Protection Agency. Our Mission and What We Do. https://www.epa.gov/aboutepa/our-mission-and-what-we-do.

LETTER SUBMITTED BY REPRESENTATIVE HALEY STEVENS

MICHIGAN STATE UNIVERSITY | HURLEY CHILDREN'S HOSPITAL

PEDIATRIC PUBLIC HEALTH INITIATIVE

November 11, 2019

Congresswoman Haley Stevens
227 Cannon House Office Building
Washington, DC 20515

Dear Congresswoman Stevens,

Thank you for your leadership on the House Science Committee, and for your passion for protecting the people of Michigan from environmental health threats. As you of course know, people in Michigan are exposed daily to an array of contaminants and pollution that threaten our health and well-being. We expect and rely on the EPA to provide guidance and support to make decisions based on the best-available science to protect human health and the environment. This expectation is embedded in the mission of the agency.

I know from my work as a pediatrician in Flint that when the EPA succeeds, people are protected, and when the EPA fails, people get sick. This is especially true for our most vulnerable communities, and most disparately for our children, both here in Flint and around the state. Let the story of the Flint water crisis serve as a tragic reminder of the consequences of undermining science – not only the science of water treatment, but also the science of lead's neurotoxicity. The lessons of Flint demand that we respect science and scientists, strengthen public health regulations, and govern based on the precautionary principle to fully protect the health and development of our nation's children.

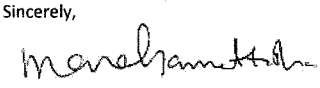
Unfortunately, the newly revised EPA proposal, "Strengthening Transparency in Regulatory Science," undermines essential protections and established science-based decision-making processes; shockingly, it does so to an even greater extent than the original proposed rule would have, despite overwhelming public opposition. The EPA must be able to use all of the research at its disposal to protect the public. The draft rule and the supplemental rule go in the opposite direction.

There is no justifiable reason for limiting the use of the best available science in decisions about air pollution, chemical safety, lead exposure, and more. This science, which has already undergone quality-checks such as peer review, often necessarily contains confidential information, such as personal health data, that cannot effectively be anonymized. And, as public health studies form the backbone of environmental protections, removing their ability to inform EPA decision making would have catastrophic consequences for public health and safety.

People in our communities are already suffering from cumulative and day-to-day harms caused by pollution that EPA is supposed to regulate. Transparency should not be weaponized and science should not be politicized. We need the EPA to act quickly, decisively, and accurately—and to do so, it must use the best available science.

As a public health pediatrician on the front lines of one of our nation's most emblematic environmental and public health crisis, I urge you to do all you can to stop this rule from moving forward and to defend the critical role of science at the EPA. Thank you again for your time and attention to this important issue.

Sincerely,



Mona Hanna-Attisha MD MPH FAAP
Founder and Director, MSU-Hurley Pediatric Public Health Initiative
Associate Professor, Department of Pediatrics and Human Development
C.S. Mott Endowed Professor of Public Health, Division of Public Health
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hannamon@msu.edu

LETTER SUBMITTED BY REPRESENTATIVE PAUL TONKO

November 12, 2019

The Honorable Eddie Bernice Johnson, Chairwoman
The Honorable Frank Lucas, Ranking Member
Committee on Science, Space and Technology
United States House of Representatives
Washington, DC 20515

Dear Chairwoman Johnson and Ranking Member Lucas:

Thank you for holding today's hearing on the U.S. Environmental Protection Agency's (EPA) "Strengthening Transparency in Regulatory Science" proposed rule. As environmental groups, representing millions of members invested in public health and environmental stewardship, we write to reiterate our ongoing concern over the rule's detrimental impacts on EPA's ability to protect communities from harmful pollution. We strongly oppose this proposal's efforts to restrict the use of the best available science in EPA policymaking. This approach would fundamentally compromise EPA's ability to set standards that protect us all from dangerous pollution. Please request that EPA ensure its use of science in decision making is protected and this rule does not move forward.

The proposed rule was developed without consultation with the agency's Scientific Advisory Board or other scientific authorities, and has been widely criticized by leading scientific organizations and public health organizations. Editors of the nation's leading scientific journals, the Presidents of the National Academies of Sciences, Engineering, and Medicine, the President of Harvard University and nearly one hundred leading Harvard scientists and medical experts, EPA's own Science Advisory Board, and other scientific experts have voiced concerns about the proposed rule.

CBO analysis of failed legislation that formed the basis for the proposed rule concluded that it would significantly reduce the number of studies relied upon by EPA, perhaps by as much as 50 percent.[1] Basing pollution standards on the best available science is of the utmost importance for protecting public health, and inclusion of the best available science – not just half of it - in the EPA's decision-making process must therefore be protected at all costs.

The proposed rule is based on the false premise that a scientific study cannot be considered rigorous or reliable without public availability of underlying data. This faulty notion would require the EPA to ignore scientific studies central to important decision making around public health and environmental protections.

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[1] *See* Susanne S. Mehlman, Jon Sperl & Amy Petz, Cong. Budget Office, H.R. 1030: Secret Science Reform Act of 2015 at 2-3 (2015) ("CBO expects that EPA . . . would base its future work on fewer scientific studies . . . . CBO expects that the agency would probably cut the number of studies it relies on by about one-half . . . ."); Jon Sperl & Amy Petz, Cong. Budget Office, H.R. 1430: Honest and Open New EPA Science Treatment (HONEST) Act of 2017 at 1-2 (2017) ("EPA officials have explained to CBO that the agency would implement H.R. 1430 with minimal funding . . . . That approach to implementing the legislation would significantly reduce the number of studies that the agency relies on . . . .").

If EPA were forced to exclude studies because the data cannot be made public, it would severely undermine the legitimacy and quality of its decision-making process, compromising the agency's ability to protect human health and the environment.

In addition, the proposed rule raises troubling concepts that are contrary to scientific best practices in chemical assessment, such as those discussed extensively in the seminal National Academies report, Science and Decisions, including ignoring the report's conclusion that thresholds of effects for chemical exposures are the exception rather than the rule given biological and exposure variability across the population.

For the sake of the air and water the EPA has been tasked with protecting, and the millions of human lives that rely on these resources, EPA must not finalize this proposal.

We note that Administrator Wheeler has stated he intends to offer a supplemental notice to the proposed rule for public comment. Recent reporting suggests the supplemental proposal would dramatically expand the applicability of the flawed approach outlined in the 2018 proposal—thereby expanding the damage to EPA's ability to protect public health and welfare. This reported supplemental notice remains fundamentally at odds with EPA's duty to protect the public as informed by the best available science. The agency must not finalize either proposed approach.

Sincerely:

Environmental Defense Fund

Union of Concerned Scientists

Earthjustice

Natural Resources Defense Council

Environmental Protection Network

Clean Air Task Force

MEMORANDUM SUBMITTED BY REPRESENTATIVE SEAN CASTEN

From: Christopher Horner
To: Hyde, Timothy N.; Tompson, Randy
CC:
BCC:
Subject: Federal Agency Science
Date: 12/23/1996 1:56:01 PM

Attachments:

Gentlemen: The following is the document we discussed. Have a happy holiday. CCH
M E M O R A N D U M

TO: Mr. Tim Hyde
Mr. Randy Johnson
RJ Reynolds Tobacco Company

FROM: Mr. Christopher C. Horner
Bracewell & Patterson, L.L.P.

DATE: December 23, 1996

RE: Background and Proposed Program to Address Federal Agency Science

Per our earlier conversations, the following sets forth what needs to be done to reform agency science, focusing on the need based upon your interests, and how you are positioned to take a behind the scenes leadership position. It provides an overview of the issues relevant to this goal, and details a program taking advantage of the increasingly flagrant way regulators have perverted the scientific process, hiding behind a wall of selected scientists to essentially cow industry and Congress into accepting fringe scientific conclusions.

Summary

We propose creating, beginning with congressional oversight and a goal of enacting legislation, required review procedures which EPA and other federal agencies must follow in developing "extra-judicial" documents (i.e., those documents produced as guidance, science or other government products issued by regulatory agencies which are not necessarily at time of publication ripe for judicial review). This is important to your organization because, at some point in the near future, EPA will most likely be ordered to re-examine ETS. The only way to do

so on a level playing field is to construct explicit procedural hurdles the Agency must follow in issuing scientific reports.

Because there is virtually no chance of affecting change on this issue if the focus is ETS, our approach is one of addressing process as opposed to scientific substance, and global applicability to industry rather than focusing on any single industrial sector. Thus the examples of questionable science, to justify these standards. Congress must require those examples serve as the test cases.

