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Abstract

Under President Trump, the Environmental Protection Agency (EPA) was largely successful in at least temporarily achieving the administration's policy goals. It did so, in part, by significantly altering or distorting the processes used under prior Republican and Democratic EPA leadership to obtain consensus opinion of the scientific community on issues pertinent to EPA's science-based regulatory activities. In this article I explore the extent to which these changes reflect replacing the norms of science with norms more appropriate to the advocacy practices of law. Under the Biden Administration, we can anticipate restoration of the norms of science that previously guided the scientific consensus processes used by EPA. However, the lesson of the Trump administration is that these norms need buttressing by developing and strengthening laws that govern the selection of members of EPA's external scientific and technical advisory committees, their deliberative processes, and the literature reviewed by EPA.

† Dean Emeritus of the University of Pittsburgh Graduate School of Public Health. From 1981–83 he was chair of EPA's Clean Air Scientific Advisory Committee and subsequently served as President Reagan's appointee as EPA Assistant Administrator for Research Development. He is a member of the National Academy of Medicine, for whom he has chaired or served on more than twenty committees. He has also chaired numerous committees related to environmental issues at the local, national, and international levels. He is particularly interested in the interface between science and law and has written on this subject in the legal and scientific literature. In 2015, he was a visiting professor at the University of Cologne Department of Political Science and European Affairs.

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INTRODUCTION

When teaching students or colleagues about participating in regulatory or other law-based proceedings, I often begin by talking about playing basketball while growing up in New York City. I wasn't particularly good, so my playing time was mostly in pickup games at different local courts. While the central objective always was to score by putting the ball through the hoop, each court had its own subsidiary rules which could affect the outcome. Do you need to win by one or two baskets? How many times did you have to pass the ball before your team could score? For science-based regulatory decision making, scientists and policy makers have the same central objective – to use the best science for the most effective policies. But the subsidiary rules may differ for each decision process depending upon such factors as the legal basis for the regulation and on intra-agency practices often developed over decades. For street basketball, the rules could change, so it was important to check before you started playing. But the rules were always consonant with the central objective of scoring the most baskets. Further, it was a given that the rules would never change in the middle of the game.

In this paper, I will review how the Trump administration's EPA leadership attempted to, and partially succeeded, in changing the central objective of basing EPA's regulatory decision-making on the

best possible science. They did so by altering subsidiary rules on how this science is obtained and interpreted, in some cases blatantly in the midst of a regulatory decision process.

I contend that these changes can be understood largely as altering the processes to approximate truth from those used by science to those used by law. In essence, the EPA made a move from consensus to confrontation. Although law and policy (and politics) differ from each other, throughout this article I will intentionally conflate them to focus on the common denominator of advocacy which is central to law, focusing on the area in which their overlap is most pertinent to my thesis of the central role of advocacy.[1] I note that, of the fifteen EPA administrators confirmed by the U.S. Senate, nine have been lawyers.[2]

Law and science are distinguished professions. Each has an identifiable knowledge-based core that requires advanced education. Each has a high level of societal recognition, responsibility and accountability. Each has long-standing traditions and standards that underlie their ethical code of conduct. For much of what they do, lawyers and scientists act separately. In some instances, the two professions work together, such as in the fields of toxic torts, forensic evidence, and patent law. In these areas their respective roles are reasonably well-defined, although subject to change.[3] One activity

1. Janice V. Arellano, writing the Practice Points column on the American Bar Association web page, points out that "Law students and new attorneys need to understand that the practice of law and policymaking are completely different areas but require the development of similar skill sets of quality writing, advocacy and networking." Janice V. Arellano, *Using Litigation Skills in the Public Policy Arena*, A.B.A (Feb. 28, 2017), https://www.americanbar.org/groups/litigation/committees/minority-trial-lawyer/practice/2017/using-litigation-skills-in-the-public-policy-arena/ [https://perma.cc/65WG-9QQP]. Much scholarly work about the science/law and science/policy interfaces has covered the role of evidence and the role of advocacy. *See generally* Wendy E. Wagner, *The "Bad Science" Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 L. & CONTEMP. PROBS. 63 (2003); SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 87 (1990) [hereinafter THE FIFTH BRANCH]; Sheila Jasanoff, *Procedural Choices in Regulatory Science*, 4 RISK 143-60 (1993).

2. Seven of the first eight EPA Administrators (counting Ruckelshaus twice) were lawyers. This was followed successively from 2001 to 2017 by five non-lawyers. Of the six non-lawyers, four had previously worked at EPA and the other two had been state governors. The two most recent EPA Administrators, Scott Pruitt and Andrew Wheeler, are both lawyers. *EPA's Administrators*, EPA, https://www.epa.gov/50/epas-administrators [https://perma.cc/Q48Y-69MX].

3. An example of a change is the Supreme Court's *Daubert* decision that increased the role of judges in deciding what science can be put in front of a jury. *See* Margaret A. Berger, *What has a Decade of Daubert*

which brings scientists and lawyers in close contact is science-based regulation at the EPA. In this article, I will draw on significant experience performing and interpreting environmental health science, including service as President Reagan's appointee as the EPA Assistant Administrator for Research and Development, and on an acquaintance with the law.[4] Through the years I have learned much from legal scholars who have focused on explaining the law science interface to lawyers and to judges.[5] But my primary approach, and bias, is that of a physician scientist and a toxicologist who recognizes that much of what is understood about health science has come from observing the perturbations in human biology caused by diseases and by toxic agents. In this article I am attempting to further the understanding of the law-science interface by observing the perturbations caused by the Trump Administration, focusing particularly on the U.S. Environmental Protection Agency.

Wrought? 95 AM. J. PUB. HEALTH S59 (2005). *See infra* Section II.F for further discussion of the *Daubert* decision.

4. I am a physician who in 1966–68 served in the U.S. Public Health Service Division of Air Pollution prior to it being incorporated into the newly formed EPA. I have authored over 200 papers in the scientific literature, mostly on environmental topics. Relevant to the present article is my background in science advisory functions, at EPA and to some extent in law. Publications in the legal literature include co-authoring the Reference Guide on Toxicology in the Federal Judicial Center's Reference Manual on Scientific Evidence for each of its three editions, writing a few papers on toxic substances and tort or regulatory law, and co-authoring a textbook for nonlawyers (RUSSELLYN S. CARRUTH AND BERNARD D. GOLDSTEIN, ENVIRONMENTAL HEALTH LAW: AN INTRODUCTION (2013)). In toxic tort suits I have worked roughly equally for plaintiffs and defense. I am an elected member of both the American Society for Clinical Investigation and the National Academy of Medicine and have chaired over a dozen National Academy of Sciences committees related to environmental science and public health. President Reagan appointed me as Assistant Administrator for Research and Development, serving under Administrators Ruckelshaus and Thomas. I chaired the Clean Air Science Advisory Committee under Administrator Gorsuch, and as an academic have chaired or served on a variety of ad hoc EPA committees. For the Health Effects Institute, I chaired the Research Committee. I have chaired advisory committees for other federal or state agencies, the UN Environmental Program and the World Health Organization. More recently I served as a member of the Science Policy Committee of the Federation of American Societies of Experimental Biology. During my career I have served in an advisory capacity roughly equally for environmental NGOs and for the chemical and petrochemical industries.

5. I particularly acknowledge Sheila Jasanoff, Wendy Wagner, Gary Marchant, John Applegate, Joe Cecil and David Faigman and his colleagues, and the late Margaret Berger who through the years have been willing to spend time attempting to educate a physician about the law/science interface. I apologize to them and to the reader for my misunderstandings and oversimplifications.

I will first look at differences between the two fields relevant to my thesis that replacement of EPA's scientific consensus processes with those most appropriate to the law are central to understanding many of the actions of Trump's EPA leadership. I will consider pertinent distinguishing characteristics between law and science, including the role of advocacy; ethical standards; metrics of success; and the difference between going up alleys to see if they are blind versus not asking a question for which you do not know the answer. I will consider the role of the EPA's organizational structure in setting the tone for the interface between science and law, and will describe some of the previous attempts to perturb the consensus processes relevant to the scientific underpinning of governmental decision.

These consensus approaches have in the past helped regulators make reasonably effective science-based rules, doing so not because science is necessarily good, but because such rules are inherently more likely to be successful in achieving the EPA's mandated goals.[6]

I will not respond to the numerous diatribes against the EPA's science and scientists, some of which include recommendations to remove the Office and Research and Development (ORD) from the EPA, or to dismantle the EPA because it can't get its science right.[7] While alterations and refinements to the processes for obtaining the scientific basis for regulation have been not infrequent in the past, it is my opinion that at no time has the EPA's approach to understanding the science appropriate for regulation been subject to such drastic change as has occurred under the Trump administration.[8]

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6. A recent critique of EPA's actions on air pollution repeated the pertinent old saw "Science without policy is science; policy without science is gambling." Gretchen T. Goldman & Francesca Dominici, *Don't Abandon Evidence and Process On Air Pollution Policy*, 363 SCIENCE 1398 (2019).

7. *See* Henry I. Miller, *Happy Birthday EPA?*, REGULATION 4, 6 (2011), https://www.cato.org/sites/cato.org/files/serials/files/regulation/2011/4/regv34n1-brieflynoted.pdf [https://perma.cc/5U8C-F589]. *See also The EPA: More Trouble Than It's Worth and Should Be Abolished, Says Dr. Miller*, AM. COUNCIL SCI. & HEALTH (Mar. 29, 2011), http://www.acsh.org/factsfears/newsID.2484/news_detail.asp [https://perma.cc/FS4T-MG9K]. Jay Lehr of the Heartlands Institute has argued that EPA ought to be disbanded and its responsibilities turned over to states, an opinion that he says is motivated in part by EPA's incredibly poor science. Jay Lehr, *Foreword to* RICH TRZUPEK, REGULATORS GONE WILD: HOW THE EPA IS RUINING AMERICAN INDUSTRY, at xi (2011). For an antidote to these critiques, *see generally* Wendy Wagner, *It Isn't Easy Being a Bureaucratic Expert: Celebrating the EPA's Innovations*, 70 CASE W. RES. L. REV. 1093 (2020).

