

Regulatory Science Transparency: Assessment of the Environmental Protection Agency's Proposed Rule on Strengthening Transparency in Regulatory Science

A. Alan Moghissi^{a,c,*}, Richard A. Calderone^a, Lisa M. Jaeger^{a,d}, Lismary Real^a, Yousef Alessa^a, Mansour Alsharif^a, Henry Debrah^a, Destini Garrison^a, Anita Ginigeme^a, Bralen Lamoureux^a, Yanzhuo Li^a, Yuhan Lin^a, Camden Ogletree^a, Hadeel Shadid^a, Saher Sohail^a, Soha Sohail^a, Misti Persaud^b, Natalie Ephraim^b, Joohye Oh^b, Tianze Pan^b, Lauren Trippe^b

^aGeorgetown University Medical Center, Washington, DC

^bGeorgetown University Department of Chemistry, Washington, DC

^cInstitute for Regulatory Science, Alexandria VA

^dBracewell LLP, Washington, DC

Abstract

In its proposed rule, Strengthening Transparency in Regulatory Science, the Environmental Protection Agency (EPA) requires transparency in certain areas of regulatory science. The proposed rule mandates public access to the details of studies that address dose response and models. This paper is the result of a study conducted by graduate students at Georgetown University. The study relied upon a specific process for selecting a small number from an exceptionally large number of responses to study the subject. The evaluation of the responses was largely based on Best Available Regulatory Science (BARS) and Metrics for Evaluation of Regulatory Science Claims derived from BARS. The results of the study indicate that opposition to the EPA's proposed rule is largely based on the claim that its implementation would eliminate key studies that contain confidential data from consideration during the regulatory process. Although the proposed rule would allow exemptions from the public access requirements, there is opposition to making exemptions available at the discretion of the EPA Administrator. The study concluded that a regulatory science process called "controlled transparency" would be a reasonable solution to compliance with transparency requirements while protecting confidential information.

Keywords: Environmental Protection Agency Transparency Rule, pivotal regulatory science, regulatory science transparency, Best Available Regulatory Science, controlled transparency, dose response, mathematical model

1. Introduction

There is a global consensus that transparency within governmental decisions is not only desirable but necessary. An internet search for items that included "transparency" resulted in 10^6 to 10^7 entries. At the same time, it is recognized that there are limitations to transparency. For example, certain information on national security, including research and development of military equipment, or computer programs and their applications, are classified and are not publicly available. Similarly, much information on medical treatments of patients are protected. There are also other data that are not publicly available, such as private advancements in certain scientific studies with potential patent or financial consequences. Clearly, transparency requirements must reflect certain limitations. In this

paper, all information including data that are classified or include personal data and other materials that cannot be publicly released are referred to as confidential information.

Regulatory science is a relatively new and evolving scientific discipline. As described by Moghissi et al. [54], its origin is traceable to the early years of the U.S. Environmental Protection Agency (EPA). The first organization devoted to this scientific discipline and the first professional society dedicated to a segment of this discipline (toxicology and pharmacology) were established in the early 1980s. In 2011, Margaret Hamburg, then Commissioner of the U.S. Food and Drug Administration (FDA), developed a strategy for advancing regulatory science [82].

It appears that the EPA finally has recognized the significance of regulatory science as a scientific discipline. In its proposed rule, Strengthening Transparency in Regulatory Science

*Corresponding author: A. Alan Moghissi, Email: moghissi@nars.org

[81], EPA proposes steps that it claims will ensure the agency's compliance with federal transparency and data integrity laws. EPA also asserts that the proposed steps will ensure that, "*its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility*". In its rulemaking, the EPA acknowledges the importance of transparency in all regulatory science and that all regulatory decisions, "*should describe and document any assumptions and methods and should address any variability and uncertainty*" in the underlying science.

However, EPA proposes to mandate transparency and other requirements for only a subset of its regulatory science - specifically for, "*dose-response and models underlying pivotal regulatory science that are used to justify significant regulatory decisions*". For such agency decisions, EPA proposes to require, "*that regulatory science underlying its actions is publicly available in a manner sufficient for independent validation and that EPA describe and document assumptions and methods used*".

This paper resulted from a study conducted at Georgetown University. Graduate students were asked to select key responses to the EPA's proposed rule, and use the regulatory science process described in Best Available Regulatory Science (BARS) and Metrics for Evaluation of Regulatory Science Claims (MERSC) derived from BARS [53] to evaluate each response. Because there were about 600,000 responses to the EPA's proposed rule, the participants in the study were unable to evaluate every response. Therefore, the process was designed to randomly select at least six responses from the following groups:

1. Scientific, including medical and engineering societies
2. Public health and other not-for-profit organizations
3. Environmental organizations
4. State and local governmental agencies
5. Industrial organizations
6. Individuals

In addition, other authors of this paper identified certain key responses resulting in about 80 items for evaluation.