Background

On the surface, now appears an opportune moment for addressing agency science head on, tackling the substance. This would seem the case because the first run at legislative attempts to reform the regulatory process failed and concerned Members are searching for a new mechanism to control EPA and other regulatory bodies. The landscape of the past year is littered with examples of persistent or newly-promoted "bad science," including the Mercury Report to Congress, MACT Hazardous Waste Combustion Rule, Methylene Chloride and the Dioxin Reassessment. Regarding the latter example, as you are likely aware, for the next round of EPA Science Advisory Board (SAB) review of the Dioxin Reassessment the Agency has removed any SAB members who were too vocal in their disagreement with the Agency. There will still be SAB review, but it will be an already-transparent group of "agreeable" scientists. So, in addition EPA is flagrantly "stacking the deck" with those whose conclusions are predetermined and in the Agency's favor.

Irrespective of this pattern, it is clear the 104th Congress was singularly unsuccessful in managing the Agency on a chemical-by-chemical or industry-by-industry basis. EPA actions demonstrate the it has taken measure of its legislative and industry adversaries, and decided upon aggressive campaigns on several of these issues to impose its policy-driven will upon scientific conclusions. The Agency helps create, and responds, to, the political winds, so you should anticipate no relief on re-evaluating ETS. EPA has of late played its public relations card very well, avoiding long news cycles for its proposals -- even timing them around holidays when readership is at its nadir -- while engaging the environmental press for the coming conflicts. EPA, helped by the backlash of the generally "pro-environment" public to a poorly implemented reg-reform agenda, has fostered an atmosphere where "industry" are reluctant to match the Agency's hardball tactics out of fear either that Congress would duck/mismanage the issue, or of Agency retribution. Thus, through a lack of industry support and unfavorable press, Congress has to date lacked the requisite support to effectively use the oversight powers of the legislative branch.

It is in this climate you will face a chastened but at least as aggressive EPA on re-evaluating the ETS study.

Project Approach

To improve the climate, and process, under which ETS and others are reviewed, we recommend initiating reforms by playing a strong role in molding and guiding Congress's oversight of EPA's latest Clean Air Act initiative (on PM 2.5/ozone). Such an effort would work toward requiring EPA to institute certain procedural changes to the pre-regulatory process. These would serve as a set of checks and balances to ensure a fair and equitable development and publication of scientific findings (i.e., reform the scientific process). It is that process, which is beyond the reach of the Administrative Procedure Act, which sets the stage for the rulemaking process. These procedures could then be subject to judicial review without the courts becoming involved in specific scientific issues (i.e., discern if EPA followed the requisite steps, rather than if it achieved the "right" answer).

When EPA announced its proposal to regulate particulate matter and tropospheric ozone, despite their news cycle management, the set the predicate for procedural change. These proposed regulations, based on questionable science, are not focused on those industries that comprise EPA's "usual suspects", but rather all industries including small businesses. Congress is expected to conduct heavy oversight of this process, with most leaders expressing that the actions are unnecessary and unrealistic. EPA has already signaled a desire to compromise as the process moves forward, and will start airing its options in the January 14-15 initial public hearings. It is critical to our overall goal that EPA not be allowed to change the forum into an industry-by-industry examination. Equally important, the process should not devolve into "outdoor air" interest seeking to shift the focus to "indoor air" interests. Instead, the efforts we envision focus on the process by which EPA arrived at its scientific conclusions, avoiding to the extent possible specific scientific issues, contaminants, or industries.

While some will approach these hearings as regulation-specific, as you can appreciate, from our perspective the greater problem is EPA (and OSHA) "science," encompassing all the scientific reports, studies, guidance documents and procedures produced by the nonregulatory offices of these agencies. None of these products are subject to timely challenge. In some instances, industry must wait years before regulations are promulgated, thus allowing industry to sue. Then, when industry has that opportunity, the court is faced with the ramifications of overturning years of EPA actions and policies based on this scientific document. Moreover, industry face mindsets such as "how can a

document which has been around for so long be wrong?" (the "historical credibility" argument). Finally, once industry's hands are tied in Washington, EPA or OSHA has distributed the documents or guidance to the press or states, forcing industry to face a public relations nightmare.

Thus, as we seek to create a regime where this cycle is a thing of the past while highlighting problems with contemporary studies. These studies will be the first "test cases" for the reformed process. This requires developing (1) overall criteria for a "sound science" process, and (2) a record, through congressional oversight, on how the Agency typically does not meet those criteria.

To illustrate, criteria could be as follows:

"Sound Science" Criteria - any government scientific program must have four components:

Inclusive - The scientific community, the public, Congress, and other Executive Branch agencies are given fair and timely access to review and affect change in the development of the science/document.

Transparency - the public can follow the developmental process the steps followed to develop the final science/document.

Able to be reproduced - Can the answer be reproduced from the record?

Algorithm - Given the set of all available scientific knowledge on the subject would independent groups arrive at the same answer?

[a possible fifth component which could be included as a deal closer could be:
Not judicially reviewable - This may seem counterintuitive, but one of the aspects of reg-reform which its opponents exploited to bring it down was the belief that everything would be litigated. Thus, it may be possible to achieve reforms through the principle that the scientific portions of a successful program should not be easily placed before the courts. Instead, the courts should be able to easily look at procedures followed (e.g., did the Agency follow its own procedures).]

We envision these new steps being "field tested" on, e.g., the methylene chloride study, ETS, etc. which, having been used as justification for reform would be held and reviewed under the new procedures.
To ensure Agency compliance Congressional oversight is also required. This at worst builds a record for judicial review and at best sets in

motion a set of enforceable procedures. We intend to develop for the Hill a set of scientific and procedural questions on scientific issues which different committees could then use. This requires:

Written Record - Submit lengthy, detailed questions to the agency requiring written responses. This creates a written record which the Agency often seeks to avoid, because it otherwise is permitted to develop scientific documents without responding explicitly (unlike the proposal/promulgation process) to public concerns.

Followup Hearings - Once the Agency has responded use this record both within and across an issue in oversight on how the Agency develops science. (e.g., this is an ideal place to inquire into risk assessment default values and risk criteria, which seem to change from office to office).

We envision the end results of the oversight hearings to be: (1) EPA publication in the Federal Register of a formal process for handling "extra-judicial" documents; (2) new legislation; and/or (3) inclusion in environmental or regulatory reform legislation which appears moving in the 105th Congress.

This approach merely ensures a fair hearing, but that is typically all the situations require to avoid the skewed result the federal agency prescribes. Critically, this approach also circumvents the tenuous situation you otherwise likely will face, of seeking after-the-fact, RJR-specific congressional support to undo the Agency's work.

What makes the National Association of Manufacturers a strong base for the above work is NAM's broad, yet non-specific, business base. Its one of a small handful, at best, of broad based associations not associated with particular industries. Thus, their lead on this general issue will not bog the hearings down in "anti-environmental," industry-specific rhetoric, nor create an environment where specific industries can legitimately fear Agency retaliation.

Conclusion

We envision a program, using contemporary studies and reports to illustrate how the Agency skews its results in the pre-regulation stage, to create set, reviewable science procedures. That process and its criteria will first be tested on those current examples of Agency misfeasance, which obviously must be sent back to the Agency or otherwise placed on hold in the interim. We need to meet again with you to discuss this proposal and how to best implement it, specifically beginning with the audiences with NAM and NFIB we discussed. We need another meeting, to hammer out the presentation to the two

referenced audiences, and reach consensus with you on the issues and approach we intend to pursue. Until we speak with you on this further, Happy Holidays.

CCH

/cch

DOCUMENTS SUBMITTED BY DR. MARY RICE

HHS.gov U.S. Department of Health & Human Services

Health Information Privacy

Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

This page provides guidance about methods and approaches to achieve de-identification in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The guidance explains and answers questions regarding the two methods that can be used to satisfy the Privacy Rule's de-identification standard: Expert Determination and Safe Harbor[1]. This guidance is intended to assist covered entities to understand what is de-identification, the general process by which de-identified information is created, and the options available for performing de-identification.

In developing this guidance, the Office for Civil Rights (OCR) solicited input from stakeholders with practical, technical and policy experience in de-identification. OCR convened stakeholders at a workshop consisting of multiple panel sessions held March 8-9, 2010, in Washington, DC. Each panel addressed a specific topic related to the Privacy Rule's de-identification methodologies and policies. The workshop was open to the public and each panel was followed by a question and answer period. Read more on the Workshop on the HIPAA Privacy Rule's De-Identification Standard. Read the Full Guidance - PDF.

General

1.1 Protected Health Information
1.2 Covered Entities, Business Associates, and PHI
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Glossary of Terms

Protected Health Information

The HIPAA Privacy Rule protects most "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or medium, whether electronic, on paper, or oral. The Privacy Rule calls this information *protected health information* (PHI)[2]. Protected health information is

information, including demographic information, which relates to:

- the individual's past, present, or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Protected health information includes many common identifiers (e.g., name, address, birth date, Social Security Number) when they can be associated with the health information listed above.

For example, a medical record, laboratory report, or hospital bill would be PHI because each document would contain a patient's name and/or other identifying information associated with the health data content.