8. In an op ed I described why I would have resigned as chairperson of CASAC appointed by Gorsuch, or Assistant Administrator of EPA appointed by Reagan, had either attempted to do what Administrator's Pruitt and Wheeler have attempted. Bernard D. Goldstein, *Opinion: If I Were Still Working at the EPA, I Would Resign*, THE WASH. POST (Apr. 2, 2019), https://www.washingtonpost.com/opinions/if-i-were-still-

I write from the perspective of an academic scientist. My focus will be on two Congressionally-mandated EPA advisory committees: the Clean Air Scientific Advisory Committee (CASAC) and the Science Advisory Board (SAB).[9] I generally will not consider the specifics of the science underlying the many EPA decisions under Scott Pruitt and Andrew Wheeler, which have relaxed environmental controls.[10] Nor is the heightened involvement of stakeholders, including communities, which have characterized environmental health science in recent decades, directly pertinent to this paper.[11]

I. DIFFERENCES BETWEEN SCIENCE AND LAW PERTINENT TO ENVIRONMENTAL REGULATION

A. The Role of Advocacy

Central to the legal profession is advocacy for clients. Central to science is a belief that scientific facts speak for themselves.[12] In my view

working-at-the-epa-i-would-resign/2019/04/02/88e6e2b8-519a-11e9-88a1-ed346f0ec94f_story.html [https://perma.cc/C4CZ-PWGS]. Ronald Reagan came to Washington with much the same anti-EPA rhetoric as Donald Trump and chose Anne Gorsuch as EPA Administrator. Ms. Gorsuch was previously considered the most anti-science of EPA's Administrators. Terry Yosie & Bernard D. Goldstein, *Environmental Science at EPA: Providing Good Science for Relevant Policy*, EPA AT 50 (A. James Barnes, John D. Graham and David Konisky, eds.), to be published by Rowman and Littlefield 2021. *See also* Bernard D. Goldstein, *EPA at 40: Reflections on the Office of Research and Development*. 21 DUKE ENV'TL. L. AND POLICY F. 295 (2010).

9. The Clean Air Scientific Advisory Committee was established in the 1977 Clean Air Act Amendments. 42 U.S.C. § 7409(d)(2) (1977). The EPA Science Advisory Board was authorized in the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA). 42 U.S.C. § 4365 (2018).

10. Nadia Popovich et al., *The Trump Administration Rolled Back More Than 100 Environmental Rules. Here's the Full List.,* N.Y. TIMES (July 15, 2020), https://www.nytimes.com/interactive/2020/climate/trump-environment-rollbacks.html [https://perma.cc/RY86-9WMR].

11. *See, e.g.,* two major advisory processes that have placed risk assessment within the context of stakeholder involvement: THE PRESIDENTIAL/CONG. COMM'N ON RISK ASSESSMENT AND RISK MGMT., FRAMEWORK FOR ENV'TAL HEALTH RISK MGMT. (1997), https://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=36372 [https://perma.cc/XUC4-7VHA]; NAT'L RSCH. COUNCIL OF THE NAT'L ACADS., SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT (2009). For a discussion of community partnerships at the National Institutes of Environmental Health Sciences, *see* Maureen Lichtveld et al., *Then and Now: Lessons Learned from Community Academic Partnerships in Environmental Health Research*, 15 ENV. RES. 117 (2016).

12. Of course, these are central tendencies rather than absolute rules: advocacy in law is bounded by numerous constraints, and advocacy

the role of advocacy is the most relevant distinction between science and law and is central to other distinguishing factors discussed below.

The different approaches to advocacy between law and science are central to the changes imposed or sought by Trump's EPA leadership. One example is the difference in the way that experts are chosen to participate. While at the EPA I was fascinated by the confusion caused by the two different approaches to select scientists used by both EPA and its stakeholders during and subsequent to the regulatory process.[13] On most issues for which there was a reasonably large body of scientific information and of informed scientists, one could imagine that separate polling of each of the perhaps thousands of knowledgeable scientists as to the appropriate numerical standard would lead to a range of numbers that would fit a bell-shaped curve.[14] The EPA's approach, common to consensus processes, has been to carefully select a much smaller number of representative scientists with the relevant breadth and depth of expertise to serve on a committee to review the evidence and through a deliberative process make a numerical recommendation that would approximate the center of the bell-shaped curve. As discussed in more detail below, the reward structure in science leads the committee participants to usually, but not always, come toward a general agreement.[15] In contrast, during the seemingly inevitable lawsuits resulting EPA decisions, an ethical and well-trained lawyer will look for individual scientists at one end of the interpretation spectrum knowing full well that the lawyer on the opposing side will be doing the same at the other end of the spectrum. The fact that an ethical, well-trained journalist seeks to balance their story about any controversial issue by quoting scientists at either end of the curve tends to reinforce the public impression that there are two opposing points of view rather than a reasonable scientific consensus somewhere in the center, or that there is a preponderance of scientists at one end.[16]

B. Ethical Issues

An illustration that law and science can have contrasting ethical obligations relevant to the role of advocacy and pertinent to public health regulation is the Bridgestone Tire incident. As described by New York Times reporter Keith Bradsher, more than 270 people are believed to have died in vehicle accidents caused by a specific tire product

certainly occurs in science, particularly for one's own interpretation of scientific findings.

13. Bernard D. Goldstein, *Risk Assessment and the Interface Between Science and Law*, 14 COLUM. J. ENV'TL. L. 343 (1987).

14. *Id.*

15. *See infra* Part II, Section C and note 27 (discussing deterring factors).

16. Climate change is an example. *See infra* note 32.

defect.[17] This was known to law firms specializing in this type of product defect which sued the tire maker on behalf of their clients.[18] The defect was also known to the similarly-specialized expert consultants that were the plaintiff's experts in the bulk of these cases.[19] However, over a five-year period as the deaths and injuries accumulated, the defect was apparently not reported to the National Highway Transportation Safety Authority (NHTSA).[20] In addition to receiving higher monetary awards for a non-disclosure agreement, the attorneys and consultants did not want to risk NHTSA making a decision that would not support their present and future clients.[21] Dr. Martinez, a trauma physician who formerly headed NHTSA, is quoted as saying, "[i]t's outrageous—I can't say that enough" and "[i]f I saw something was killing my patients and I didn't say anything because that would reduce the demand for my services, I would be putting my benefit over the benefit of my patients and the public, and that would clearly be unethical."[22] But Geoffrey Hazard, Jr., a University of Pennsylvania Law School professor reputed to be an expert on legal ethics, is quoted by Bradsher as saying that the lawyers had not broken any laws or ethical codes: "[t]hey had a civic responsibility the same as you or I do, but they didn't have a legal duty."[23]

C. Metrics of Professional Success

Success in advocacy is a major determinant of success in many, but not all, of the activities performed by the legal profession, whether

17. Keith Bradsher, *S.U.V. Tire Defects Were Known in '96 but Not Reported,* N.Y. TIMES (June 24, 2001), https://www.nytimes.com/2001/06/24/business/suv-tire-defects-were-known-in-96-but-not-reported.html [https://perma.cc/73LX-K9YW].

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.* Similarly, attempts to understand the potential impact on human health of unconventional shale gas drilling have been impeded by the signature of non-disclosure agreements as part of the settlement agreement between the shale gas company and those who believe their health has been affected. One such settlement for $750,000 was disclosed and widely reported. Sophia Pearson, *Range Resources Paid $750,000 in Fracking Accord*, BLOOMBERG NEWS (Mar. 21, 2013), https://www.bloomberg.com/news/articles/2013-03-21/range-resources-paid-750-000-in-fracking-accord. A potential impact on scientific evaluation of a problem of interest to regulatory authorities is that individuals agreeing to non-disclosure awards, or hoping to obtain a significant monetary settlement, would not participate in epidemiological studies thereby lessening the power of such studies to detect any effect. Bernard D. Goldstein, *Flowback*, 33 THE ENV'T F. 25-29 (2016).

through devising successful negotiation strategies or through convincing judges or juries to provide favorable court decisions. Fictional or actual depictions of successful advocacy against the odds are well-known to the public, as well as to the lawyer and to the law student. If accused of malfeasance I am sure that we all would use effectiveness in advocacy as a major criterion for choice of a lawyer. Similarly, the major determinant of success for expert consultants is the ability to help their clients be successful, irrespective of the rights or wrongs of their scientific arguments.[24]

In contrast, in academia or in public scientific organizations the scientist is continually aware that if their study is to be scientifically meaningful, or helpful to their career, other scientists must repeat or attempt to build upon their published study.[25] If the findings of other scientists are not supportive, the academic's reputation will suffer, as will their future success.[26] Advancement in science in academia as well

24. Keith A. Spencer, *The Art of Scientific Deception: How Corporations Use "Mercenary Science" to Evade Regulation*, SALON (Feb. 2, 2020), https://www.salon.com/2020/02/02/the-art-of-scientific-deception-how-corporations-use-mercenary-science-to-evade-regulation/ [https://perma.cc/7SCY-3QTD].

25. For broader discussion of recognition of scientific success, *see infra* note 27.

26. Bibliometric approaches that count citation frequency to evaluate the success of individual scientists have been in use for decades. Journal Impact Factor was the first and is the simplest. It is defined as the yearly average number of scientific literature citations published in the last two years for a specific journal article. Eugene Garfield, *The Clarivate Analytics Impact Factor*, CLARIVATE, https://clarivate.com/webofsciencegroup/essays/impact-factor/ [https://perma.cc/L6VP-8WU8] (originally published in *Current Contents*, June 20, 1994).