2. Assessment Process

The concepts of Best Available Regulatory Science (BARS) and Metrics for Evaluation of Regulatory Science Claims (MERSC) derived from BARS are traceable to the 1970s, when the senior author of this paper was employed at the EPA. As reviewed by Moghissi et al. [53], BARS/MERSC resulted from several studies and publications. BARS/MERSC provides a framework for evaluating and identifying scientific assertions. Figure 1 shows the details of BARS/MERSC.

Scientific Rules and Reproducibility Principles are among BARS principles; these are well-established and thus will not be addressed in this paper. Similarly, Open-mindedness and Skepticism Principles are also well recognized; these imply

that the society, as well as the regulatory scientific community, must be willing to consider new scientific ideas. However, those who make a regulatory scientific claim are obligated to provide evidence supporting their claim. The Reproducibility Principle describes the ultimate objective of science. It implies that a scientific claim is reproducible if any individual with sufficient knowledge, equipment or facility can reproduce it.

The Ethical Rules Principle embraces four requirements: Truthfulness, Communicability, Transparency, and Scientific Ethics. Adopting a transparency requirement is the stated purpose of EPA's proposed rule. Implicit in transparency is accessibility to confidential information. There are three potential options when regulatory science decisions rely on the results of confidential studies. While the first option is currently practiced and uses the results of confidential studies, the second option avoids using the results of confidential studies because the raw data of the studies are not publicly available. The third option is the BARS process called Controlled Transparency, which requires that confidential information be provided for reevaluation to organizations that meet the necessary requirements for handling such information.

MERSC provides three pillars derived from BARS Principles. The first pillar addresses the Reliability of Regulatory Science, categorized as: 1) personal opinion, 2) gray literature, 3) peer reviewed regulatory science, and 4) consensus processed regulatory science. However, as described by Brainard et al. [8], many papers that were thought to have met a highly reliable standard, including some published in *Science and Nature*, have been retracted. Therefore, regulators would be well advised to ensure reproducibility of relevant results of a scientific study published in a peer-reviewed journal.

The MERSC pillar Areas Outside of the Purview of Science – the third pillar – is often violated by the influence of ideologies, beliefs, faith, societal, political, or any other non-scientific objectives in assessing the validity of scientific information. Thus, under this pillar, the scientific foundation of a policy is identical if it is performed in the U.S., Russia, China, Saudi Arabia, Brazil, Israel, or Cuba. In contrast, the societal conclusions derived from science can be significantly different between the countries identified above.

Another pillar of MERSC that is particularly relevant to the evaluation of regulatory science claims is classification of Evolving Regulatory Science that categorizes the level of maturity of regulatory science consisting of proven, evolving, borderline, and fallacious information. Relevant parts of this pillar to this study are Evolving, and Borderline Regulatory Science Claims.

2.1. Evolving Regulatory Science

This group includes a large segment of science used in the regulatory process. It includes: 1) Reproducible Evolving Science consisting of reproducible information dealing with a subject whose foundation is not completely understood; 2) Partially Reproducible Evolving Regulatory Science consisting of scientific information that is derived from Proven or Reproducible Evolving Science, but it uses assumptions, extrapolations, default data, and other processes in deriving its results and conclu-

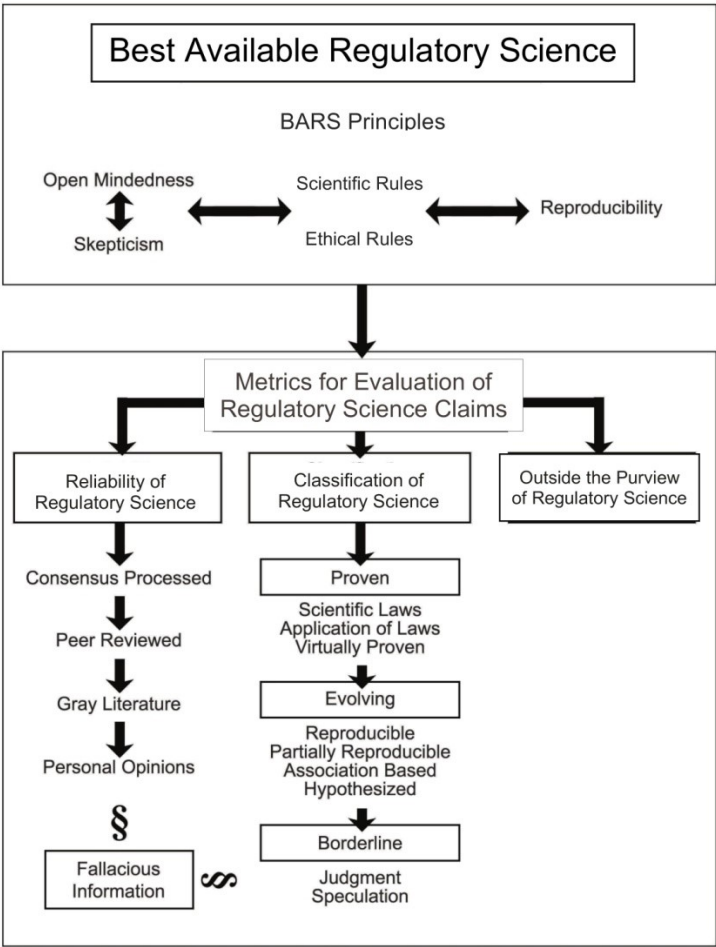


Figure 1: Description of best available regulatory science and metrics for evaluation of regulatory science claims [53].