By contrast, a health plan report that only noted the average age of health plan members was 45 years would not be PHI because that information, although developed by aggregating information from individual plan member records, does not identify any individual plan members and there is no reasonable basis to believe that it could be used to identify an individual.

The relationship with health information is fundamental. Identifying information alone, such as personal names, residential addresses, or phone numbers, would not necessarily be designated as PHI. For instance, if such information was reported as part of a publicly accessible data source, such as a phone book, then this information would not be PHI because it is not related to heath data (see above). If such information was listed with health condition, health care provision or payment data, such as an indication that the individual was treated at a certain clinic, then this information would be PHI.

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Covered Entities, Business Associates, and PHI

In general, the protections of the Privacy Rule apply to information held by covered entities and their business associates. HIPAA defines a covered entity as 1) a health care provider that conducts certain standard administrative and financial transactions in electronic form; 2) a health care clearinghouse; or 3) a health plan.[3] A business associate is a person or entity (other than a member of the covered entity's workforce) that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of protected health information. A covered entity may use a business associate to de-identify PHI on its behalf only to the extent such activity is authorized by their business associate agreement.

See the OCR website http://www.hhs.gov/ocr/privacy/ for detailed information about the Privacy Rule and how it protects the privacy of health information.

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De-identification and its Rationale

The increasing adoption of health information technologies in the United States accelerates their potential to facilitate beneficial studies that combine large, complex data sets from multiple sources. The process of de-identification, by which identifiers are removed from the health information, mitigates privacy risks to individuals and thereby supports the secondary use of data for comparative effectiveness studies, policy assessment, life sciences research, and other endeavors.

The Privacy Rule was designed to protect individually identifiable health information through permitting only certain uses and disclosures of PHI provided by the Rule, or as authorized by the individual subject of the information. However, in recognition of the potential utility of health information even when it is not individually identifiable, §164.502(d) of the Privacy Rule permits a covered entity or its business associate to create information that is not individually identifiable by following the de-identification standard and implementation specifications in §164.514(a)-(b). These provisions allow the entity to use and disclose information that neither identifies nor provides a reasonable basis to identify an individual.[4] As discussed below, the Privacy Rule provides two de-identification methods: 1) a formal determination by a qualified expert; or 2) the removal of specified individual identifiers as well as absence of actual knowledge by the covered entity that the remaining information could be used alone or in combination with other information to identify the individual.

Both methods, even when properly applied, yield de-identified data that retains some risk of identification. Although the risk is very small, it is not zero, and there is a possibility that de-identified data could be linked back to the identity of the patient to which it corresponds.

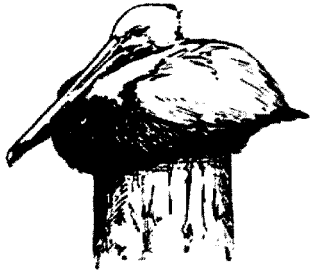
Regardless of the method by which de-identification is achieved, the Privacy Rule does not restrict the use or disclosure of de-identified health information, as it is no longer considered protected health information.

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The De-identification Standard

Section 164.514(a) of the HIPAA Privacy Rule provides the standard for de-identification of protected health information. Under this standard, health information is not individually identifiable if it does not identify an individual and if the covered entity has no reasonable basis to believe it can be used to identify an individual.

§ 164.514 Other requirements relating to uses and disclosures of protected health information.
(a) *Standard: de-identification of protected health information.* Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.



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MANDATING THE RELEASE OF HEALTH RESEARCH DATA: ISSUES AND IMPLICATIONS

GEORGE D. THURSTON

Mandating the Release of Health Research Data: Issues and Implications

George D. Thurston*

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I. INTRODUCTION

"Show me the data!" sounds a lot like a soundbite from a Hollywood movie, but it accurately characterizes the demands that U.S. industry representatives and legislators on Capitol Hill have in recent years been making of researchers who study environmental and occupational health problems. Indeed, in July 1997, an amendment to a 1998 appropriations bill in the U.S. House of Representatives was proposed that, if passed, would have required researchers with government grants to make their raw medical and scientific data publicly available within ninety days after the first public reporting of any study results.[1] No hearings were held on the implications of such a step. Only defense-related research and cases in which "adverse economic harm to

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1. *See* Jocelyn Kaiser, *Data Release Proposal Raises Alarm*, 277 SCIENCE 627 (1997).

commercial proprietary interests ... would result" would have been exempted from this blanket data release mandate.[2] Is this proposal to mandate a blanket release of federally funded research data a necessary and worthwhile solution to a real problem that is impeding the advance of scientific knowledge? Or, alternatively, are the cries for Congress to take such an action merely a manifestation of vested interests' attempts at undermining the credibility of researchers who publish results that run counter to their financial interests?

According to the journal *Science*, the data release amendment proposed by Representative Robert B. Aderholt (R-AL) was, in part, a response by Congress to industry demands for data from Harvard School of Public Health air pollution studies, the results of which were at the center of proposed new air pollution regulations.[3] The studies' authors objected to making their raw research data publicly available because it would violate the crucial confidentiality agreements they had made with study subjects to protect their individual privacy.[4] Although these Harvard researchers were willing to share the data with other scientists when that confidentiality could be protected, they were not willing to capitulate to unrestricted release of the personal health records.[5] In the end, this particular congressional amendment was defeated by a vote of nineteen to thirty-four.[6] Discussion of such a measure, however, will no doubt surface on the Hill again in the near future, as demands for congressional action are likely to continue due to other regulatory measures being questioned by industry. It is therefore important to air both the issues involved in, and the implications of, such a mandate for the release of federally funded health effects research data.

At first glance, this proposal may seem to be a simple and straightforward idea. The basic logic behind the proposal, apparently, was that the data collection was paid for, at least in part, by the government, therefore it should be available to the public and to anyone else who wishes to evaluate it further. In a cover letter to his colleagues in the House, the sponsor of the amendment stated that "the federal government does not have a standardized government-wide process for making research data available for independent review. My amendment seeks to remedy this while still allowing for a limited number of

2. *Amendment to Treasury, Postal Service, and General Government Appropriations Bill, 1998* (offered by Rep. Robert B. Aderholt (R-AL), July 25, 1997) (rejected July 31, 1997) [hereinafter *Amendment to Treasury Bill*].

3. *See* Jocelyn Kaiser, *Government Grants: Academia Wins a Round on Raw Data*, 277 SCIENCE 758 (1997).

4. *See id.*

5. *See id.*

6. *See* H.R. REP. No. 105-240 (1997)

exceptions .... I strongly believe that sunshine is the best antiseptic."[7] In addition, the argument has been made that government regulations that are based upon federally funded health research might cost billions of dollars to affected businesses and industries.[8] Accordingly, it is important to make doubly sure that the research is right. Thus, there were some seemingly plausible rationales for such a measure, however, practicality and ethical concerns quickly arose.

In the days that followed the congressional proposal, numerous confidentiality, logistical, and fairness objections came to light from other legislators, the Clinton Administration, and the nation's research universities.[9] Representative George E. Brown, Jr. (D-CA), ranking minority member of the House's Science Committee, expressed his "deep concern" that "the amendment as drafted would create significant legal uncertainties and substantial and unnecessary costs for scientists, research universities, high tech industries, and federal agencies."[10] In addition, the White House Office of Management and Budget enumerated potential problems, including the impeding of commercial agreements and the risk of problems if the data were not analyzed correctly by others unfamiliar with the data collection process.[11]

This Article provides a detailed consideration of the ongoing data access debate in the context of the United States Environmental Protection Agency's (EPA or the Agency) recent air pollution regulations and the research upon which they are based, followed by a discussion of the key issues surrounding the data access debate in general. These key issues include the potential effects of a mandate requiring the release of health research data on: (1) the scientific credibility of the research involved, (2) the confidentiality of research participants' medical records, (3) the intellectual ownership of research ideas and their results, and (4) the speed of research progress in the medical and public health fields. Information from past cases of data release demands and their aftermath are supplied as examples. Consideration is then given to whether there are sufficient deficiencies in the current practices of scientific assessment and data sharing that warrant such government mandated intervention

7. Letter from Rep. Robert B. Aderholt (R-AL) to the House of Representatives (July 24, 1997) (on file with author).

8. *See* Madeleine Jacobs, *EPA Should Take a Breather*, CHEM. & ENG. NEWS, Apr. 14, 1997, at 5; *see also* Philip H. Abelson, *Proposed Air Pollutant Standards*, 277 SCIENCE 15 (1997); Jocelyn Kaiser, *Showdown Over Clean Air Standards*, 277 SCIENCE 466 (1997).

9. *See* Kaiser, *supra* note 3, at 758.

10. Letter from Rep. George E. Brown, Jr. (D-CA), Ranking Minority Member, House of Representatives Science Committee, to Rep. Bob Livingston (R-LA), Chairman, House Committee on Appropriations (July 28, 1997) (on file with author) [hereinafter Brown Letter].