Reflecting the central role of these measures in determining scientific merit, more complex bibliometric measures continue to be developed. *See, e.g.,* Jorge E. Hirsch, *An Index to Compare Scientific Research Output Among Similar Scientists*, 102 PROC. NAT'L ACAD. SCI. 1659 (2005). *See also* David van Dijk et al., *Publication Metrics and Success on the Academic Job Market*, CURRENT BIOLOGY R516, R516 (2014) (using the National Library of Medicine's Pub Med to obtain data from over 25,000 published scientists, David van Dijk and his colleagues found that journal impact factor is more important than total number of publications in becoming a principal investigator on a grant). *See also* Charles B. Wright & Nathan L. Vanderford, *What Faculty Hiring Committees Want*, 35 NATURE BIOTECHNOLOGY 885, 886 (2017) (As another example, based on focused interviews of members of hiring committees for faculty in the life sciences, Charles B. Wright and Nathan L. Vanderford reported that grant funding and publication history received the highest scores for recruitment at all faculty levels, and that evidence of national and international recognition were particularly important at the level of associate and full professor). The news staff of the journal *Nature* wrote an article "Do Metrics Matter" based on a survey of its readers and selective interviews. In addition to describing the angst about bibliometrics, they confirmed the major role for publication in high-

as in government science agencies, is based on an interlocking series of factors all of which depend heavily upon peer recognition. Success in publication requires convincing others in their scientific field who are selected by editors to peer review manuscripts. Having one's findings replicated by others will lead to citation. Success in obtaining grants is dependent upon the judgment of peers who review grant proposals for funding agencies.[27] Also important are indicia of national recognition such as being chosen to serve on scientific review committees for the National Academies and for other relevant organizations, including NIH or NSF grant review committees, and, for an environmental scientist, being chosen to serve on advisory committees for such organizations as the EPA, National Science Foundation or National Institute of Environmental Health Sciences (NIEHS).[28] At a significant promotion level, the University Provost or similar decisionmaker often will additionally solicit letters from scientists in the field who are not otherwise directly associated with the candidate.[29] Academic scientists fully recognize that those who are reviewing their work or who are approached for a recommendation about them may well be the ones

ranking journals, citations, and grants. They also quote senior academic administrators about the importance of external letters. Alison Abbott et al., *Do Metrics Matter?*, 465 NATURE 860 (2010).

27. *See How Scientists Are Selected to be Members of a Chartered Review Group*, NAT'L INST. OF HEALTH CTR FOR SCI. REV., https://public.csr.nih.gov/ForReviewers/BecomeAReviewer/CharteredReviewers_[https://perma.cc/D3YE-TT9M] (note the statement that "expertise is the paramount consideration"). For information about NIH study sections that review grant applications, *see Study Sections*, NAT'L INST. OF HEALTH CTR FOR SCI. REV., https://public.csr.nih.gov/StudySections [https://perma.cc/D3YE-TT9M].

28. Being chosen to serve on respected scientific committees reflects the ability to publish in the area of committee concern, just another of the interlocking metrics of success. *See generally* NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS (2005), https://www.nationalacademies.org/_cache_5e69/content/4884885770000079.pdf [https://perma.cc/Z498-G73T]; *see also* Harry P. Selker et al., *CTSA Consortium Consensus Scientific Review Committee (SRC) Working Group Report on the SRC Processes*, 8 CLINICAL AND TRANSLATIONAL SCI. 623 (2015).

29. For the importance of external letters in promotions, see, for example, Robert E. Baker, *Tenure and Promotion Guidelines: External Reviewer Qualification and Selection Process, College of Education and Human Development*, GEO. MASON UNIV. (May, 2020), https://cehd.gmu.edu/assets/docs/faculty/tenurepromotion/ExternalReviewerQualificationandSelectionProcess.pdf [https://perma.cc/D97X-DYFW]. Note that the promotion package is not complete until the dean's office receives at least as many letters from outside experts chosen by the dean as it has from experts recommended by the candidate. *Id.* Also specified is that these external experts must be narrowly in the same field as the candidate, thus highly likely to be aware of the candidate's stature. *Id.*

who have observed their fidelity to the tenets of science while serving with them on any of these committees, including those for EPA. Based on these considerations, academic scientists are well aware that getting the science wrong, or being judged to be other than a dispassionate scientist, can have significant adverse career consequences.

In contrast, much of the scientific consultant industry who are specifically hired to support an industry's desire to lessen the impact of the EPA's science-based regulatory activities performs like legal advocates. Their success is based on their ability to obtain and retain clients, which in turn is based in large part on the likelihood that they can devise ways to help their clients counter the scientific basis for EPA's unwanted regulatory activities.

Current EPA leadership has turned this distinction between academic scientists and industry consultants on its head. Based on their assertion that academic scientists who receive funding from EPA must be inherently biased in favor of EPA's regulatory positions, Trump's EPA leadership temporarily banned such scientists from serving as advisors.[30] The EPA administrator's office became more involved in advisory committee selection processes, with the result that SAB and CASAC academic scientists were replaced by consultants.[31]

30. This was overturned in the U.S. District Court for the Southern District of New York in *Natural Resources Defense Council, Inc. v U.S. Environmental Protection Agency* 19cv5174 (DLC) (Feb. 20, 2020). Note that EPA's funding of external scientists is through an external peer review process modeled largely on that of NIH, with the addition of a scoring by EPA staff for program relevance. Review of EPA's external scientific processes by the NAS has generally been highly positive. NAT'L ACADEMIES OF SCIENCES, ENG'G, AND MED., A REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S SCIENCE TO ACHIEVE RESULTS RESEARCH PROGRAM 3 (2017).

31. An analysis by the Government Accountability Office (GAO) compared the source of SAB committee members at the end of the George W. Bush administration and two periods during the Obama administration with that of the Trump Administration. The first three time periods were remarkably similar in the source of SAB members, including having no one who came from the consultant industry. But the Trump administration decreased the number from academia by about a third, increased the number of industry representatives and chose five consultants. U.S. GOV'T ACCOUNTABILITY OFF., GAO-19-280, EPA ADVISORY COMMITTEES: IMPROVEMENTS NEEDED FOR THE MEMBER APPOINTMENT PROCESS (2019). *See* Marianne Lavelle, *Trump's EPA Skipped Ethics Reviews for Several New Advisers, Government Watchdog Group Finds*, INSIDE CLIMATE NEWS (July 26, 2019), https://insideclimatenews.org/news/16072019/gao-epa-ethics-reviews-science-advisory-board-industry-consultants-academics-removed-trump-pruitt/ [https://perma.cc/DXQ7-C4NZ]; Robyn Wilson, *Trump's EPA Replaced Scientists with Industry Advisors Under the Guise of 'Conflicts of Interest,'* THE HILL (Feb. 25, 2018, 7:30 AM), https://thehill.com/opinion/energy-environment/375308-trumps-epa-replaced-scientists-with-industry-advisors-under-the [https://perma.cc/BCT4-SFWH].

D. The Role of the Literature

A pervasive difference between the practice of science and that of law is based on how practitioners have been trained to utilize the relevant literature. Imagine a law student about to participate in a moot court in which their skills as an advocate will be tested. Also imagine the student's roommate, a graduate student in the sciences, is to present a thesis proposal. Similarities are evident. Both will be nervous. Their audiences will contain professors and peers whom the students desire to impress and who may well have some say about their career trajectory. Both will have been given advice about professional conduct, ranging from how to organize their presentations to what clothes to wear. Importantly, both students will have worked hard to master the broad literature pertinent to their specific presentations, whether it be relevant judicial decisions or the peer-reviewed scientific literature. But it is in the presentation of this literature that a significant difference between the training of the two students will become clear.

Suppose there is a somewhat obscure published judicial decision potentially adverse to the position being advocated by the law student. While our law student must be prepared to provide a counterargument should this judicial decision be brought up by their opponent, the student would likely lose points if they were to be the one to first refer to this decision as their opponent otherwise may not know about or recognize its relevance. In contrast, our budding scientist faced with the existence of a similarly obscure peer-reviewed scientific publication that arguably would refute their thesis, would need to include this publication in the presentation at the risk of being perceived as incompetent for not finding the publication, or unethical for not discussing it.

Senator Edmund Muskie is reputed to have asked for a one-handed scientist when chairing a Senate hearing at which the head of an NAS Committee presented with equal emphasis the scientific findings that on the one hand supported or on the other hand opposed allowing supersonic transport to fly over the United States.[32] While frustrating to Senator Muskie, the NAS Committee head, in using both hands, was keeping to the norms of science.

Approaching the scientific literature as something to be manipulated to support an advocacy position is also at play in the

32. Ira Flatow, *Truth, Deception, and the Myth of the One-Handed Scientist*, THE HUMANIST (Dec. 11, 2012), https://thehumanist.com/magazine/november-december-2012/features/truth-deception-and-the-myth-of-the-one-handed-scientist [https://perma.cc/9TWL-TBBF]. In teaching potential expert scientific witnesses, I point out that the standard formulation of "the whole truth and nothing but the truth," in a legal proceeding really means the "whole truth and nothing but the truth as defined by the specific questions asked by the lawyers."

proposed "Transparency in Regulatory Science" rule which is discussed in Section IIIB below.

E. Going Up Alleys to See if They Are Blind vs. Don't Ask Questions Unless You Know the Answer

Scientific research has been characterized as "going up alleys to see if the alleys are blind."[33] In contrast, lawyers are taught that in a courtroom it is not wise to ask questions whose answers may be unforeseen.[34]

The Trump Administration's reluctance to ask questions about the impacts of climate change is well documented.[35] One can characterize some of the attempts of climate deniers as intentionally going up alleys that are known to be blind.[36] This follows the playbook of the tobacco industry to manufacture doubt.[37] Cutting back on climate change research at the EPA is particularly problematic, as the appropriate

33. The quote is attributed to Barstow Bates. *Research is the Process of Going Up Alleys to See if They're Blind,* QUOTE INVESTIGATOR, https://quoteinvestigator.com/2016/03/28/alleys/ [https://perma.cc/WD2U-6MPU].

34. *See e.g.*, Gerry Oginski, *On Cross-Examination at Trial Why Don't You Ask a Question If You Don't Know the Answer to It?,* N.Y. MED. MALPRACTICE & ACCIDENT TRIAL L., https://www.oginski-law.com/faqs/on-cross-examination-at-trial-why-don-t-you-ask-a-question-if-you-don-t-know-the-answer-to-it-.cfm [https://perma.cc/LT5H-ZMUC].

35. *See, e.g.*, Juliet Ellperin, *EPA Now Requires Political Aide's Sign-off for Agency Awards, Grant Applications*, WASH. POST (Sept. 4, 2017), https://www.washingtonpost.com/politics/epa-now-requires-political-aides-sign-off-for-agency-awards-grant-applications/2017/09/04/2fd707a0-88fd-11e7-a94f-3139abce39f5_story.html [https://perma.cc/9AWC-QB8A] (noting that John Konkus, an EPA political appointee, was reportedly given the job of eliminating EPA funding from all studies related to climate change).