sions. This class includes extensive information and data used in dose response and mathematical models; 3) Association-Based Evolving Regulatory Science, also called correlation, evidence-based, or observation studies that attempt to correlate an effect to a cause; notably, epidemiological studies fall in this class, with the level of reproducibility ranging from unknown to reasonable; and 4) Hypothesized Evolving Regulatory Science consisting of an organized response to an observation, an idea, or any other initiating thought process.

2.2. Borderline Regulatory Science

This group consists of two classes: 1) Judgment when decisions must be made without having the necessary information, including basic principles, the relevant data, and other scientific requirements; and 2) Speculation consisting of information that is based on the intuition of an individual who wants to stimulate a discussion or initiate a research project.

2.3. Implementation of Ethical Rules Principle of BARS

Key elements of the Ethical Rules Principle reflect the exhortation of Thomas Jefferson, “If we think [the people are]

not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion by education”. Based on the Jeffersonian Principle, the regulatory science process categorizes the affected community as follows:

Specialists: This group consists of individuals who, based on their education and experience, have enough knowledge to understand specific scientific subjects.

Knowledgeable Individuals: This group consists of individuals who have enough education and experience to comprehend scientific claims, provided they are translated into a language that is understandable to members of this group. For example, mathematical equations must be described in words; unique terminologies, vocabulary, abbreviations, acronyms, and any unique processes must be translated into a language that a knowledgeable individual can follow.

Others: Originally, the Jeffersonian Principle was intended to address the needs of all citizens, regardless of their education. Ideally, the process described for knowledgeable individuals should be appropriately modified to also cover this group.

The Ethical Rules Principle of BARS requires that, at a minimum, all regulatory science documents must be translated into a language that is comprehensible by knowledgeable non-specialists and preferably by the entire impacted population.

2.4. Assessment of Definitions Proposed by the EPA

The proposed rule includes several key definitions:

Regulatory Science

The EPA proposes a definition of regulatory science, the main focus of the regulatory effort. As this term is extensively used in many contexts, it is desirable to compare the EPA definition with some examples of other definitions, as follows:

- (a) Regulatory science definition proposed by the EPA: *“Regulatory science means scientific information including assessments, models, criteria documents, and regulatory impact analyses that provide the basis for EPA final significant regulatory decisions”* [81].
- (b) Regulatory science definition by the FDA: *“Regulatory science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality and performance of all FDA-regulated product’s”* [82].
- (c) Legal Regulatory science definition: As described by Moghissi et al. [54], the legal profession has dominated the definition of regulatory science. A recent definition provided by Wagner et al. [84] claims that regulatory science consists of two steps: scientific assessment to be followed by application of scientific assessment by policy makers.
- (d) Definition of Regulatory Science Discipline: As stated above, regulatory science is an emerging scientific discipline and a reasonable definition is: Regulatory science consists of the applied version of various scientific disciplines used in the regulatory processes. Examples of regulatory science disciplines include regulatory toxicology, regulatory ecology, regulatory pharmacology, regulatory microbiology, regulatory atmospheric sciences, and regulatory biomedical engineering, to mention a few.

Pivotal Regulatory Science

EPA proposes to apply the rule requirements to a subset of its regulatory science actions (pivotal) that underlies a subset (final and significant) of its regulatory decisions. As defined in the proposed rule: *“Pivotal regulatory science means the specific scientific studies or analyses that drive the requirements and or quantitative analysis of EPA final significant regulatory decisions”*.

Requirements for Pivotal Regulatory Science: According to the EPA: *“When promulgating significant regulatory actions, the Agency shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation”*. The rule further requires EPA to describe and document any assumptions and methods used.

Peer Review: In several places, EPA emphasizes the need for independent review of pivotal regulatory science. Section 30.7 of the proposed rule requires peer reviewers, *“to articulate the strengths and weaknesses of EPA’s justification for the assumptions applied and the implications of those assumptions”*.

Exemptions from Transparency Requirements: In section 30.9, the EPA proposes exemptions to transparency requirements: *“If it is not feasible to ensure that that all dose response data and models underlying pivotal regulatory science are publicly available in a fashion sufficient for independent validation, in a manner that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security”*.

2.5. Assessment of Responses to Transparency Requirements

The study faced an initial hurdle of a regulatory record containing several hundred thousand responses. The authors recognize the limitation in having to select about 80 from about 600,000 responses. However, as mentioned earlier, an attempt was made to select representative samples from each category of responses. The list of references identifies agreement or disagreement with the proposed rulemaking.