11. *See* Kaiser, *supra* note 3, at 758.

into medical and public health research, or whether the side-effects of this proposed solution are worse than the initially perceived problems. Finally, alternative approaches to addressing the question of the validity of published scientific research are also proposed.

II. THE CASE AT HAND: AIR POLLUTION EPIDEMIOLOGY

The National Ambient Air Quality Standards (NAAQS), the cornerstone of the nation's air pollution control program, are aimed at establishing air quality requirements sufficient to protect public health and welfare.[12] The Clean Air Act (CAA)[13] and its Amendments[14] require that these national air quality standards be set at a level stringent enough to protect the health of the public, with an adequate margin of safety.[15] The CAA Amendment of 1977, as adopted by Congress, requires that each of the NAAQS be reviewed by the EPA at least every five years in order to determine whether the NAAQS are still appropriately protective of public health and welfare based on the most recent research information.[16] Revisions of the NAAQS by the EPA Administrator are based upon scientific air quality criteria documents that are prepared by the EPA for the air pollutant under review and subsequently reviewed by an independent scientific advisory panel, the Clean Air Scientific Advisory Committee (CASAC).[17]

In 1979, upon review of the nation's photochemical oxidants standard, the EPA relaxed the ozone (O_3) NAAQS from a once-per-year, one-hour maximum of 80 parts per billion (ppb) up to 120 ppb, due to a lack of published information supporting the then existing standard.[18] Ozone is a secondary pollutant, or one that is formed in the atmosphere in the presence of sunlight from precursor pollutants, most notably nitrogen oxides and hydrocarbons that are emitted by a variety of sources, including automobiles, coal-fired power plants, and industry.[19] This

12. *See* Clean Air Act § 109, 42 U.S.C. § 7409 (1994).
13. *See* CAA §§ 101-618, 42 U.S.C. §§ 7401-7671q.
14. *See* Clean Air Act Amendments of 1966, Pub. L. 89-675, 80 Stat. 954; Clean Air Amendments of 1970, Pub. L. No. 91-604, 84 Stat. 1676; Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685; Clean Air Act Amendments of 1990, Pub. L. No. 101-549, 104 Stat. 2399 (codified as amended in scattered sections of 42 U.S.C.).
15. *See* CAA § 109(d), 42 U.S.C. § 7409(d).
16. *See* CAA Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 385 (codified as amended in scattered sections of 42 U.S.C.).
17. *See* CAA § 109(d), 42 U.S.C. § 7409(d).
18. *See* National Ambient Air Quality Standards for Ozone, 44 Fed. Reg. 8201, 8204 (1979).
19. *See Review of EPA's Proposed Ozone and Particulate Matter NAAQS Revisions—Part 2 Before the Subcomm. on Health and Environment and the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 105th Cong. 146 (1997) (prepared statement of Dr. George D. Thurston, Assoc. Prof., Dep't of Envtl. Medicine, New York University School of Medicine) [hereinafter *Thurston Testimony*].
20. *See* National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856, 38,856-96 (1997) (to be codified at 40 C.F.R. pt. 50).
21. *See* National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,652-711 (1997) (to be codified at 40 C.F.R. pt. 51).
22. *See Thurston Testimony*, *supra* note 19, at 146.
23. *See Clean Air Act: Ozone and Particulate Matter Standards, Hearings Before the Subcomm. on Clean Air, Wetlands, Private Property, and Nuclear Safety and the Comm. of Environment and Public Works*, 105th Cong. 138 (1997) [hereinafter *Hearings*].
24. *See* Air Quality Standard Coalition, News Release (Nov. 25, 1996).
25. *See* S. 1084, 105th Cong. (1997); H.R. 1984, 105th Cong. (1997).

standard remained in effect until 1997, when the EPA, after a long and extensive review of both new epidemiological and controlled pollutant exposure health studies, determined that the ozone NAAQS should be tightened back to a value of 80 ppb, but averaged over eight hours and allowing as many as three violations per year.[20] This new standard is therefore less protective than the once-per-year 80 ppb one-hour maximum standard in effect before 1979, but somewhat more protective than the pre-1997, 120 ppb one-hour maximum standard.

In 1997, the EPA also determined, after a similar extensive scientific review process, that the particulate matter (PM) NAAQS should also be modified to better protect the public health.[21] Fine PM (i.e., small particulate matter) is primarily composed of two components: carbonaceous primary particles, or soot, emitted directly from combustion sources such as diesel buses, coal and oil-fired power plants, and other industries; and, secondary particles formed in the atmosphere from gaseous pollutants such as sulfur dioxide and nitrogen oxides emitted from sources such as coal-fired power plants, automobiles, and industry.[22] In the case of PM, it was decided that a new standard was needed which focused on fine particles less than 2.5 micrometers in diameter ($PM_{2.5}$), which are particles small enough to reach deep into the human lung and most likely to have the highest concentrations of especially toxic PM components (e.g., acids, lead, arsenic, etc.).[23]

The implementation of these new air quality standards will require various businesses and industries to control their companies' air pollution emissions of gases and particles that some fear may cost large sums of money. This fear has caused those potentially affected parties to scrutinize the new standards intensely, and many of them have collectively or individually objected to the standards.[24] Partially in response to these industry concerns, Congress held numerous hearings on the new standards, including the consideration of bills to block the new standards.[25] However, no Congressional action has been taken to date to reverse the new air quality standards.

During the period when the EPA developed the new standards, demands surfaced for the release of the underlying health and scientific data upon which the key epidemiological pollution-health effects studies were based to set the new standards. In particular, in May 1994, Dr. George T. Wolff, a scientist for General Motors and the Chair of CASAC at that time, and Dr. Roger O. McClellan, the President of the Chemical Industry Institute of Toxicology (CIIT) and a former chair of CASAC, sent a letter to EPA Administrator Carol Browner asking that the EPA make demands for data and for data reanalyses.[26] However, neither Wolff nor McClellan indicated any scientific wrong-doing on the part of investigators in their letter.[27] Although this issue and the sending of a letter were discussed at a CASAC meeting, the Wolff and McClellan letter was not sent as a result of a consensus of the entire CASAC panel that the EPA should request such data, but at the initiative of these two specific CASAC panel members.[28] During congressional hearings in early 1997, these two scientists testified in opposition to the EPA's proposed $PM_{2.5}$ standard, with Wolff stating that "I can't endorse the present proposal,"[29] and McClellan stating that "the serious shortcomings in the scientific data on $PM_{2.5}$ and PM_{10} led me to not support the promulgation of either an annual or a 24-hour $PM_{2.5}$ standard."[30] The Wolff and McClellan letter to the EPA stated that:

> several recent published reports have indicated effects on both morbidity and mortality at about the level of the current PM_{10} standard. In some cases, the analyses are extremely complex because of the need to correct a wide range of potential confounders, such as temperature, cigarette smoking and other pollutants .... It is crucial that two or more groups analyze the same key data sets linking exposure and morbidity/mortality response to verify the adequacy of the complex analyses and that different analysts using the same data reach similar conclusions .... The EPA should take the lead in requesting that investigators make available the primary data sets being analyzed so that others can validate the analyses.[31]

In 1997, the Air Quality Standards Coalition (AQSC), in a submission to the EPA during the proposed O_3 and $PM_{2.5}$ NAAQS

26. *See* Letter from George T. Wolff, Ph.D., Chair, Clean Air Scientific Advisory Committee, and Roger O. McClellan, D.V.M., Past Chair, Clean Air Scientific Advisory Committee, to Carol Browner, Administrator, EPA (May 16, 1994) (on file with author) [hereinafter Wolff Letter].

27. *See id.*

28. EPA SCIENCE ADVISORY BOARD, CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE, SO_2 CLOSURE & PARTICULATE MATTER, TRANSCRIPT OF PROCEEDINGS 169-70 (Apr. 12, 1994) (on file with author).

29. *Hearings*, *supra* note 23, at 38 (testimony of Dr. George T. Wolff).

30. *Id.* at 139 (testimony of Dr. Roger O. McClellan).