36. For example, deniers of a major role for humans claim that climate change is due to naturally occurring temperature cycles or other ongoing phenomena related to solar activity which ought to be investigated. *See, e.g.,* INT'L CLIMATE SCI. COALITION, https://www.climatescienceinternational.org/ [https://perma.cc/FF8G-VWWZ]. The goal is to inappropriately manufacture doubt about our rapidly occurring current anthropogenic climate changes, but the fact is that global climate change is occurring far too quickly to be due to natural cycles. *See, e.g.*, *How is Today's Warming Different From the Past?,* NASA EARTH OBSERVATORY (June 3, 2010), https://earthobservatory.nasa.gov/features/GlobalWarming/page3.php [https://perma.cc/6QPQ-PBXZ].

37. *See infra* Section IV for Scott Pruitt's attempt to develop a red team, blue team approach to evaluating global climate change. A book that more generally considers the role of manufacturing doubt is NAOMI ORESKES & ERIK M. CONWAY, MERCHANTS OF DOUBT, ch. 1 (Bloomsbury Press 2010).

focus for the Agency's research activities should be on answering questions asked by the public and by policymakers about the personal and community impacts of climate change, an area that in my view has not been sufficiently emphasized.[38]

I discuss below the EPA's new rule to "Strengthen Transparency in Regulatory Science" as the misapplication of scientific norms that are fully appropriate for the Food and Drug Administration (FDA) but not to the EPA. It could also more cynically be considered as an attempt to limit the availability of science through not allowing peer-reviewed literature to be considered.[39]

1. COVID-19 and NAAQS Standards as an Example of Don't Ask the Question

More recently, Administrator Wheeler has used the "don't ask any questions" approach to avoid considering the role of the COVID-19 pandemic in margin of safety considerations for the new particulate and ozone standards.[40] The NAAQS standard-setting process is a superb example of incorporating public health concepts into setting regulations. The formulation in the Clean Air Act is that the standard should be set to protect public health with an adequate margin of safety.

Almost uniquely among public health bills, Congress has spelled out, and the courts affirmed, directions relative to including an "adequate margin of safety."[41] Congress appears to have been prescient

38. *See Climate Change Research,* EPA, *https://www.epa.gov/climate-research* [https://perma.cc/GS4V-ZYWU] (detailing EPA's acceptance of the role of studying the health and environmental impact of climate change). *See also* Bernard D. Goldstein & Michael R. Greenberg, *Global Climate Change and the "So What" Issue: Reversing the Impact of Donald Trump*, 108 AMER. J. PUB. HEALTH S78 (2018); Nick Watts et al., *Health and Climate Change: Policy Responses to Protect Public Health*, 386 THE LANCET 1861 (2015); *see generally*, Jonathon A. Patz et al., *Climate Change: Challenges and Opportunities for Global Health*, 312 J. AMER. MED. ASSN. 1565 (2014).

39. *See infra* Section III.B.

40. Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 82,684 (Dec. 18, 2020) (to be codified at 40 C.F.R. pt. 50); Review of the Ozone National Ambient Air Quality Standards, 49 Fed. Reg. 49,830 (Aug. 14, 2020) (to be codified at 40 C.F.R. pt. 50).

41. The term "adequate margin of safety" is used 41 times in EPA's 65-page particulate matter standard federal register document. Subsequent cites are to the specific page in EPA's Federal Register notice promulgating standards for particulate matter (*see* Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg.). The cited pages also contain citations to key judicial decisions related to the margin of safety. I quote from EPA's Federal Register notice as readers appropriately may question whether I have the background to interpret court decisions or am interpreting them differently than EPA does. The language about the margin of safety in the present Federal Register notice

in regards to our current COVID-19 pandemic. It is clearly telling the Agency to consider whether there are grounds for greater stringency than just the science that CASAC has considered in its recommendation. The specific language, as quoted from EPA's Federal Register notice for the NAAQS for particulates, is that the margin of safety should: "address uncertainties associated with inconclusive scientific and technical information"[42] and "provide a reasonable degree of protection against hazards that research has not yet identified,"[43] and that the EPA administrator should set the margin of safety even if "the risk is not precisely identified as to nature or degree."[44] Further, the Congressional language goes beyond just leaving the decision about the margin of safety to the discretion of the Administrator and specifies three factors that the Administrator should consider in setting the margin of safety: "[i]n addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s), and the kind and degree of uncertainties."[45]

Considering these three factors leads to the following conclusions about the potential interaction between particulates or ozone and COVID-19. "Nature and severity" includes death and debilitating disease. The "size of the sensitive population" is at least in the many millions. As to "the kind and degree of uncertainties," we know that COVID-19 shares with PM 2.5 and ozone having greater effects in those with pre-existing lung and heart disease., and current evidence points to COVID-19 causing persistent lung and heart damage, even in

differs little from that of President Reagan's 1987 particulate standard. Revisions to the National Ambient Air Quality Standards for Particulate Matter, 52 Fed. Reg. 24,634, at 24,635 (July 1, 1987) (to be codified at 40 C.F.R. pt. 50).

42. Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. at 82,686, 82,714. The references given at 82,686 is to Lead Industries Ass'n v. EPA, 647 F.2d 1130, 1154 (D.C. Cir. 1980); American Petroleum Institute v. Costle, 665 F.2d at 1186; Coalition of Battery Recyclers Ass'n v. EPA, 604 F.3d 613, 617–18 (D.C. Cir. 2010); Mississippi v. EPA, 744 F.3d 1334, 1353 (D.C. Cir. 2013). The language is similar at 82,714 without the references.

43. Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. at 82,686, 82,714. The two quotes are coupled similarly at 82,686 and 82,714.

44. *Id.* at 82,686. The full quote is "Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree."

45. *Id.* (citing Lead Industries Ass'n, 647 F.2d at 1161–62; Mississippi, 744 F.3d at 1353).

individuals with milder cases.[46] As a physician with experience in pulmonary medicine, I find it almost inconceivable that a virus which so viciously attacks the heart and lungs will not make things worse when combined with present or past exposure to a pollutant that also attacks the heart and lungs, and vice versa. [47]

Further, the job of considering the margin of safety is given to the Administrator, not to CASAC.[48] CASAC made its recommendation before there was knowledge about the pandemic, but Mr. Wheeler's particulate standards were promulgated more than nine months after President Trump's declaration of a pandemic.

Mr. Wheeler was asked about COVID-19 in a newspaper interview and responded by saying that there are uncertainties about the number of deaths.[49] He is right in terms of the level of scientific proof that

46. For a review of persistent disease following recovery from acute COVID-19, *see* Denyse D. Lutchmansingh, et al., *A Clinic Blueprint for Post-Coronavirus Disease*, 159 CHEST 2021 949 (2021). A study in Belgium of non-hospitalized patients nine months after the pandemic began showed persistent respiratory symptoms. Roy Meys et al., *Generic and Respiratory-Specific Quality of Life in Non-Hospitalized Patients with COVID-19*, 9 J. CLINICAL MED. 3993 (2020).

47. Bernard Goldstein, *EPA Must Consider COVID-19 In Setting Air Pollution Standards*, THE HILL (June 28, 2020), https://thehill.com/opinion/energy-environment/504908-epa-must-consider-covid-19-when-setting-air-pollutant-standards [https://perma.cc/L4KZ-SVYQ]. Note that when this piece was written in June 2020 there was already sufficient X-ray evidence of lung scarring to predict longer term effects, so Mr. Wheeler had more than ample time to take residual lung damage into account in the margin of safety. There is one mention of COVID-19 – as the reason for closing the EPA public docket library (at 82,864). Clearly, Mr. Wheeler knows about COVID-19, as EPA has used it as a rationale to decrease oversight of potentially-polluting industries (Susan Bodine, Memorandum: COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program. March 26, 2020).

48. Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. at 82,686.

49. Michel Wilner, *At EPA, Coronavirus Disrupts Research and Raises Questions about Air Quality Impact*, PITTSBURGH POST-GAZETTE (Aug. 9, 2020), https://www.post-gazette.com/news/insight/2020/08/09/At-EPA-coronavirus-disrupts-research-and-raises-questions-over-air-quality-impact/stories/202008090029 [https://perma.cc/9A5Z-SPP5]; *see also* EPA, EPA RESPONSE TO SIGNIFICANT COMMENTS ON THE PROPOSED NATIONAL AMBIENT AIR QUALITY STANDARD FOR PARTICULATE MATTER (Apr. 30, 2020), https://www.epa.gov/sites/production/files/2020-12/documents/pm_naaqs_response_to_comments_final.pdf [https://perma.cc/7R6B-LXJT] (EPA's official response to comments it received about COVID-19 is: "[t]here are many variables related to COVID-19 health outcomes, and, as COVID-19 is an emerging disease, there are still many unknowns. Understanding the links between air pollution exposure and COVID outcomes is a complicated process that will take many years. The research in this area is new and emerging . . . "

CASAC would need when it considers the likelihood of adverse effects at given pollutant levels.[50] But his answer is not at all pertinent to the rationale for the Clean Air Act requirement that a NAAQS standard have an adequate margin of safety as described above. He could have asked EPA scientists, or CASAC,[51] or the NAS, or assembled an expert committee to look at COVID-19 in relation to the margin of safety for the particulate and ozone standards. But he chose the lawyerly approach of not asking a question whose answer does not help his advocacy position.

F. Other Differences: Temporal Factors, the Choice of Judge and Jury, and the Admissibility of Evidence

Temporal factors also play a role in the difference between how lawyers and scientists act. Sheila Jasanoff, in her carefully considered distinction between regulatory science and research science, has contrasted the temporal aspects of regulatory deadlines and political pressures with the open-ended nature of research science.[52] A legal process in a court of law, or an effort in a regulatory agency working to meet a judicial or Congressional deadline, must be based on information available at the time the decision is made. In contrast, a scientist operates with the constant recognition that it is likely the truth eventually will be known, and that when it is there could be adverse career consequences if it turns out that the scientist was wrong. It is the rare scientific paper that does not have a temporizing statement

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and "[t]he EPA will consider these new studies for inclusion in the air quality criteria for the next PM NAAQS review." The implication of this statement is that EPA has not read its own FR notice about what it is to consider in setting the standard).

50. *See* Paul J. Villeneuve & Mark S. Goldberg, *Methodological Considerations for Epidemiological Studies of Air Pollution and the SARS and COVID-19 Coronavirus Outbreaks*, 128 ENVTL. HEALTH PERSP. 1, 11 (Sept. 2020) (a methodological critique that highly questioned the validity of then existing published studies that had suggested an association between COVID-19 and air pollution).