As described above, the EPA limits the transparency requirements to dose response and models. Transparency is a key element of the Ethical Rules Principle of BARS/MERSC. There is also a consensus in the various segments of government, the media, and the public that societal decisions would benefit from transparency. However, many responders opposed the transparency requirements as proposed by the EPA based on their perception that the proposed rule would preclude certain important epidemiological studies from being used in the regulatory process, such as the Six Cities Study [19] and the American Cancer Society Study [69], that have been the foundation of several key regulatory standards. In contrast, several responders agreed with the EPA’s transparency requirement, arguing that it would give the public and the affected community the benefit of being informed about the scientific foundation of regulatory decisions.

A response by the National Academies of Science, Engineering, and Medicine [50] to EPA’s proposed rulemaking identified key problems in excluding scientific data that are significant in the regulatory decision process. The National Academies encouraged EPA, *“to seek objective, expert advice on complexities of this rule and how it would be implemented”*. Another thoughtful response was from Berg et al. [6], the editor-in-chief of *Science*, along with the editor-in-chief of *Nature* and several authors. They indicated that Transparency and Openness Promotion have been adopted by many journals and that scientific data in published studies are normally evaluated in the peer review process. Therefore, excluding relevant studies simply because they do not meet transparency standards would adversely affect the decision-making process. However, as described by Brainard et al. [8], there have been retractions of certain papers, including some published in *Nature* and *Science*.

Opposition to the EPA proposed rule is overwhelmingly focused on the transparency requirements that pivotal regulatory

science data must be publicly available for independent validation. However, as described in the section on exemptions from transparency requirements, EPA recognizes that certain data cannot be made publicly available. Therefore, the only possible reason for opposition to the proposed rule would be the verification requirements inherent in the acceptability of regulatory science.

The list of references identifies the agreement or disagreement of responders to the proposed rule. Several members of Congress expressed opposition to the EPA's proposed rule. Senator Chris Coons, representing 12 Democratic Senators [14], opposed the proposed rule. Similarly, certain Democratic members of the House of Representative opposed the rule [34, 74].

Many scientific societies, as well as public health and non-profit organizations [3, 17, 49, 56, 29, 36, 38, 47, 11, 60, 30, 15, 35, 80, 87, 45, 46], largely opposed the transparency requirement. A significant response opposing the rule came from about 70 organizations [3] consisting mostly of medical and public health professional societies, such as the American Medical Association, but also from other organizations, such as the American Geophysical Union, the Center for Open Science, and the Ecological Society of America. This group [3, 17, 49, 56, 29, 36, 38, 47, 11, 60, 30, 15, 35, 80, 87, 45, 46] suggests that, when feasible, scientists should strive for appropriate public access to data to maximize independent validation and trust in the scientific process. This group also agrees that public access to the raw data of many scientific studies is not feasible. There are also several public health and non-profit organizations that agree [51, 75, 88, 24] with the proposed rule, including an organization [51] that identified areas for improvement.

Several state, local and tribal organizations provided comments on the proposed rule [79, 66, 57, 18, 10, 52, 58, 37, 77, 85]. Again, here the opposition to the proposed rule was based on the required public access to the raw data of studies to be included in the regulatory process. An interesting case was the statement of the mayor of a Colorado municipality [77] who opposed the rule on behalf of the Environmental Defense Fund, an environmental organization. As expected, environmental organizations [61, 86, 33, 44, 67, 89, 39, 16, 28] rejected the proposed rule. These organizations and their supporters claim that implementation of the EPA's proposed rule would cause significant adverse human health and environmental effects. As before, the primary argument was the exclusion of studies whose raw data would not be publicly available. In contrast, several organizations [28, 1, 2, 64, 73] supported the EPA's proposed rule. For example, Peter Ruane [73], representing the American Road and Transportation Builders Association, endorsed the EPA proposed rule and claimed that transparency will enhance economic opportunities. Finally, there were many responses by individuals including those who represented others [4, 5, 7, 9, 12, 13, 20, 21, 22, 23, 25, 26, 27, 31, 32, 40, 42, 41, 43, 48, 55, 59, 62, 63, 65, 68, 70, 71, 72, 76, 78, 83, 90, 91, 92]. Like other responders, there were those who agreed, disagreed, or had comments.

The evaluation of dose response and models is impacted by the choice of statistical processes, management of uncertain-

ties, inclusion of societal objectives such as political vision in science, and related issues. However, with the possible exception of the National Academies [50], no response reviewed for this study addressed these and related issues.

A reasonable finding of the study is that almost all opponents of the proposed rule identified no process for inclusion of studies whose results are not publicly available in the regulatory process. Apparently, the opponents did not consider the proposed exemptions included in section 30.9 on protection of personal privacy, confidential business information, and sensitive national and homeland security data.