31. Wolff Letter, *supra* note 26.

comment period, cited the letter from Drs. Wolff and McClellan as a basis for requesting the data from the key Harvard "Six Cities" Studies. The AQSC submission requested that the studies be made "available in the rulemaking docket for assessment by other investigators and request EPA to reaffirm the existing PM standards until such time that these assessments are completed."[32] In its literature, the AQSC describes itself as "a broad-based coalition whose membership includes more than 500 corporations, associations and interest groups," whose goal is "to assure that the ... [EPA] makes scientifically ... sound decisions as it reviews the National Ambient Air Quality Standards for ozone and particulate matter."[33] However, the AQSC is described elsewhere as "a group of oil, steel, trucking, agricultural and auto companies, formed last July [1996] to fight the EPA's newly proposed air quality standards."[34] Thus, among the members of the AQSC are auto manufacturers, an industry group that includes General Motors, as well as oil companies and chemical manufacturers, two sectors well represented in the list of companies supporting the CIIT.[35] Indeed, CIIT's financial supporters include the Chemical Manufacturers Association, Chevron Corporation, Ethyl Corporation, Exxon Corporation, Texaco Inc., and Unocal Corporation.[36] In addition, the Mobil Corporation ran advertisements on the editorial pages of U.S. newspapers critical of the EPA proposal, including one ad stating that "data from a key study—the Harvard 'Six Cities'—has never been made public, despite repeated requests from scientists over a three-year period."[37] Thus, the most pointed demands for these studies' data have most often come from individuals and organizations either directly or indirectly supported by companies expected to be adversely affected by the new air standards based on those studies.

These recent demands for data release and reanalysis of the Harvard work have largely ignored the fact that these same Harvard researchers and their data have previously been reviewed for scientific integrity by the National Institutes of Health (NIH), Office of Scientific Integrity

32. Letter from Charles J. DiBona, President, American Petroleum Institute, and Andrew Card, President, American Automobile Manufacturers Association, Air Quality Standards Coalition Co-Chairs, to EPA Air Docket Section, Docket No. A-95-54(PM) (Mar. 12, 1997) <http://www.nam.org/bulletin/RER/rercmt.html>.

33. Air Quality Standard Coalition, News Release (Nov. 25, 1996).

34. Hanna Rosin, *Shades of Gray: St. Boyden's Unholy Money Trail*, 216 THE NEW REPUBLIC 21 (1997).

35. *See* National Association of Manufacturers Air Quality Standards Coalition (1998) (visited Apr. 29, 1998) <http://www.nam.org/air.html>.

36. *See* Chemical Industry Institute of Toxicology Supporting Companies (1998) (visited Apr. 29, 1998) <http://www.ciit.org/SUPPC/suppc.html>.

37. Mobil Corporation, *EPA: Let Science Do Its Job* (visited May 15, 1997) <http://www.mobil.com/this/news/opeds/970515_oped.html>.

(OSI), and the Health Effects Institute (HEI) and were cleared of any misconduct or scientifically inappropriate analyses.[38] The OSI investigation, which was the result of separate accusations raised in the mid-1980s, found that "there is no basis whatsoever for the allegations of serious errors and gaps in the database," and that "the quality control program of the Six Cities Studies considerably surpasses that of most continuously operating monitoring programs."[39] Furthermore, the HEI, which receives one-half of its fiscal support from the automotive industry and one-half from the U.S. government, subsequently commissioned an extensive reevaluation of the data and research methods of the Harvard team in conducting time-series analyses of various U.S. cities' daily records of mortality and PM pollution.[40] The HEI review found that the reanalysis results "agree closely with the earlier conclusions that particulate air pollution is tied to increased risk of death, even when weather and other pollutants are taken into account."[41] Thus, the Harvard researchers have in fact provided their data for evaluations in the past, and these previous evaluations have consistently confirmed the validity of their data and analytical methods.

However, in response to the continuing demands for the Harvard researchers' air pollution studies' data, Mary Nichols, then the EPA's Assistant Administrator for Air and Radiation, sent letters to Drs. Joel Schwartz and Douglas Dockery of the Harvard School of Public Health, as well as to Dr. Arden Pope, the lead author of another key PM study, stating that:

> there has been considerable interest in your research on the health effects of air pollution, including requests by members of Congress, governors of several states, and others for the raw data underlying your published research .... EPA is confident of the scientific integrity of your studies and their appropriateness for purposes of consideration in the Agency's present rulemaking on particulate matter without a separate or additional review of the underlying data. Nevertheless, given the strong interest in your research, EPA would encourage reasonable accommodations within the scientific and governmental community that would permit other interested scientists and agencies to understand fully the basis for your work. We therefore request that you make data associated with your published studies available to interested parties as rapidly as possible.[42]

38. Letter from Suzanne W. Hadley, Ph.D., Deputy Director, Office of Scientific Integrity, Department of Health & Human Services, to Michael W. Roberts, Esq., Office of the General Counsel, Harvard University (Nov. 15, 1990) (on file with author) [hereinafter Hadley Letter].

39. *Id.*; *see also NIH Clears Harvard Researchers*, WALL ST. J., Dec. 7, 1990, at A3.

40. Letter from James H. Ware, Dean for Academic Affairs, Harvard School of Public Health, to Mary D. Nichols, Assistant Administrator for Air and Radiation, EPA, (Apr. 8, 1997 (on file with author) [hereinafter Ware Letter].

41. Pamela Zurst, *Air Pollution Link to Rise in Deaths Confirmed*, CHEM. & ENG. NEWS Apr. 8, 1997, at 9.

Dr. James H. Ware, the Dean of the Harvard School of Public Health, subsequently recommended to Ms. Nichols that the Harvard "Six Cities" data be reviewed and tested by the HEI. Dr. Ware wrote "[w]e believe that HEI is well qualified to conduct a review process that will be thorough and fair, without jeopardizing confidentiality concerns."[43] This review is presently in progress. Thus, in this case, the concerns raised by industry and industry-funded groups concerning the results of this research are being addressed, without the need for a public release of the research health data.

In promulgating the new $PM_{2.5}$ air quality standards in the Federal Register, the EPA summarized the comments that it received during the NAAQS comment period regarding the issue of raw data availability.

> Several commenters questioned EPA's ability to rely on studies demonstrating an association between PM and excess mortality without obtaining and disclosing the raw "data" underlying these studies for public review and comment. In particular, a number of commenters cited Dockery, D.W., et al. 1993 and Pope, C.A. III, et al., 1995, as studies upon which EPA relied without obtaining and disclosing the underlying raw data .... A few commenters argued that section 307(d) of the [Clean Air] Act requires that EPA obtain the raw data underlying these studies and that a failure to do so contradicts the plain language of section 307(d)(3) of the Act, which requires EPA to place in the docket any "factual data on which the proposed rule is based." Other commenters argued that under section 307(d)(8) of the Act, a failure to obtain and disclose the underlying raw data used in the studies would constitute an error "so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made." According to one commenter, without the raw data and an opportunity for an analysis of it, "EPA has no legal alternative other than to conclude that no new air quality standard would be appropriate within the meaning of CAA section 109(a)(1)(B)." Finally, a number of commenters have argued that recent caselaw under the Clean Air Act and other statutes makes clear that EPA has a legal obligation to obtain and disclose the data used in these studies.[44]

In that same preamble, the EPA responded to those comments:

42. Letter from Mary D. Nichols, Assistant Administrator for Air and Radiation, EPA, to Dr. Douglas Dockery, Harvard School of Public Health (Jan. 31, 1997) (on file with author).

43. Ware Letter, *supra* note 40.

44. National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,689 (1997).

> In developing the proposed revisions to the PM NAAQS, the Administrator relied on the scientific studies cited in the rulemaking record, rather than on the raw data underlying them. In this case, the raw data consists of responses to health questionnaires based on information supplied by individual citizens, or computer tabulations of this information, which remains confidential, and air quality and monitoring data, most of which is now publicly available. EPA does not generally undertake evaluations of raw, unanalyzed scientific data as part of its public health standard setting process. Only in extreme cases—for example where there are credible allegations of fraud, abuse or misconduct—would a review of raw data be warranted. It would be impractical and unnecessary for EPA to review underlying data for every study upon which it relies as support for every proposed rule or standard. If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment.[45]

Thus, while the EPA did request that the researchers in specific cases release their data for review, the Agency refused to require the release of such data as a requirement for a study's inclusion in the standard setting process.

III. ISSUES AND IMPLICATIONS

A. *Research Credibility*

While the EPA ruled that there is no need for peer-reviewed, health study raw data to be released as a routine part of the NAAQS process, industry's public demands for the raw air pollution-health data in the case of the CAA standard setting process succeeded in generating skepticism in the press regarding the credibility of air pollution epidemiology results.[46] Thus, an unrestricted public release of such studies' subject health data would indeed provide one means for the researchers to allay any concerns that they are trying to hide something. Once the data were examined by all interest groups and reanalyzed by others, it would have the benefit of removing even the most remote possibility that the researchers are hiding anything, but at what cost?

The open and informed discussion of scientific issues and protections against biased analyses or reporting of scientific results are

45. *Id.* at 38,689 (citations omitted).