51. Again quoting the language from the FR notice for the new particulate standard, EPA notes that beyond advice on the appropriate level for the standard, CASAC is given other advisory functions by statute including "(i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards." Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. at 82686. Mr. Wheeler may not have been willing to bring the issue to CASAC as Mark Frampton, a pulmonary physician, who would be by far the most knowledgeable CASAC member about the potential interaction between COVID-19 and air pollutants, was among the minority of CASAC members who argued before the pandemic for a more stringent long-term particulate standard.

52. THE FIFTH BRANCH, *supra* note 1, at 82.

pointing out that more research is needed to confirm the findings.[53] This leads scientists on consensus committees to try to huddle up with other committee scientists, thus facilitating achieving a consensus opinion.[54]

Yet another difference which appears to be pertinent to current EPA leadership's activities is that opposing counselors routinely maneuver to have a judicial venue or a judge whose legal philosophy is consonant with their advocacy position.[55] When juries are involved, it is also the lawyer's obligation to do their best to pick jury members whose life experiences and viewpoints will likely be favorable to their client.[56] In contrast, an organization seeking to understand the consensus position of the scientific community should pick those with the greatest expertise in the pertinent scientific disciplines. When policy considerations call for representation of opposing sides, it is the responsibility of the organization to ensure that balance occurs. Without such balance, a consensus position that reflects the current understanding of the scientific community is unlikely. Further, it is likely that the taint of bias will affect the credibility of the committee's recommendations.

Rules of evidence also govern the admissibility of scientific evidence into court cases. Switching from the *Frye* to the *Daubert* tests at the federal level and in many states, has been accompanied by giving the judge a larger role in deciding which expert evidence in considered.[57]

53. That research leads to further research is sufficiently implicit in the scientific method that the unqualified statement that more research is needed has been banned by the British Medical Journal. Fiona Godlee, *More research is needed—but what type?*, THEBMJ (Aug. 25, 2010), https://www.bmj.com/content/341/bmj.c4662 [https://perma.cc/GMN5-G3XV]. In a website aimed at graduate students, a researcher in New Zealand has said that the phrase more research is needed "is the final sentiment of an overwhelming proportion of journal articles, and is repeated so often at academic conferences that I've been tempted to sell it on t-shirts." Anaise Irvine, *More Research is Needed*, THESISLINK (Mar. 29, 2017), https://thesislink.aut.ac.nz/?p=5179 [https://perma.cc/PX2B-ZDNV].

54. *See supra* note 26. Other reasons for moving toward the middle of the curve include the deference we tend to give to experts in other disciplines than our own when, as is usual for EPA, the decision is based on science from multiple disciplines. Further, the deliberative committee approaches that allow discussion of the science tend to lead to consensus.

55. For a Supreme Court decision on venue shopping related to patent law, see TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514 (2017).

56. Clarence Darrow, *How to Pick a Jury*, CLARENCE SEWARD DARROW (1936), http://law2.umkc.edu/faculty/projects/ftrials/DAR_JURY.HTM [https://perma.cc/3BZ2-UNVK].

57. *See* Angelica Cappellino, *Daubert vs. Frye: Navigating the Standards of Admissibility for Expert Testimony*, EXPERT INST. (July 24, 2020), https://www.expertinstitute.com/resources/insights/daubert-vs-frye-navigating-the-standards-of-admissibility-for-expert-

The earlier *Frye* test, derived from a Supreme Court decision related to the validity of lie detectors, was primarily based on considering whether an expert's testimony was in keeping with the consensus of the scientific community.[58] In the newer *Daubert* test, derived from the toxic tort issue of whether a commonly prescribed "morning sickness" pill was responsible for fetal abnormalities, the focus switched to whether the appropriate scientific methodology was used in the scientific literature on which the expert opinion was based – that is, how the expert got to the opinion.[59] This provides more focus on the individual studies, in essence leading the judge to be given a much more active role in deciding whether science is admissible. The recently promulgated "Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information (Transparency Rule)," with its wide-ranging and poorly-defined authority given to the EPA Administrator to select or deselect individual studies, can be viewed as providing a similar gatekeeper role, with the Administrator in the role of a not-impartial deciding judge.[60]

II. ORGANIZATIONAL AND SCIENTIFIC ISSUES RELATED TO THE SCIENCE/POLICY INTERFACE IN THE EPA

A. Comparison with Other Federal Agencies: Organizational Issues

Comparing EPA with other science-based regulatory agencies highlights two issues related to the interface between science and policy at EPA. One is that the EPA was not founded by an act of Congress. The second is its inclusion of an in-house scientific organization at an organizational level equivalent to its policy offices.

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testimony/#:~:text=Generally%2C%20the%20difference%20between%20the,list%20of%20factors%20to%20consider [https://perma.cc/76BN-CHAC]; *see also* Daubert v. Merrell Dow Pharm. Inc., 509 U.S. 579 (1999); and *see Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

58. *Frye*, 293 F. at 1014.

59. The Federal Rules of Evidence Section 702, derived from the *Daubert* decision and since amended for clarity, states that a qualified expert witness may testify in the form of an opinion or otherwise if: (a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) The testimony is based on sufficient facts or data; (c) The testimony is the product of reliable principles and methods; and (d) The expert has reliably applied the principles and methods to the facts of the case. FED. R. EVID. 702. Each of these four components has words or phrases that can be variously defined and applied (e.g., "reliable," "sufficient," "reliably applied").

60. Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information, 86 Fed. Reg. 470 (Jan. 6, 2021) (to be codified at 40 C.F.R. pt. 30).

When it was formed in 1970, the decision that the EPA should have a scientific arm may well have been based on inertia. To establish the EPA, President Nixon amalgamated existing components of different federal agencies.[61] When the dust settled, of the 84 sites that were now the "property" of the new agency, half were laboratory facilities.[62] Congress did agree to the EPA's formation and signaled approval of the EPA having an in-house science program by funding a new research facility in Cincinnati.[63] But, in contrast to the FDA, the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission and other similar agencies, the EPA does not have a founding act that in essence provides it a Congressionally-mandated mission statement.[64]

The evidence that this would have been a bad idea, at least until now, comes from an experiment unintentionally devised by Congress fifty years ago. The EPA and OSHA were both formed in 1970. The EPA began with its own R&D program, while OSHA, as part of the Department of Labor, was established with a separate R&D program in a different federal agency (The National Institute of Occupational Safety and Health, which is part of the Centers for Disease Control in the Department of Health and Human Services).[65] Having different intra-agency, OMB, and congressional oversight and budgetary review processes, OSHA and NIOSH sometimes do not appear to be well-coordinated.[66] Early in the EPA's history, the salience of the argument

61. Special Message from the President to Cong. about Reorganization Plan No. 3 of 1970 (July 9, 1970) https://archive.epa.gov/epa/aboutepa/reorganization-plan-no-3-1970.html [https://perma.cc/7CCU-DAB5].

62. Dennis C. Williams, *Why Are Our Regional Offices and Labs Located Where They Are? A Historical Perspective on Siting*, EPA HIST. (March 1993), https://www.epa.gov/history/why-are-our-regional-offices-and-labs-located-where-they-are-historical-perspective-siting [https://perma.cc/9V7U-XYSB].

63. *Id.* Among the founding documents leading to the formation of EPA, I can find none that specifically raised the question of whether EPA should have its own science and technology function.

64. Bernard D. Goldstein, *Science and an EPA Mission Statement*, 101 ENV'T HEALTH PERSP. 466–67 (1993).

65. Occupational Safety and Health Act of 1970 § 22, 29 U.S.C. 671; *About the Office of Research and Development (ORD)*, U.S. ENVTL. PROT. AGENCY, https://www.epa.gov/aboutepa/about-office-research-and-development-ord [https://perma.cc/5C35-PX24].

66. For example, many of OSHA's enforceable standards are substantially different from the standards formally recommended by NIOSH. As just one of many examples, the OSHA enforceable limit for toluene is 200 parts per million (ppm; 8 hour average), while NIOSH has recommended that the limit should be 100 ppm (10 hour average). *See ToxFAQs for Toluene*, AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, https://www.atsdr.cdc.gov/Toxfaqs/TF.asp?id=160&tid=29

that the EPA's science could become biased because of internal political interference led Congress to direct the formation of scientific advisory processes which incorporated the external scientific community, notably the Clean Air Scientific Advisory Committee (CASAC) as part of the 1977 Amendments to the Clean Air Act, and the upgrading of the Science Advisory Board (SAB) following passage of the EPA Science Advisory Board Reform Act of 1978.[67] The number of CASAC committee members were specified, and the committee was given an important role in the activities leading to the setting of National Ambient Air Quality Standards (NAAQS). The SAB reform assured the committee's independence in providing advice, including its involvement in any major EPA scientific issue.[68] If these aspects of the EPA were to be dismantled, it might be worth considering removing ORD from virtual captivity by the EPA's political concerns and placing it within NIEHS, the Centers for Disease Control, or other governmental organizations.

B. Comparison with Other Federal Agencies: Scientific Issues

I have chosen to consider the EPA's new "Transparency Rule," at least in part, as a misunderstanding of the applicability to the EPA of the scientific norms that govern how the FDA makes decisions about allowing the marketing of clinical interventions. I argue that these FDA rules are specific to the FDA and not generalizable to the EPA. The FDA, like the EPA, is a complex organization with different types of organizations to regulate and a variety of regulatory tools to use. The FDA has a strong advisory process, with many major decisions being formally recommended by panels of external scientists with a large variety of disciplinary expertise.[69] One source of confusion, or of

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[https://perma.cc/48XB-WE5P]. As EPA Assistant Administrator (AA) for the Office of Research and Development, I could fully expect to present my budget proposal for the forthcoming year to the same oversight groups who would also hear from other EPA AAs who were heading EPA policy offices. These oversight groups were within EPA, at the White House Office of Management and Budget, and within Congress. I could be certain that at every level each of these AAs would be asked whether ORD's current and planned activities were supportive of policy office goals. The coordinating role of oversight processes is less likely to occur when the organizations report so differently within the federal structure. The geographical separation between OSHA and NIOSH also precludes the informal "elevator conversations" that at EPA are effective in communicating and coordinating science and policy, although OSHA and NIOSH have worked hard to successfully bridge the distance between Washington DC and Morgantown, WV.