Despite the limited number of responses included in the present study, several responses seemed to have been shepherded by specific organizations, as some responses shared similar phrasing and sentences.

3. Discussion

As described above, regulatory science is an emerging scientific discipline based on the application of scientific principles in the regulatory process. The EPA's definition of regulatory science is descriptive of how the Agency intends to use regulatory science in its decision-making process. Similarly, the definition of pivotal regulatory science is reasonable, as it describes how EPA intends to use a specific regulatory science subject in its decisions.

EPA's transparency rule raises several areas of concern. A major issue is the reason for selecting only two areas, dose response and models, to be included in pivotal regulatory science, rather than covering all other scientific – including engineering – subjects that are used in major regulatory decisions.

Dose response and models are both at the low end of Evolving Regulatory Science, requiring the inclusion of assumptions and frequently default data. Unfortunately, as currently practiced, scientific assessments also include societal objectives such as policy/political vision of the regulators. The task of the scientific community is to provide to policy makers the status of relevant science, including its uncertainties, potential options for assumptions, and their consequences. The task of policy makers, including regulators, is to decide and justify the decision as compared to potential alternatives.

The application of the Jeffersonian Principle would significantly improve the acceptability of regulatory and other policy decisions. Typically, scientific assessments, including those dealing with dose response and models, inherently include uncertainties requiring assumptions and judgements. Often, they also require the inclusion of default data and societal objectives. The Jeffersonian Principle requires that various elements of uncertainty be translated into a language that is understandable to knowledgeable non-specialists and ideally to the public. Such an option would replace the current process used by many regulators who justify their decisions by stating “the scientists tell me”. Once the science is translated, members of Congress, regulators and most members of the scientific community would be able to understand and participate in the decision process.

Another important issue is the perceived definition of transparency. Many epidemiological and other studies include per-

sonal and private information that can be modified to exclude privacy and related materials without impacting the core information. However, such a process is complex and is beyond the scope of this paper. There is a well-established process to reevaluate a scientific subject claim including epidemiological studies without violating the confidentiality requirements. For example, many universities and research organizations that study human subjects are required to establish and maintain an Institutional Review Board (IRB). There is no reason for not providing the epidemiological data to a university or any other organization with a functioning IRB for reevaluation. The BARS/MERSC process includes Controlled Transparency implying a reevaluation of a scientific claim by qualified organizations. Once Controlled Transparency is implemented, EPA's transparency requirements are met.

Finally, another key issue is reproducibility, a subject that was emphasized in several responses. There is an unambiguous distinction between two kinds of reproducibility based on the level of maturity of science. As described earlier, the Reproducibility Principle of BARS/MERSC implies that any individual with relevant knowledge can reproduce a scientific study. In contrast, for obvious reasons, if the study requires assumptions its reproducibility requires acceptance of the same assumptions.

4. Conclusions

The proposed EPA rule constitutes the first step in implementing transparency requirements of regulatory science. There are several needed revisions of the proposed rule:

1. The transparency requirements should be extended beyond dose response and models. The affected community and the society would benefit from regulatory science transparency in all regulatory decisions.
2. A key element of the BARS/MERSC Ethical Rules Principle is Controlled Transparency, which mandates that confidential information and data be provided to those who are legally qualified to receive and evaluate the results of the relevant studies. The application of Controlled Transparency would expand interested parties' access to relevant information.
3. The EPA and other regulatory agencies should attempt to comply with the Jeffersonian Principle and translate relevant regulatory science into a language that is understandable to knowledgeable non-specialists. Regulators would greatly benefit if key members of society, such as legislative and judicial officers, could understand the scientific foundations of policy and regulatory decisions.

It is also desirable to ensure scientific interaction among key members of the EPA, scientific organizations that provide comments on to the proposed transparency rule, key opponents and supporters of the rule, and others. Such interaction would improve the acceptability of transparency requirements, identify potential shortcomings of the proposed rule, and forge paths to address the shortcomings.

5. Declaration of Conflicting Interest

The authors declare no conflicts of interest.

6. Article Information

This article was received June 17, 2019, in revised form July 24, 2019, and made available online September 12, 2019.

7. References

- [1] Addington, D. S. (2018, May 29). Comment submitted by David Addington, Senior Vice President, General Counsel, National Federation of Independent Business (NFIB) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0843>
- [2] Alliance of Automobile Manufacturers. (2018, August 21). Comment submitted by Alliance of Automobile Manufacturers on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6162>
- [3] American Lung Association. (2018, August 28). Mass Comment Campaign sponsored by American Lung Association et al. on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6455>
- [4] Bailey, M. A. (2018, August 15). Comment submitted by M. Bailey on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6098>
- [5] Batchelder, E. (2018, June 4). Comment submitted by E. Batchelder on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1397>
- [6] Berg, J., Campbell, P., Kiermer, V., Raikhel, N. & Sweet, D. (2018). Joint statement on EPA proposed rule and public availability of data Science. *Science*, 360. doi: 10.1126/science.aau0116
- [7] Boulton, T. E. (2018, June 6). Comment submitted by T. E. Boulton on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2477>
- [8] Brainard, J. (2018). Rethinking retractions. *Science*, 362, 390-393. doi: 10.1126/science.362.6413.390
- [9] Branch, K. (2018, July 9). Comment submitted by K. Branch on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4482>
- [10] Buchanan, S. (2018, June 18). Comment submitted by Susan Buchanan, MD, MPH, Director, Great Lakes Center for Children's Environmental Health on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2977>
- [11] Buchta, W. G. (2018, July 17). Comment submitted by William G. Buchta, MD, MPH, FACOEM President, American College of Occupational and Environmental Medicine (ACOEM) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4589>