46. *See* Laura Johannes, *Pollution Study Sparks Debate Over Secret Data*, WALL ST. J., Apr. 7, 1997, at B1; Scott Allen, *Clean-Air Researchers Pressured to Show Data*, BOSTON GLOBE, Mar. 4, 1997, at A1.

indeed important to an informed debate regarding scientific issues. But, a key question about any policy mandating a blanket release of data as a means to advance debate on a scientific issue is: who is most likely to reexamine the publicly released data, and with what goal(s)? The three major groups that spring to mind are: (1) competing researchers wishing to capitalize on the more expensive and time-intensive work already done by the original researchers, by analyzing aspects of the data that the original authors have not yet had an opportunity to investigate;[47] (2) regulatory agencies wishing to verify the research results before relying on the studies for regulatory decision-making; and (3) vested interest groups that would be adversely affected by regulations, laws, or lawsuits based upon the published research.[48]

However, it is not necessary to speculate what might occur because past experience tells us much about what happens when health researchers allow open access to their data. The case of Dr. Herb Needleman and his research on the adverse effects of lead exposure on children provides one relevant case in point.[49] Dr. Needleman wrote:

> [H]aving satisfied myself that the tooth was a valid marker of past [lead] exposure . . . I studied a sample of children who were asymptomatic for lead, classifying them by dentine lead levels. The data showed that after controlling for a number of covariates, children with elevated lead in their teeth scored lower on tests of psychometric IQ, speech and language function, and on measures of attention . . . . The lead industry, in the form of the International Lead Zinc Research Organization . . . began to call for copies of my original data. I declined. I had seen what had happened to good data when massaged and distorted by industry technicians, and while I was happy to share my data with any bona fide scientist—and did—I was not willing to include the lead industry.[50]

As part of a lawsuit brought by the Department of Justice against three lead polluters, Dr. Needleman did ultimately have to make his records available for examination to witnesses on behalf of the lead industry, including a grantee of the International Lead Zinc Research Organization and someone who had appeared in testimony for Lead Industry Associates.[51] While the case was eventually settled out of court,

47. *See* Allen, *supra* note 46, at A1. Indeed, multiple analysis and publications often result from a single data set, and this step would deprive the original authors the opportunity to further "mine" their data set.

48. It might be well worth the expense to such vested interests to extensively investigate whether any conflicting conclusions could be derived from the same data.

49. *See* Herbert L. Needleman, *Salem Comes to the National Institutes of Health: Notes from Inside the Crucible of Scientific Integrity*, 90 PEDIATRICS 977 (1992).

50. *Id.* at 977-78.

51. *See id.* at 978.

Dr. Needleman indicated that these witnesses had written a lengthy document critiquing Needleman and his research that was forwarded to the National Institutes of Health by a law firm.[52]

As reported by Dr. Needleman:

> These kinds of issues are generally considered methodological disagreements and are fought out in the pages of journals; I could not understand why they were defined by my critics as scientific misconduct. Similar criticisms were raised before the EPA in 1982 and dismissed. These facts notwithstanding, in October of 1991, I was notified by the Dean of my medical school that an inquiry into charges of misconduct was being done at the instruction of NIH's Office of Scientific Integrity.[53]

Months after the hearing, Dr. Needleman was finally cleared, but he concluded that:

> If my case illuminates anything, it shows that the federal investigative process can be rather easily exploited by commercial interests to cloud the consensus about a toxicant's dangers, can slow the regulatory pace, can damage an investigator's credibility, and can keep him tied up almost to the exclusion of any scientific output for long stretches of time, while defending himself.[54]

Dr. Needleman's situation was also reported in an article in *The Chronicle of Higher Education* (*Chronicle*), along with that of a researcher who investigated the effects of tobacco company advertising on children, Dr. Paul Fischer.[55] Dr. Fischer's research was one of several studies published in the *Journal of the American Medical Association* (*JAMA*) that indicated children's attraction to the Camel cigarette "Joe Camel" advertising character.[56] R.J. Reynolds (RJR) responded by hiring consultants to analyze the studies and subpoenaed the research data supporting each of the studies.[57] The company's demands reportedly included that "the researchers supply the names and telephone numbers of all of the children who had participated in the studies."[58] As described by the *Chronicle*:

> Paul Fischer expected his college to back him. The request, he says, violated "the principles of confidentiality and academic freedom." Instead, the Medical College of Georgia sided with the tobacco company. Last year, it turned over the documents .... Consultants to the cigarette industry then started criticizing his research. In disgust over the college's response, Dr. Fischer resigned and entered private practice in medicine.[59]

Since then, the substance of Dr. Fischer's research was subsequently verified by others,[60] including RJR itself in a memoranda that recently acknowledged that the company specifically targeted children in their advertising.[61] As reported by Dr. Fischer in a letter to *JAMA*:

> Our findings have been validated by other investigators. Henke studied 83 children aged 3 to 8 years using a similar board-game design and found a 54% recognition rate for Joe Camel, compared with 51% in our study. In a study funded by RJR, Mizerski looked at recognition rates among 790 children aged 3 to 6 years and found that 52% of all subjects could match Joe Camel with a cigarette and that an additional 8% associated him with a lit match, for an overall recognition rate of 60%. A third study, also funded by RJR and conducted by the Roper Group, surveyed 1,117 children aged 10 to 17 years and found a total awareness rate of the Joe Camel logo of 86%. The consistency of the findings across age groups, geographic populations, and various study designs validates the findings in our first report.
>
> Based on an estimated rate of 3,000 new teenage smokers per day, more than 5 million US teenagers have become regular smokers since the publication of our study. The most recent research not only confirms that advertising affects smoking rates, but also indicates that this effect is 3 times greater for teenagers than adults. Given the health consequences of cigarettes, tobacco industry advertising should be viewed as a major public health risk.[62]

More recently, Dr. John P. Pierce and colleagues have provided further confirmation, publishing the first longitudinal study (i.e., following subjects over time) indicating that tobacco company ads and promotional activities are indeed causally related to the initiation of smoking among adolescents.[63]

Ironically, on January 14, 1998, internal RJR memoranda were released that, according to the *Washington Post*, indicate that the company:

> sought for decades to reverse the declining sales of its brands by developing aggressive marketing proposals to reach adolescents as young

52. *See id.*
53. *Id.*
54. *Id.* at 980.
55. *See* Stephen Burd, *Scientists See Big Business on the Offensive*, THE CHRON. OF HIGHER EDUC., Dec. 14, 1994, at A26-A31.
56. Paul M. Fischer, M.D., et al., *Brand Logo Recognition by Children Aged 3 to 6 Years. Mickey Mouse and Old Joe the Camel*, 266 JAMA 3145 (1991).
57. *See* Burd, *supra* note 55, at A27.
58. *Id.* at A30.
59. *Id.* at A26.
60. *See* Paul M. Fischer, M.D., *Recognition of Cigarette Advertisement Product Logos*, 277 JAMA 532 (1997) (citation omitted).
61. *See* John Mintz & Saundra Torry, *Internal R.J. Reynolds Documents Detail Cigarette Marketing Aimed at Children*, WASH. POST, Jan. 15, 1998, at A01.
62. Fischer, *supra* note 60 (citations omitted).
63. John P. Pierce et al., *Tobacco Industry Promotion of Cigarettes and Adolescent Smoking*, 279 JAMA 511 (1998).

> as 14 years old.... The 81 documents contrast sharply with the company's repeated public declarations that it does not target young people, collectively sketching a picture of a company that seemed decades ago to determine that its financial future depended on recruiting a new generation of smokers. Many of the documents outline RJR's thinking that led up to the 1988 launch of its controversial Joe Camel cartoon advertising campaign.[64]

Thus, the criticized researcher was proven correct, and the vested interest company that attacked him was apparently seeking to discredit research findings that some individuals in that company must have known to have merit.

The Needleman and Fischer experiences are hardly unique, as the financial incentives to interest groups for such attacks on researchers are large. As recently noted by Dr. Richard A. Deyo in the *New England Journal of Medicine*:

> Attacks on health researchers are not new. Pierre Louis, for example, was vilified nearly two centuries ago for suggesting that bloodletting was an ineffectual therapy. In an open society such as ours, controversy is common and often socially useful. The fact that scientists are sometimes challenged by special-interest groups should be no surprise. However, with widening media coverage of health research, growing public interest in health hazards, and expanding research on the outcomes of clinical care, such attacks may become more frequent and acrimonious. The huge financial implications of many research studies invite vigorous attack.[65]

Dr. Deyo and colleagues go on to discuss three cases in other disciplines illustrating "how vituperative such attacks may be and the range of tactics employed," including: spinal-fusion surgery, multiple chemical sensitivity, and pharmaceuticals.[66] The authors conclude that:

> The common theme in these examples is an attack—through marketing, professional, media, legal, administrative, or political channels—on scientific results that ran counter to financial interests and strong beliefs. In each case, funding for the research involved peer review and the offending results were published in peer-reviewed journals. The interested parties had financial stakes in maintaining their market share or the legitimacy of a model of illness or a particular treatment. Their responses, which bypassed peer-reviewed scientific debate and further research, were nonscientific and aimed at discrediting the findings, investigators, or funding agencies. In each case, the attacks intimidated investigators, discouraged others from taking up the same lines of investigation, and took up the time of investigators and staff with legal, professional, and media responses.... The intent is to turn the tables on claimants, force them from a political to a judicial forum, and cast them as defendants.... In our cases, freedom-of-information requests, subpoenas, and complaints to the Office of Research Integrity were analogous to SLAPP [strategic lawsuits against public participation] suits.[67]

Thus, policies as democratic and important as the Freedom of Information Act requirements can be subverted and employed as mechanisms for vested interests to "attack the messenger" when the message is financially or politically unwelcome to the interest group involved. It seems inevitable that the same things would have happened with Representative Aderholt's "Sunshine" amendment, despite its well intentioned goals.