67. Environmental Research, Development, and Demonstration Authorization Act (ERDDAA). 42 U.S.C. § 4365 (2018).

68. *See* 42 U.S.C. § 7409(d)(2) (2018).

69. The language specifying the expertise that is desired for the core of FDA Science Advisory Board of 21 voting members lists 19 different areas

intentional obfuscation,[70] has led to the generalization of transparency processes which are appropriate to one part of FDA's mission, that of approving new drugs, but not to EPA's mission of setting standards to protect human health.

A longstanding desire of those opposed to the EPA's use of science for regulations that affect the fossil fuel industry is to require that the EPA only rely on studies for which all of the data are available for anyone to reanalyze.[71] This began over twenty years ago and has proceeded with many iterations and many names, including "secret science," "The HONEST Act," and most recently "Transparency in Regulatory Science."[72] Wagner has given a good summary of the history of this endeavor, and has pointed out that it is analogous to efforts under *Daubert* to disqualify science in tort proceedings.[73]

Scientific transparency sounds good. The FDA has led a major push for transparency in studies presented for regulatory agency decisions. This makes sense for the FDA. The approach required for investigating a new therapeutic agent is a randomized double-blind study in which neither the volunteer patient nor the physician knows whether the

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pertinent to FDA. Rakesh Raghuwanshi, *Science Board to the Food and Drug Administration*, FDA (Apr. 23, 2019), https://www.fda.gov/advisory-committees/committees-and-meeting-materials/science-board-food-and-drug-administration [https://perma.cc/528F-4NVT].

70. While likely to be a misunderstanding for many to whom transparency seems a nominal good, in November 2019, David Michaels and I concluded that the obfuscation is likely to be intentional on the part of EPA Administrator Wheeler. *See* David Michaels & Bernard D. Goldstein, *How EPA Director Andrew Wheeler is Using Scientific Transparency as a Weapon*, SALON (Nov. 25, 2019), https://www.salon.com/2019/11/24/how-epa-director-andrew-wheeler-is-using-scientific-transparency-as-a-weapon/ [https://perma.cc/L7LA-HU7D].

71. *See infra* note 72.

72. *See e.g.*, Bernard Goldstein, *Why the EPA's Secret Science Proposal Alarms Public Health Experts*, THE CONVERSATION (May 18, 2018), http://theconversation.com/why-the-epas-secret-science-proposal-alarms-public-health-experts-96000 [https://perma.cc/XYN8-BWR4]. *See also Strengthening Transparency or Silencing Science? The Future of Science in EPA Rulemaking: Hearing Before the H. Comm. on Sci., Space, & Tech.*, 116th Cong. 47 (2019) (statement of Linda Birnbaum, former NIEHS Director); GOLDMAN & DOMINICI, *supra* note 6; Joel Schwartz, *"Transparency" as Mask? The EPA's Proposed Rule on Scientific Data*, 379 NEW ENG. J. MED 1496, 1497 (2018); particularly informative is a study showing how little anyone wants the underlying data for EPA regulations by Lynn R. Goldman & Ellen K. Silbergeld, *Assuring Access to Data for Chemical Evaluations*, 121 ENVTL. HEALTH PERSP. 149 (2013).

73. WAGNER, *supra* note 1, at 101–02.

patient is receiving the drug or the placebo.[74] This approach is ethically justified because the volunteer who suffers from the disease may benefit if assigned to receive the drug rather than the placebo, but would not be ethical for comparing the adverse effects of a pollutant with that of a placebo.[75] Further, the circumstances of the drug trial, including the cost and the proprietary nature of the drug, usually limit major clinical trials to at most a few relatively expensive large studies funded and performed under the direction of the company.[76] Past experience with misunderstood or misrepresented drug studies has justified the FDA and similar agencies in other countries to require complete transparency, including advanced public notice of the study.[77] In contrast, for environmental health studies only in rare circumstances can one ethically ask a volunteer to be exposed to a potentially harmful pollutant to test its toxicity.[78]

74. Michael D. Green, et al., *Reference Guide on Epidemiology,* REFERENCE MANUAL ON SCI. EVIDENCE 555–56 (National Academies Press 3d ed., 2011).

75. Two issues are at play here. It is difficult to imagine that a researcher could enlist enough volunteers willing to be exposed to a potentially toxic chemical for a randomized double-blind study to have enough statistical power to find out if the chemical produces an adverse effect. Secondly, on ethical grounds, an Institutional Review Board (IRB), whose approval is required for any human study, would be highly unlikely to approve the study in the absence of any potential benefit to the volunteer.

76. The value and challenges of randomized clinical trials are evident to anyone following news accounts of the development of treatments and vaccines for COVID-19. For vaccine development from 1998–2009, *Pronker et al.* have estimated a market entry success rate of 6% at an average investment cost of $200-900 million. Esther S. Pronker, et al., *Risk in Vaccine Research and Development Quantified*, 8 PLOS ONE 1 (2013).

77. To be published in major journals or considered by the FDA, the clinical trial is required to be posted in advance on an approved transparent web site available to the public. For the decision by the editors of major journals not to accept for publication any non-registered manuscript describing a clinical trial, see Catherine De Angelis et al., *Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors.* 351 NEW ENG. J. MED., 1250, 1250–51 (2004). For the NIH clinical trials registry see *ClinicalTrials.gov,* U.S. NAT'L LIBR. OF MED., https://www.clinicaltrials.gov/ [https://perma.cc/7UGB-Z2JF] (providing a database of privately and publicly funded clinical studies conducted around the world). The background for this development included the perception that drug companies were selective in the studies they submitted to the government.

78. The National Academies of Science, Engineering and Medicine provide a brief description of the findings of an NAS Committee asked to review controlled human exposure studies. *See New Report Finds EPA's Controlled Human Exposure Studies of Air Pollution Are Warranted*, NAT'L ACADS. PRESS (Mar. 28, 2017), https://www.nationalacademies.org/news/2017/03/new-report-finds-

The inherent inability of environmental epidemiology to achieve the gold standard of a randomized double-blind control trial, the greater uncertainties related to measuring the exposure of individuals, and the usual lack of a one-to-one relationship between a pollutant and a disease[79] means that there is a much greater likelihood of some unforeseen confounding in any one study.[80] For example, if a pollutant increases the extent of asthma attacks in the general population by twenty percent, this impact may be more than sufficient to trigger EPA regulation. But asthma attacks have many causes, including different local sources of pollen, personal stress levels, respiratory infections, indoor allergens, and other triggers.[81] Accordingly, any one study could be confounded by variations in other causes of asthma. Without randomization to most effectively control for these potential confounding factors, the EPA has relied on reviewing the breadth and depth of all of the relevant studies, using peer review as a valuable first screen. In essence, there is a web of science that must be evaluated for informed regulatory decision-making. Not surprisingly, the links in this web will be of different strength, depending upon the specifics of the study and its relevance to the decision under consideration.[82] EPA's

epas-controlled-human-exposure-studies-of-air-pollution-are-warranted [https://perma.cc/MJ8G-ZMPF].

79. A rare exception to the general rule that pollutants cause effects that have other causes as well is mesothelioma, which serves as a signature disease of asbestos exposure. Curtis W. Noonan, *Environmental asbestos exposure and risk of mesothelioma,* 5 ANNALS OF TRANSLATIONAL MED. 234 (2017) ("Asbestos exposure is the only established risk factor known to be causally related to mesothelioma."). Another important difference is that in the drug trial the dose of the agent to the individual is relatively rigidly controlled. In contrast, studies of exposure to environmental agents often require extrapolation from indirect measurements, such as regional pollutant levels, or estimates based on whether a community is upwind or downwind from an overturned tanker car. See *Exposure Assessment Tools by Approaches – Indirect Estimation*, EPA, https://www.epa.gov/expobox/exposure-assessment-tools-approaches-indirect-estimation-scenario-evaluation [https://perma.cc/4YR5-RS8P].

80. *See* GREEN, *supra* note 74, at 563–64.

81. *Common Asthma Triggers*, CDC (Aug. 21, 2020), https://www.cdc.gov/asthma/triggers.html [https://perma.cc/QJF3-5L2X].

82. For example, consider two studies showing a similar positive relation between summertime ozone levels and emergency room visits for asthma in different communities. In one study, community pollen levels are available and the investigators have shown that the pollen levels are unrelated to asthma incidence. In the second, community pollen counts are not available. Although a weaker study because it cannot evaluate pollen as a possible confounder, the second study strengthens the overall web of science supporting the reported association (e.g., the observed association between ozone and asthma attacks could have been negative rather than positive). The concern is that an EPA administrator would discard the first study and focus on the weakness in the second study.

revised transparency proposal, allowing the Administrator to pick and choose among the studies to be considered, raises the possibility of preferential choice of studies aimed at biasing the outcome.[83]

In interpreting the web of studies, one must also consider biological plausibility. The EPA almost uniformly considers biological plausibility in its scientific analyses underlying regulation.[84] For example, there was much doubt about initial findings of cardiovascular effects of particulates reported in epidemiological and animal toxicology studies until mechanistic pathways between lung and heart were clarified. [85]

Perhaps the real goal of the "transparency" proposal is to sufficiently narrow the number of published papers considered in the EPA's scientific analysis so that the technique of discrediting the opponent's science by "corpuscularization" can come into play. This term, coined by Thomas McGarity, refers to the goal of discrediting every one of the scientific papers used by opposing advocates by finding at least a small blemish in each, thereby claiming that each paper

83. The EPA SAB, when it finally was allowed to weigh in on the full proposal, expressed concern about the definitional issues. Michael Honeycutt, *Subject: Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled Strengthening Transparency in Regulatory Science*, OFF. OF THE ADMIN. SCI. ADVISORY BOARD (Apr. 24, 2020), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf [https://perma.cc/6NXF-SQEC]. See my discussion of the specific example of the chemical industry's attacks on a significant paper supporting formaldehyde as a cause of human leukemia. Industry obtained the raw data and hired consultants to find alleged blemishes but never sought to repeat the study in another exposed population. *See* Bernard Goldstein, *Presentation to the Joint Hearing of the Subcommittee on Investigations & Oversight and the Subcommittee on Environment of the House Committee on Science, Space and Technology*, ENV'T PROTECTION NETWORK 5–6 (Mar. 27, 2019), https://www.environmentalprotectionnetwork.org/wp-content/uploads/2019/03/IRIS-Testimony-March-27-2019-Goldstein.pdf; Bernard Goldstein, *The HONEST Act is Actually Dishonest and Will Hurt the EPA*, THE HILL (Apr. 20, 2017), https://thehill.com/blogs/pundits-blog/energy-environment/329671-the-honest-act-is-actually-dishonest-and-will-hurt-the [https://perma.cc/X7LR-JXRL].