- [12] Caldie, C. (2018, June 18). Comment submitted by C. Caldie on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-3071>
- [13] Chiu, W. A. (2018, June 5). Comment submitted by Weihsueh A. Chiu, PhD, Professor, Veterinary Integrative Biosciences, Texas A&M University on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1949>
- [14] Coons, C., Merkley, J. A., Smith, T., Shaheen, J., Markey, E. J., Durbin, R. J., . . . Sanders, B. (2018, August 28). Comment submitted by Christopher A. Coons, Senator, United States Senate et al. on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6863>
- [15] Cure Alzheimers Fund. (2018, August 31). Anonymous public comment on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-8826>
- [16] D'Angelo, W. J. & Green, J. J. (2018, August 7). Comment submitted by Wayne J. D'Angelo and Joseph J. Green, Kelley Drye & Warren LLP, Counsel, Steel Manufacturers Association (SMA) and Specialty Steel Industry of North America (SSINA) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-5171>
- [17] Demetri, G. D. & Foti, M. (2018, August 23). Comment submitted by George D. Demetri, Chair and Margaret Foti, Chief Executive Officer, American Association for Cancer Research (AACR) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6357>
- [18] DePaulo, W. V. (2018, May 30). Comment submitted by William V. DePaulo, Esq., Keeper of the Mountains Foundation (KOTM) and People Concerned About Chemical Safety, INC. (PCACS) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree with concerns]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2169>
- [19] Dockery, D. W., Pope, C. A., Xu, X., Spengler, J. D., Ware, J. H., Fay, M. E., . . . Speizer, F. E. (1993). An Association between Air Pollution and Mortality in Six U.S. Cities. *New England Journal of Medicine*, 329, 1753-1759. doi: 10.1056/NEJM199312093292401
- [20] Dunn, J. D. (2018, July 6). Comment submitted by J. D. Dunn on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4430>
- [21] Epstein, M. (2018, June 19). Comment submitted by Dr. M. Epstein on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-3076>
- [22] Falxa, G. A. (2018, June 4). Comment submitted by G. A. Falxa on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1461>
- [23] Faust, D. G. (2018, June 6). Comment submitted by Drew Gilpin Faust, Office of the President, Harvard University on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2431>
- [24] Ferrara, P. & Dunn, J. D. (2018, July 11). Comment submitted by Peter Ferrara, Senior Fellow and John Dale Dunn, Policy Advisor, The Heartland Institute on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4541>
- [25] Frey, B. (2018, July 9). Comment submitted by B. Frey on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4487>
- [26] Geltman, E. A. G. (2018, July 23). Comment submitted by Elizabeth Ann Glass Geltman, Professor, Environmental Health Policy, City University of New York (CUNY) School of Public Health on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4848>
- [27] Goldman, L. R. (2018, August 2). Comment submitted by L. Goldman on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-5119>
- [28] Graul, F. (2018, June 5). Comment submitted by Faye Graul, Executive Director, Halogenated Solvents Industry Alliance (HSIA) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1944>
- [29] Gropp, R. (2018, July 13). Comment submitted by Robert Gropp, PhD, Co-Executive Director, American Institute of Biological Sciences (AIBS) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4594>
- [30] Hemker, K. J. (2018, June 5). Comment submitted by Kevin J. Hemker, President, The Minerals, Metals, & Materials Society (TMS) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1943>
- [31] Herring, A. H. (2018, June 7). Comment submitted by Amy H. Herring, Professor of Statistical Science & Global Health, Co-Director, Duke Center for Health Data in Action on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2548>
- [32] Hisao, G. S. (2018, August 10). Comment submitted by G. S. Hisao on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-5580>
- [33] Jaggar, K. (2018, July 23). Comment submitted by Karuna Jaggar, Executive Director, Breast Cancer Action (BCAction) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4836>
- [34] Johnson, E. B. (2018, May 30). Comment submitted by Eddie Bernice Johnson, Ranking Member, Committee on Science, Space, and Technology, Congress of the United States House of Representatives on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1012>
- [35] Kennedy, R. F. (2018, June 5). Comment submitted by Ronald F. Kennedy, Director of Governmental Relation, New York State Bar Association Section of Environmental and Energy Law (SEEL) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1012>