Therefore, while there may be the initial benefit to researchers' credibility if they are willing to release all their underlying health data, past experience tells us that interest groups with a financial stake in the research outcome will likely be the primary user of that released data. These interest groups may use the data in order to further their own interests, irrespective of the merits of the original research, with little public health assessment benefit, and with the potential of significant public health disbenefit if appropriate public health measures are delayed by such tactics.

B. Confidentiality of Participant Medical Records

In March and April of 1997, as the pressure grew on the Harvard School of Public Health researchers to address the industry demands for their data, stories appeared in the *Wall Street Journal* and the *Boston Globe* on the topic.[68] In the *Wall Street Journal* article, one of the researchers pointed out that "giving up this data in violation of our agreements would completely cripple our ability to go out and do epidemiological studies of any type."[69]

Similarly, in the preamble of the Federal Register promulgation of the new PM standard, the EPA also pointed out that:

> such data are often the property of scientific investigators and are often not readily available because of ... arrangements made to maintain confidentiality regarding personal health status and lifestyle information of individuals included in such data. Without provisions of confidentiality,

64. Mintz & Torry, *supra* note 61, at A01.
65. Richard A. Deyo et al., *The Messenger Under Attack—Intimidation of Researchers by Special-Interest Groups*, 336 NEW ENG. J. MED. 1176 (1997).
66. *Id.* at 1176-77.
67. *Id.* at 1177-78.
68. *See* sources cited *supra* note 46.
69. Johannes, *supra* note 46, at B1.

the possibility of conducting such studies could be severely compromised.[70]

Thus, the mandated release of health data collected in confidence during a research study, as proposed during the 105th Congress, would force researchers to violate the confidentiality agreements made with study participants at the start of the research years before. Retrospectively obtaining each subject's permission to release those data could be an onerous task, and may not be possible at all, in those cases where the subject has since died without designating responsible next-of-kin.

Moreover, when conducting new studies, investigators would have to tell subjects that their data would be publicly available at the end of the study, which could severely hamper researchers' ability to recruit new study populations. Thus, even if such data release mandates were to be applied only to new studies, one effect of the proposed data release mandate would be to stifle new research efforts funded by the federal government.

Ironically, these data release requirements would not apply to privately funded research, such as that funded by regulated industries, who have been among the most reticent in the past to make all of their private research data available to others. This bias in the data release requirement would be as unjustified as the present requirements in the House of Representatives that witnesses testifying before a committee must reveal their past government funding, but need not reveal past funding by interest groups that may have a vested interest in the outcome of the hearing.[71] Thus, under proposals such as Representative Aderholt's, vested interest groups will still be free to selectively publish research that supports their positions, while only government funded research will be encumbered by the data release requirements that, as will be shown below, will hamper its ability to expeditiously obtain research independent of special interest group influence upon which to base scientific assessments of health risks.

In light of these important concerns, and to at least partially offset the onerous effects of such a data release mandate, it seems possible that Congress might instead set up a new governmental agency, or assign an existing agency, with the task of collecting the data from researchers, and then releasing it to qualified parties on a limited basis, in order to at least partially protect the privacy rights of individuals. For example, this is presently done by the National Center for Health Statistics (NCHS) for

70. *See* National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,689 (1997) (to be codified at 40 C.F.R. pt. 51).

71. *See* Rules for the Comm. on Commerce: Rule 4(b)(2), 143 CONG. REC. H368-01, H369 (1997).

certain proprietary death certificate information, such as the date of death.[72] However, such a proposal for government control of data releases would raise the question of who is more appropriate to make decisions about sharing original research data: the individuals who collected it and were given permission to access the personal information by the subjects in question, or a government bureaucracy?

C. *Intellectual Ownership Rights*

A scientific data set often represents years of effort by a researcher and his or her colleagues, including: the conception of a research idea; the preparation of a research proposal for submission to a granting agency; obtaining institutional scientific Internal Review Board (IRB) approval to ethically collect the data; obtaining permission from each study participant; the collection, quality assurance, and statistical analysis of the data; and the preparation of reports documenting the work in the peer-reviewed literature. Usually, more than one publication results from a single data set, as there are multiple aspects of a data set that can be investigated. In the case of the Harvard Six Cities Studies, more than 100 research publications have resulted from this single data set. Oftentimes, further funding for support from agencies is obtained to investigate the many other scientific aspects of the data records. If the data were released after the first public use, then others could use the data to seek that funding to analyze and publish these further findings before the original researchers. In the case of the Six Cities Studies, the numerous publications and hundreds of thousands of dollars in research moneys that the researchers have accumulated for their institutions could have been lost to other competing researchers and institutions eager to get their hands on the Harvard data sets. Thus, a mandated "taking" of a data set from an original investigator shortly after the first public presentation of results from the study, as proposed in the 105th Congress,[73] and making it available to others for free, could represent a major loss, professionally and financially, to that investigator and his or her research institution.

If research is funded by a federal grant, does the government maintain any rights to demand access to those data beyond its rights to obtain data sets collected without federal funding? Congressman Brown, in his letter to the House Committee on Appropriations at the time of the Aderholt amendment, discussed this issue.

72. *See* National Center for Health Statistics, Centers for Disease Control and Prevention (last modified Mar. 3, 1998) <http://www.cdc.gov/nchswww/index.htm>.

73. *See Amendment to Treasury Bill*, *supra* note 2.

> [I]t is important to understand that the federal government usually supports research through grants, not through contracts. The distinction is significant. The purpose of a grant is to support or stimulate activity which serves the public good, such as the increase and diffusion of scientific knowledge. Unlike a contract, a grant does *not* purchase the product of the grantee's work. (See Government Accounting Office, *Principles of Federal Appropriation Law* (2d Ed.) pages 10-3 through 10-10.)
>
> For this reason, it has traditionally been understood that researchers receiving federal grants nevertheless retain significant property interests in their research. Congress has explicitly recognized and even recently expanded those property rights. For example, grantees have the right to copyright documents they produce with grant support, and can own and patent intellectual property created under the grant. (See Office of Management and Budget Circular A-110.) Just last year, Congress passed the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113), which expanded the rights of persons receiving federal research support to own and license intellectual property created with federal support.[74]

Thus, the government apparently has no more right to insist that researchers who have collected scientific data as part of a federally funded grant release their data than it has to make the same demands of private industry funded research. As a result, any such mandates for the public release of data sets underlying published research results should apply equally to both industry and government funded research, and should be viewed as a "taking" of property from those investigators.

D. *Effect on Scientific Progress*

The proposed mandate to require raw data release upon first public use of results from those data, although aimed at advancing scientific knowledge, would undoubtedly have the reverse effect in many ways. As previously noted, a researcher in the Six Cities Studies, Dr. Douglas Dockery, pointed out in a *Wall Street Journal* article that violating their subject agreements would cripple their ability to do new epidemiological studies.[75] Potential subjects would be less likely to participate in research where their personal medical data will be made public. In addition, Dr. Joel Schwartz, another Six Cities data researcher, also noted in that same article that "[n]o epidemiologist can afford to be buried in so much time-consuming controversy for every study, yet that is what industry promises for every data set they get their hands on."[76] Dr. Needleman's experience

74. Brown Letter, *supra* note 10.
75. *See* Johannes, *supra* note 46, at B1.
76. *Id.*

is confirmation of the real-world potential for a realization of Dr. Schwartz's concerns. In addition, there would likely be a reluctance on the part of researchers to publicly release any research results from a study until all possible research opportunities are exhausted, if they must release their data after doing so. Financial considerations would likely ensure that the first completed results from a data set might well be used solely as justification in subsequent grant applications for further funding, rather than expeditiously published, and would therefore not be available to the public, the research community, or regulatory agencies until years later, when all further research avenues had been exhausted. In other words, the requirements for public release of data would have the overall effect of inhibiting, not enhancing, scientific progress and would thereby also have the effect of inhibiting governmental agencies from being fully informed about the most up-to-date state of scientific knowledge when making regulatory decisions.