84. Each of the Integrated Scientific Assessments for NAAQS air pollutants has a section on biological plausibility, as do many other EPA scientific analyses. *See* EPA, INTEGRATED SCIENCE ASSESSMENT FOR PARTICULAR MATTER 17 (2019).

85. *Id.* at 6 (discussing the role of PM2.5 in causing cardiovascular effects).

should be totally disregarded from consideration by the judge or jury, rather than considered as part of a reinforcing web of science.[86]

C. The Status of ORD Within EPA

Under President Trump the status of ORD within the EPA was degraded. This is the first time that a president failed to nominate anyone for Senate confirmation as the EPA Assistant Administrator for Research and Development.[87] Having the science arm of the EPA headed by someone nominated by the President and confirmed by the Senate puts that individual at the same level as the heads of the program offices (e.g., Office of Water; Office of Air and Radiation). Instead, current ORD leadership has a well-respected internal EPA scientist, Dr. Jennifer Orme-Zavaleta as Principal Deputy Assistant Administrator and Acting Chief Science Advisor. However, Administrator Pruitt created a new position, Deputy ORD Assistant Administrator for Science Policy. Pruitt originally chose Richard Yamada, PhD, who as an assistant professor had a reasonably well-respected scientific publication record in applied mathematics and genetics. Yamada became involved in scientific policy after serving on the staff of the House Science, Space and Technology Committee.[88] Administrator Wheeler replaced Yamada with David Dunlap, a chemical engineer who has long been involved in environmental consulting.[89] Dunlap's recent service as director of environmental affairs

86. *See* Thomas O. McGarity, *Science in the Regulatory Process: On the Prospect of "Daubertizing" Judicial Review of Risk Assessment*, 66 L. & CONTEMP. PROBS 155 (2003).

87. *See How to Rebuild the US Environmental Protection Agency*, NATURE.COM: EDITORIALS (Dec. 16, 2020), https://www.nature.com/articles/d41586-020-03539-z [https://perma.cc/586C-A5RZ]. Senate Republicans blocked President Obama's choice, Dr. Thomas Burke, to head ORD. *Senate Republicans Threaten to Block Confirmation of EPA Research Chief.* SCIENCE MAG. (June 2015), https://www.sciencemag.org/news/2015/06/senate-republicans-threaten-block-confirmation-epa-research-chief [https://perma.cc/BH2L-GHLJ].

88. The committee was chaired by Lamar Smith (R, Texas), a climate denier, who repetitively led the committee to propose laws related to transparency and EPA science advisory processes. Michael Hiltzik, *Column: Good Riddance to Rep. Lamar Smith (R-Texas), the Most Obnoxious Climate Change Denier in Congress.* LOS ANGELES TIMES (Nov. 3, 2017). https://www.latimes.com/business/hiltzik/la-fi-hiltzik-lamar-smith-20171103-story.html [https://perma.cc/W2H9-3YUD]. Yamada's activities on this committee presumably led to his choice for this new ORD Deputy Administrator for Science Policy. Scott Waldman, *Meet the Man Helping EPA to Reshape Science*, E&E NEWS (May 23, 2018), https://www.eenews.net/stories/1060082467 [https://perma.cc/9B7B-WC2B].

89. Brandi Buchman, *EPA Names Former Koch Industries Figure Chief of Research*, COURTHOUSE NEWS SERV. (Oct. 1, 2018), https://www.courthousenews.com/epa-names-former-koch-industries-

for Koch Industries is not mentioned in his biography on EPA's website,[90] nor does it appear that he has published in the scientific or technical literature. Dunlap's job is described as representing "the Administrator and Deputy Administrator at various task force, panel, and committees on science and operational program activities related to the development of Agency science policies and regulations."[91] In other words, rather than a scientist or engineer confirmed by the U.S. Senate, an advocate chosen by the EPA Administrator was the interface between ORD's scientific and technical staff and EPA's regulatory decision processes.

III. ACHIEVING SCIENTIFIC CONSENSUS

Frustration by stakeholders at how scientific evidence is incorporated into legal and regulatory processes, and not just those of the EPA, has been a virtual constant throughout the EPA's existence and has led to proposals for change.[92] The following brief review of consensus processes is aimed at serving as a background to the discussion of the changes proposed or made by the Trump administration.

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figure-chief-of-research/ [https://perma.cc/LT96-J8EB]; Annie Snider, *Koch Alumnus at EPA Worked on Toxic Chemical Despite Recusal Plan*, POLITICO (Oct. 17, 2019, 10:00 AM), https://www.politico.com/news/2019/10/17/koch-dunlap-epa-formaldehyde-049060 [https://perma.cc/WLH6-W8NW].

90. Bess Levin, *Trump Quietly Planted a Top Koch Official Inside the E.P.A.*, VANITY FAIR (Feb. 5, 2019), https://www.vanityfair.com/news/2019/02/trump-put-a-koch-official-in-charge-of-americas-drinking-water [https://perma.cc/7CER-6B7P]. I confirmed Levin's position that the lack of mention of Mr. Dunlap's prior position at Koch Industries is distinctly unusual. The EPA website provides a list of each of its Headquarter and Regional Offices; including its leadership at the Assistant Administrator (AA), Deputy AA or Regional Administrator levels, with in many cases a link to their biographies. On Dec 31, 2020, I found 19 biographies of individuals who were not long-term EPA employees. With the sole exception of Mr. Dunlap, all of these biographies specified their prior position before coming to EPA. EPA appears to have omitted Mr. Dunlap's prior position to obscure the fact that EPA's Deputy Administrator for ORD came from an advocacy position at Koch Industries.

91. *PFAS Technical Program*, AIR & WASTE MGMT. ASS'N, https://www.awma.org/pfastechprogram [https://perma.cc/CU6Y-9NKX] (including Dunlap's EPA biography that has since been removed from EPA website).

92. One example of responding to such concerns is an external review of EPA's science commissioned by EPA Administrator William Reilly. It includes a favorable review of CASAC's activities. U.S. ENVTL. PROTECTION AGENCY, EPA 600/9-91/050, SAFEGUARDING THE FUTURE: CREDIBLE SCIENCE, CREDIBLE DECISIONS (1992).

Approaches to obtain the considered opinion of the scientific community vary based upon the goals of the process, the legal structures in which they take place, the culture of the organizations involved, and the breadth and depth of the science to be considered. In 2004, Russellyn Carruth and I critiqued the scientific review process then recently adopted by the World Trade Organization (WTO) to assist in a WTO Panel deliberation.[93] We noted the importance of determining how to fairly choose the experts for a contentious issue; pointed out the need to consider the number of experts in relation to the breadth of disciplines involved; criticized the WTO for hearing from the experts individually rather than having them discuss the issues jointly with the WTO panel; and criticized the failure of an iterative approach which could clarify the uncertainties in dispute resolution.[94] We recommended changes to move toward a consensus panel.[95] These are many of the same changes that are needed to repair the damage inflicted by the Trump administration on the consensus processes developed through decades of trial and error at EPA. Described below are a number of consensus processes used by various organizations.

Perhaps most pertinent to mixing law with science was a proposal for a "Science Court" made almost 50 years ago by Alvin Weinberg. He noted that many of the science-related issues facing government were, in his words, "trans-scientific." He advocated approaching these difficult problems by borrowing standard legal procedures,[96] including examination and cross-examination of scientists about their findings and interpretation.

Wendy Wagner, in her 2003 review of various attempts to reform regulatory science, notes the then-active campaign from those concerned with "bad science" to implement a "regulatory *Daubert*" approach.[97] Wagner has pointed out that the Information Quality Act, the Shelby Amendment, and similar initiatives can be seen as a backdoor attempt to bring *Daubert* to administrative agencies.[98]

Another possible means of improving the delivery of informed scientific opinion to the law is based on the recognition that, under Rule

93. Russellyn S. Carruth & Bernard D. Goldstein, *The Asbestos Case: A Comment on the Appointment and Use of Nonpartisan Experts in World Trade Organization Dispute Resolution Involving Health Risk,* 24 RISK ANALYSIS, 471, 471–81 (2004).

94. *Id.*

95. *Id.*

96. *See* Alvin Weinberg, *Science and Trans-Science*, 10 MINERVA 209 (1972) (describing the complexity of issues that Weinberg called trans-science might today fit under the heading of "wicked problems" such as sustainability and climate change).

97. WAGNER, *supra* note 1, at 66–67.

98. *Id. See supra* Section III.B.

706 of the Federal Rules of Evidence, a federal court judge has the authority to bring in their own experts.[99] Joe S. Cecil of the Federal Judicial Center, working with the National Academies of Science and with the American Association for the Advancement of Science has been particularly active in advocating for judges to take advantage of this opportunity. [100] He found that when judges brought in their own experts, in 56 of 58 instances the courts' rulings were consistent with the expert panel's findings.[101] Yet it appears that most judges are not comfortable with bringing in their own experts, and I am not aware of a rush to do so.[102]

From 1977–2013 the U.S. National Institutes of Health (NIH) held consensus development conferences primarily on controversial topics relevant to clinical decision-making.[103] The topics were often of particular interest to government agencies who needed to decide whether to pay for a specific treatment.[104] An Institute of Medicine review of the NIH Consensus Development conference program was generally positive.[105] However, Itzhak Jacoby, who was an advocate of using science courts for difficult regulatory decisions, and was involved in the development of the NIH Consensus Conference program, became

99. Supreme Court Justice Stephen Breyer, in an introductory chapter to the Federal Judicial Center's Reference Manual on Scientific Evidence, provides an insightful overview of the issues facing judges in making decisions in the face of conflicting scientific experts. He is cautiously positive about judicial appointment of experts to serve the court. Stephen Breyer, *Introduction, in* NAT'L RSCH. COUNCIL, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 7–9 (3rd ed. 2011).