- 2018-0259-2337
- [36] Kirkland, K. H. (2018, May 24). Comment submitted by Katherine H. Kirkland, Executive Director, Association of Occupational and Environmental Clinics (AOEC) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0566>
- [37] Kohlasch, F. & Kelly, J. (2018, June 5). Comment submitted by Frank Kohlasch, Manager, Air Assessment and Analysis, Minnesota Pollution Control Agency (MPCA) and James Kelly, M. S., Manager, Environmental Surveillance & Assessment, Minnesota Department of Health (MDH) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2171>
- [38] Kraft, C. A. & Hollier, L. M. (2018, June 6). Comment submitted by Colleen A. Kraft MD, FAAP, President, CAK/avg, American Academy of Pediatrics (AAP) and Lisa M. Hollier, MD, MPH, FACOG President, American College of Obstetricians and Gynecologists (ACOG) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2425>
- [39] Kurtz, L. (2018, May 8). Comment submitted by Lauren Kurtz, Executive Director, Climate Science Legal Defense Fund (CSLDF) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0024>
- [40] Kyle, A. D. (2018, August 30). Comment submitted by A. D. Kyle on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-8663>
- [41] Langdon, J. (2018, June 21). Comment submitted by J. Langdon on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-3343>
- [42] Langman, M. M. (2018, June 5). Comment submitted by Mary M. Langman, Medical Library Association (MLA) and Association of Academic Health Science Libraries (AAHSL) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1796>
- [43] Le, V. (2018, June 6). Comment submitted by Vi Le, University of Washington on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2429>
- [44] Lee, M. (2018, August 31). Comment submitted by Michel Lee, Organization: Promoting Health and Sustainable Energy (PHASE) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-8913>
- [45] Lockwood, A. H. (2018, August 10). Comment submitted by Alan H Lockwood, MD, Board of Director, Physicians for Social Responsibility (PSR) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-5656>
- [46] Lurie, P. (2018, July 31). Comment submitted by Peter Lurie, MD, President, Center for Science in the Public Interest (CSPI) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-5022>
- [47] Mandel, S. (2018, May 23). Comment submitted by Susan Mandel, MD, MPH, President, Endocrine Society on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0559>
- [48] McCabe, D. (2018, June 6). Comment submitted by Dr. David C. McCabe, Senior Scientist, Clean Air Task Force on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2427>
- [49] McEntee, C. (2018, May 11). Comment submitted by Christine McEntee, Executive Director, Chief Executive Officer, American Geophysical Union (AGU) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0061>
- [50] McNutt, M. (2018, July 16). Comment submitted by Marcia McNutt, President, National Academy of Sciences, et al. on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science. Retrieved from <http://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4831>
- [51] Mehan, T., III. (2018, August 7). Comment submitted by G. Tracy Mehan, III, Executive Director, Government Affairs, American Water Works Association (AWWA) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree with concerns]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-5175>
- [52] Mercier, C. (2018, June 5). Comment submitted by Chris Mercier, Tribal Council Vice Chair, Confederated Tribes of the Grand Ronde Community of Oregon on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree with concerns]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2170>
- [53] Moghissi, A. A., Calderone, R. A., McBride, D. K., & Jaeger, L. M. (2017). Innovation in Regulatory Science: Metrics for Evaluation of Regulatory Science Claims Based on Best Available Regulatory Science. *Journal of Regulatory Science*, 5(1), 50-58. doi: 10.21423/jrs-v05n01p050
- [54] Moghissi, A. A., Straja, S. R., Love, B. R., McBride, D. K., & Stough, R. R. (2014). Innovation in Regulatory Science: Evolution of a New Scientific Discipline. *Technology and Innovation*, 16(2), 155-165. doi: 10.3727/194982414X14096821477027
- [55] Morenz, L. L. (2018, June 6). Comment submitted by L. Lundergan Morenz on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2471>
- [56] Naas, L. A. B. (2018, June 11). Comment submitted by Leigh Ann Burns Naas, President, Academy of Toxicological Sciences (ATS) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4540>
- [57] Nabahe, W. J. (2019, August 17). Comment submitted by Wifred J. Nabahe, Chairman, National Tribal Air Association (NTAA) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6116>
- [58] Nabahe, W. J. (2019, September 11). Comment submitted by Wilfred J. Nabahe, Chairman, National Tribal Air Association (NTAA) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9242>
- [59] Nadkarni, R. (2018, July 9). Comment submitted by R. Nadkarni on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Re-

- trieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4480>
- [60] National Center for Science Education. (2018, August 9). Comment submitted by National Center for Science Education on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-5420>
- [61] National Resources Defense Council. (2018, October 5). Comment submitted by the Natural Resources Defense Council (NRDC) (Part 1 of 7) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9293>
- [62] Nebert, D. W. (2018, August 15). Comment submitted by D. W. Nebert on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6045>
- [63] Paciorek, C. (2018, June 4). Comment submitted by C. Paciorek on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1420>
- [64] Pecnik, R. (2018, September 9). Comment submitted by Richard Pecnik, Regulatory Affairs, Gernatt Asphalt Products, Inc. on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9223>
- [65] Pennoyer, M. A. (2018, August 13). Comment submitted by M. A. Pennoyer on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-5998>
- [66] Perdue, S. B. (2018, June 6). Comment submitted by Stephanie Bergeron Perdue, Interim Executive Director, Texas Commission on Environmental Quality (TCEQ) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree with concerns]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2426>
- [67] Pierno, T. (2018, June 13). Comment submitted by Theresa Pierno, President, Chief Executive Officer, National Parks Conservation Association on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2909>
- [68] Pierotti, A. L. (2018, June 6). Comment submitted by Dr. Pierotti on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2449>
- [69] Pope, C. A., Ezzati, M., & Dockery, D. W. (2009). Fine-Particulate Air Pollution and Life Expectancy in the United States. *New England Journal of Medicine*, 360, 376-386. doi: 10.1056/NEJMsa0805646
- [70] Pressman, S. (2018, September 7). Comment submitted by S. Pressman on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9209>
- [71] Reichel, W. (2018, June 5). Comment submitted by W. Reichel on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2146>
- [72] Richmond, D. (2018, June 6). Comment submitted by D Richmond on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2480>
- [73] Ruane, T. P. (2018, September 11). Comment submitted by T. Peter Ruane, President & Chief Executive Officer, American Road & Transportation Builders Association (ARTBA) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9243>
- [74] Russ, A. & Schaeffer, E. (2018, August 16). Comment submitted by Abel Russ, Senior Counsel, and Eric Schaeffer, Executive Director, Environmental Integrity Project on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6447>
- [75] Schatz, T. A. (2018, May 25). Comment submitted by Thomas A. Schatz, President, Citizens Against Government Waste (CAGW) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0844>
- [76] Schlesinger, W. H. (2018, June 5). Comment submitted by William H. Schlesinger, President Emeritus, Cary Institute of Ecosystem Studies on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2190>
- [77] Snyder, T. (2018, June 18). Comment submitted by T. Snyder on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-3048>
- [78] Stewart, S. D. (2019, June 4). Comment submitted by S. D. Stewart on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1437>
- [79] Stine, J. L. & Malcolm, J. (2018, July 6). Comment submitted by John Linc Stine, Commissioner, Minnesota Pollution Control Agency (MPCA) and Jan Malcolm, Commissioner, Minnesota Department of Health (MDH) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4410>
- [80] Streitz, W. D. (2018, May 8). Comment submitted by Wendy D. Streitz, Executive Director, Research Policy Analysis & Coordination, University of California (UC) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0027>
- [81] U.S. Environmental Protection Agency. (2018). Strengthening Transparency in Regulatory Science, 83 FR 18768. Retrieved from <https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science>
- [82] U.S. Food and Drug Administration. (2011, August). Advancing Regulatory Science at FDA: A Strategic Plan. Retrieved from www.fda.gov/ScienceResearch/Specialtopics/RegulatoryScience/ucm267719.htm
- [83] Vision, T. J. (2018, June 5). Comment submitted by T. J. Vision on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree with concerns]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-2234>
- [84] Wagner, W., Fisher, E., & Pascual, P. (2018). Whose science? A new area in regulatory “science wars”. *Science*, 362, 636-639. doi: 10.1126/science.aau3205
- [85] Walz, B. A. (2018, August 21). Comment submitted by Barbara A. Walz, Senior Vice President, Policy and Compliance, Tri-State Generation and Transmission Association, Inc. (Tri-State) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-6155>

- [86] White, K. (2018, August 28). Comment submitted by K. White on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-7116>
- [87] Witherspoon, N. O. (2018, July 18). Comment submitted by Nsedu Obot Witherspoon, MPH, Executive Director, Children's Environmental Health Network (CEHN) on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-4597>
- [88] Wood, S. F. (2018, May 14). Comment submitted by Susan F. Wood, PhD, Executive Director, Jacobs Institute of Women's Health on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Agree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0063>
- [89] Yamamoto, A. J. (2018, May 30). Comment submitted by Andrew J. Yamamoto, Esq., Editor and Scott D. Pinsky, Esq. Environmental Law Editor, InternationalMosaic.com on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-1037>
- [90] Yamamoto, A. J. & Pinsky, S. D. (2018, August 13). Comment submitted by Andrew J. Yamamoto, Esq., Editor and Scott D. Pinsky, Esq., Environmental Law Editor, InternationalMosaic.com on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-5995>
- [91] Zarembka, A. (2018, August 30). Comment submitted by A. Zarembka on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-8655>
- [92] Zirasri, R. (2018, Aug 22). Comment submitted by R. Zirasri on the Environmental Protection Agency (EPA) Proposed Rule: Strengthening Transparency in Regulatory Science [Disagree]. Retrieved from <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9291>