E. *Unfunded Mandates*

Among the less politically popular things that Congress can do is to impose an "unfunded mandate," or a requirement for individuals to do things without providing any financial support to address these new requirements—which is exactly what these data release mandates represent. As noted in Representative Brown's letter to the Appropriations Committee:

> The Aderholt amendment would impose a significant unfunded mandate on individual researchers and universities—including state universities. To comply, universities would have to maintain a central repository of all of the raw data produced by all of its federally-supported researchers, respond to all public requests for documents at its own cost, and review all of the material before disclosure for potential legal liability for disclosure of sensitive personal or business information.[77]

F. *Are Existing Mechanisms Sufficient?*

Certainly important among the issues raised by data release mandates is the question as to whether the scope of the "solution" advanced is consistent with the "problem" it proposes to address. As stated by Representative Brown in his letter to the Appropriations Committee:

> Before we impose these costly burdens, we ought to ask ourselves what is the problem? As the ranking minority Member of the Science Committee,

77. Brown Letter, *supra* note 10.

> I am unaware that there is any general problem with federally-funded scientists failing to publish research results in public, peer-reviewed journals. I suspect that federally-funded scientists are no different than their colleagues in wanting to publish their work in respected scientific journals and to have a wide distribution of their research results.
>
> Nor am I aware that there is a general concern about the integrity of federally-funded research. The peer-review process, while not perfect, does a pretty good job of weeding out flawed research. In that regard, requiring the mandatory disclosure of raw research data would be overkill.[78]

Indeed, of the roughly 28,000 biomedical articles published each year by researchers in the United States,[79] only a small percentage have letters written to the journal editor about them, and only a handful of those are controversial enough to warrant requesting their data for reanalysis. Clearly, the requiring of tens of thousands of researchers to prepare their data in a form appropriate for public release and the setting up of a bureaucracy (or bureaucracies) to handle these data and their dissemination is regulatory overkill for a perceived problem involving such a very small percentage of these researchers.

Thus, there is no pervasive scientific credibility problem in federally-funded research that justifies the global mandates called for in Congress during 1997. A focused approach would seem much more commensurate with the scale of the perceived problem.

But what about those specific cases in which real scientific controversy does exist? Representative Brown, in his letter to the Appropriations Committee, goes on to address this point, stating:

> There may, of course, be isolated instances where there are problems . . . . Those instances need to be addressed on a case-by-case basis to ensure the careful consideration of all factors, including the confidentiality of patient and medical records. Agencies have adequate existing legal authority to obtain research results and data for federal purposes in such instances. There is no need for the sweeping across-the-board approach proposed in the Aderholt amendment.[80]

Available mechanisms used in the past to address specific concerns include an evaluation of the data integrity by a disinterested third party. In the case of the Harvard study data sets, even though there were no charges of any scientific misconduct, the HEI has again stepped in to address demands for a reexamination of the data and its analysis.[81] HEI will provide a neutral party to evaluate the scientific integrity of the data and the research that led to the important Six Cities Studies finding, without the need for the Harvard researchers to make their data publicly available.

In cases where scientific controversy surrounds a published research document that an Administrator has relied upon in making a regulatory ruling, the courts also provide an existing avenue to address concerns. A comprehensive discussion of the legal precedents surrounding the issue of research data availability is presented by the EPA in the preamble to the recent PM standard revision. One example where the courts interceded in the process is provided in *Endangered Species Committee v. Babbitt*[82] (*Gnatcatcher*), which involved the range of the coastal California gnatcatcher. In its Final Rule of the Particulate Matter NAAQS, the EPA stated that:

> the *Gnatcatcher* opinion itself notes, "courts have generally allowed agencies to rely on scientific reports." Thus, the question at issue in *Gnatcatcher* was whether specific circumstances exist in which an agency may not be entitled to rely on studies alone. In the *Gnatcatcher* case, a single author had published two directly contradictory studies on the same issue, while relying on the same data. In light of this clear contradiction, commenters in that rulemaking argued that without the underlying data it was impossible to determine whether the conclusions in either study were correct. The district court noted that:
>
> "The Secretary had before him a report by an author who, two years before had analyzed the same data and come to an opposite conclusion. It is the disputed nature of this report that distinguishes this from other cases where a scientific report alone has been considered sufficient for ESA purposes."
>
> . . . Thus, according to the court: "While courts have generally allowed agencies to rely on scientific reports * * * this is not sufficient in this case because the report itself is under serious question."[83]

In this case, the court concluded that, in the specific situation in which the author published conflicting results, the data should be made public, and this was required of the Department of the Interior.[84] This opinion appears to support the EPA's position in issuing the new $PM_{2.5}$

78. *Id.*

79. *See* National Science Board, *Science and Engineering Indicators* (1996) (visited May 28, 1998) <http://www.nsf.gov/sbe/srs/seind96/start.htm>.

80. Brown Letter, *supra* note 10.

81. *See generally* Hadley Letter, *supra* note 38.

82. 852 F. Supp. 32 (D.D.C. 1994) [hereinafter *Gnatcatcher*] (cited in National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,692 (1997)).

83. *See* National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,692 (1997) (quoting *Gnatcatcher*, 852 F. Supp. at 37).

84. *See Gnatcatcher*, 852 F. Supp. at 43.

standard that only in extreme cases is the review of raw scientific data warranted.[85] Clearly, the courts provide a working and viable mechanism to address concerns about scientific research in those situations.

Thus, there does not appear to be a pervasive problem with the integrity of peer review literature results that calls out for the type of regulatory intervention being proposed on Capitol Hill. Moreover, in the rare cases in which the integrity of peer reviewed published research is credibly questioned, not just because the results are undesirable to vested interests, there are existing mechanisms in place to address and resolve those concerns.

IV. DISCUSSION AND RECOMMENDATIONS

Overall, it should be apparent from the considerations presented that the recent proposal to mandate the immediate and unrestricted release of raw health research data underlying federally-funded medical and public health research is an overly heavy-handed and burdensome solution to the infrequent problems that arise regarding limitations in access to published research data. Moreover, such an unrestricted data-release policy has the major drawback that it will undoubtedly worsen the very real and serious present-day problem of unwarranted attacks on scientists and physicians who publish research with conclusions that run counter to vested interests.

Qualified researchers who have published research results potentially damaging to vested interests have come under intensive attacks in the media through the initiation of scientific misconduct charges, via legal actions, and by the influencing of government agencies to demand specific studies' data release. Many of these attacks have come even when no scientific misconduct is suspected. These researchers have generally been ill-prepared to defend themselves. The attacks cause them to spend a great deal of time and money in defense of charges initiated or encouraged by vested interest groups having far "deeper pockets" and significant financial incentives to relentlessly pursue the attacks. The result is extremely detrimental to the scientists involved, both financially and professionally, and in one case documented here, has actually caused a researcher to leave the field of health research, despite the fact that the substance of his research results were later confirmed by others.[86] It may also have slowed the speed at which regulators took action in the cases where scientific integrity was questioned. A data release mandate would provide vested interest groups with even more "fodder" with which to attack the research upon which federal regulations

85. *See supra* text accompanying note 45.
86. *See supra* text accompanying notes 59-61.

unfavorable to their financial interests are based. Thus, in addition to slowing scientific progress, the legal and financial burdens on research institutions, and the undermining of research subject privacy, it seems very clear that a mandate to release the underlying data behind all published, federally-funded research would greatly exacerbate the problem of unwarranted attacks on researchers.

However, in the face of inevitable, future, contentious public policy debates, how can we best ensure that the important processes of information exchange, data-sharing, and validation of results are carried out without unwittingly making the affected researchers the target of unfair criticism and harassment by vested interests? Clearly, to avoid being onerous, any solution involving data release by researchers must be focused specifically on the critical issues and results, rather than a global release of all raw data. The solution will also need to provide a structured framework for the conscientious handling of data transfer, protection, and evaluation. This might involve the designation of rules and funding for the establishment of a deliberative entity to serve the role played so well by the HEI in the case of the Harvard air pollution research results. Perhaps the National Academy of Sciences could be funded to provide a forum for the design and implementation of such a deliberative body. The key interested parties will need to be involved, or at least considered, in designing such a mechanism, including: the scientists and/or physicians conducting the research; the editors of the journals that publish such research; the potentially affected vested interest groups and industries; and the governmental agencies involved in promulgating regulations based upon the research.

The editors of the various scientific journals that publish this research have an especially important responsibility to play a larger role in setting up a mechanism to address this issue. To date, the role of these journals has largely been limited to having scientific papers carefully reviewed before publication, rejecting inadequate papers, and/or passing along major and minor revisions suggested by scientific reviewers. After that, the journals basically "wash their hands" of any subsequent problems, merely publishing any substantive letters sent in to the journal criticizing a published paper. This seems an inadequate role in today's world of scientific debate in which the stakes can be so high, and in which researchers largely are left to fend for themselves, many times not even being supported by their own research institutions. Once a journal publishes an article, it must shoulder a responsibility for that work that goes beyond the mere publishing of letters to the editor and their responses. The *New England Journal of Medicine* (*NEJM*) has taken an aggressive stand on the issue of editorial writers and potential financial