100. Joe S. Cecil & Thomas E. Willging, *Accepting Daubert's Invitation: Defining a Role for Court-Appointed Experts in Assessing Scientific Validity*, 43 EMORY L.J. 995, 995 (1994).

101. *Id.* at 1041.

102. For why judges are uncomfortable choosing their own experts, see JOE S. CECIL & THOMAS E. WILLGING, COURT-APPOINTED EXPERTS: DEFINING THE ROLE OF EXPERTS APPOINTED UNDER FEDERAL RULE OF EVIDENCE 706, 4–5 (1993).

103. For an overview of this program when it was active, *see* COUNCIL ON HEALTH CARE TECH. INST. OF MED., MED. TECH. ASSESSMENT DIRECTORY (1988), https://www.ncbi.nlm.nih.gov/books/NBK218312/pdf/Bookshelf_NBK218312.pdf [https://perma.cc/VT9Q-U4US].

104. *Retirement of the National Institutes of Health Consensus Development Program*, NAT'L INST. HEALTH, https://consensus.nih.gov/ (stating that the reason for discontinuation of these conferences was that they were created during a time when few other organizations were providing evidence reviews. But that there were now "many other organizations that conduct such reviews, including other federal agencies, academic institutions, and private organizations.").

105. CONSENSUS DEVELOPMENT AT THE NIH: IMPROVING THE PROGRAM, COMM. OF INST. OF MED. COUNCIL ON HEALTH CARE TECH. 3 (1990).

disillusioned and criticized the NIH program because it was insufficiently confrontational and did not include cross-examination of the expert witnesses.[106]

A somewhat bizarre example of an attempt to modify the consensus processes of science by building on a procedural approach useful in another context, but irrelevant to the EPA, was Scott Pruitt's advocacy of the "Red Team, Blue Team" approach to test the validity of global climate change. Originally developed by the military and now heavily used in cybersecurity, the red team is charged with testing the potential limitations of the defenses of an entity while the blue team evaluates the ability of the entity to stop, or at least limit, the effectiveness of the attack secretly chosen by the blue team.[107] As envisioned by Pruitt, the public debate would give equal credence to climate deniers, who represent a very small percentage of the scientific community.[108] John Kelly, a former Marine Corps General who was then Trump's White House Chief of Staff, put an end to this proposal.[109]

106. *See* Itzhak Jacoby, *Consensus Development at NIH: What Went Wrong*, 4 RISK 133 (1993); *see generally* Itzhak Jacoby, *The Consensus Development Program of the National Institutes of Health*, 1(2) INT'L J. TECH. ASSESSMENT IN HEALTH CARE 419, 420 (1985) (describing the creation of the Consensus Development Program). An earlier review was positive about process changes that had been made by the NIH to achieve consensus but raised continuing concerns about selection of questions and panelists. *See generally* Paul M. Wortman et al., *Do Consensus Conferences Work? A Process Evaluation of the NIH Consensus Development Program*, 13 J. HEALTH POL., POL'Y & L., 469 (1988).

107. For example, Microsoft has red teams of hackers and blue teams of those whose goal is to find and shore up potential vulnerabilities to hacking. Kris Evans, *Red vs Blue. Inside the World of the Elite Hacker and Those Trying to Stop Him,* MICROSOFT INDUSTRY BLOGS – U.K. (May 17, 2016), https://cloudblogs.microsoft.com/industry-blog/en-gb/financial-services/2016/05/17/red-vs-blue/ [https://perma.cc/FP2M-DBC8].

108. *See* Naomi Oreskes, *Scientific Consensus on Climate Change,* 306 *SCIENCE 1686 (*Dec. 3, 2004); *see also Vital Signs of the Planet,* NASA GLOB. CLIMATE CHANGE (2019), https://climate.nasa.gov/scientific-consensus/ [https://perma.cc/MV54-MBAJ] (2019 statement by the US National Aeronautic and Space Administration that 97% of climate scientists agree that anthropogenic global climate change is occurring).

109. Lisa Friedman & Julie Hirschfeld Davis. *The E.P.A. Chief Wanted a Climate Science Debate. Trump's Chief of Staff Stopped Him*, N.Y. TIMES (Mar. 9, 2018), https://www.nytimes.com/2018/03/09/climate/pruitt-red-team-climate-debate-kelly.html [https://perma.cc/49AU-9TY6]. It appears that Administrator Weaver, who was Deputy Administrator under Pruitt, seemed to believe that the double-blind studies performed at FDA are equivalent to a red team, blue team debate. Bernard Goldstein, *How EPA Administrator Completely Misinterprets Science*, THE HILL (June 20, 2019), https://thehill.com/opinion/energy-environment/449465-how-epa-administrator-wheeler-completely-misinterprets-science [https://perma.cc/S85L-XCRL].

Perhaps the most recognized and copied consensus approach globally is that of the U.S. National Academies of Science (NAS). The NAS has been heavily involved in providing committees, workshops, roundtables, or other activities, often specified by Congress, that have reviewed and facilitated EPA activities.[110]

Central to the internal NAS process is selection of committee members whose expertise covers the breadth of the charge to the committee.[111] The NAS staff solicits nominations and carefully reviews the applicants. [112] The potential for bias, or the appearance of bias, is of primary concern, including previous opinions of the candidate on the subject matter before the committee, and sources of funding that may be interpreted by others as bias.[113] For obvious reasons, the absence of a taint of bias is particularly necessary for the choice of Committee chair. On certain subjects, the NAS may occasionally decide that it would be best to balance the committee composition in terms of potential bias, such as by including both a scientist working for an environmental group and another for industry, but all members are abjured from approaching the topic as a representative of an organization.[114] Before being publicly released, the draft committee report is carefully scrutinized within NAS and by external reviewers chosen by NAS from its elected members.[115]

The Health Effects Institute (HEI) provides an example that is particularly pertinent to the issue of the credibility of EPA's air pollution health effects research. It was formed in 1980 in response to controversies concerning the scientific basis for EPA's NAAQS standards.[116] HEI is a non-profit organization with an independent Board of Directors. For its core activities, it is funded equally by the

110. Insertion of Environmental Protection Agency into the search engine of the National Academies Press finds 3,496 publications resulting from NAS activities. *See Search Results for EPA,* THE NAT'L ACADS., https://www.nap.edu/search/?rpp=20&ft=1&term=EPA [https://perma.cc/3UBU-7XPG] (last visited Feb. 18, 2021).

111. The processes are described in National Academies of Science, Engineering and Medicine. *See Our Study Process,* NAT'L ACADS., https://www.nationalacademies.org/about/our-study-process [https://perma.cc/QTG2-MYMZ].

112. *Id.*

113. *Id. See generally, Conflict of Interest Policies and Procedures,* NAT'L ACADS. OF SCI., ENG'G AND MED., https://www.nationalacademies.org/about/institutionai-policies-and-procedures/conflict-of-interest-policies-and-procedures [https://perma.cc/9ZPL-PSQT].

114. NAT'L ACADS., *supra* note 28, at 6.

115. *See generally* NAT'L ACADS., *supra* note 111.

116. Terry J. Keating, *Lessons from the Recent History of the Health Effects Institute*, 26 SCI., TECH. & HUM. VALUES 409 (2001).

EPA and the automotive industry.[117] Neither the EPA nor industry participates in the choice of the Board or of the members of HEI's Research or Review Committees. The members of the Research Committee, who select the research proposals to be funded, are chosen and make their decisions based on processes similar to those of NIH, and the members of the Review Committee, who provide a written critical review of each of the completed projects, are chosen and make their decisions using processes similar to those of NAS. [118] HEI has been favorably reviewed by social scientists as an example of a successful boundary organization, one that is accountable to two adversarial organizations.[119]

A. What Changed Under the Trump Administration?

Previously, the EPA's processes for CASAC, SAB, and many other external scientific advisory committees generally adhered to the processes of NAS. A synopsis of what was changed at the EPA under the Trump Administration includes:

> (1) The committee selection process moved from being primarily performed by professional EPA staff, who focused on the needed expertise, to a process dominated by the Administrator and other EPA political appointees.[120] One requirement created by Mr. Pruitt was that CASAC have an increased number of individuals working for state or local agencies rather than the one such individual required by Congress.[121] Unlikely to be coincidental, of

117. For a fuller description of the organization *see About HEIs*, HEALTH EFFECTS INST., https://www.healtheffects.org/about [https://perma.cc/PQ83-FBYB].

118. *Conflicts of Interest Policies*, HEALTH EFFECTS INST. (Nov. 2017), https://www.healtheffects.org/about/conflict-of-interest-policies [https://perma.cc/HQW4-8D9Q.

119. *See* David Guston, *Boundary Organizations in Environmental Policy and Science: An Introduction*, 26 SCI., TECH. & HUMAN VALUES 399, 403 (2001); *see also* THE FIFTH BRANCH, *supra* note 1, at 209–16. Its reputation for scientific objectivity has led HEI to be asked to develop approaches to contentious scientific issues, such as the potential adverse health impact of unconventional shale gas drilling, which it has done through developing an affiliated organization. *See HEI-Energy*, HEALTH EFFECTS INST., https://www.healtheffects.org/unconventional-oil-natural-gas [https://perma.cc/L74J-QXJ8].

120. Christopher S. Zarba, *The Assault Against Science Continues at the EPA*, N. Y. TIMES (Nov. 24, 2018), https://www.nytimes.com/2018/11/14/opinion/environment-trump-epa-science.html [https://perma.cc/JA5B-8Q7E].

121. Clean Air Act Amendments of 1970. 42 U.S.C. § 7409(d)(2) specifies that of the total seven members, one should be a member of the National Academy of Sciences, one should be a physician, and one person should represent state air pollution control agencies. As CASAC also opines on the secondary NAAQS standards aimed mostly at protecting ecosystems,

the seven current CASAC members, the four from state or local agencies all worked in organizations that reported to Republican administrations.

(2) The choice of the chair of CASAC, Louis Anthony Cox, is a recognized consultant statistician who has what, at best, might be called a minority view of the use of epidemiological evidence for causation in public health matters.[122] He is a consultant for the fossil fuel industry and has expressed his opinion supporting the industry on key issues related to health effects of air pollutants, including a Wall Street Journal opinion piece.[123] In my opinion, for him to chair CASAC clearly violated the norm for any scientific consensus committee.[124]

(3) A primary issue for assembling a consensus committee is that all disciplines relevant to interpreting the pertinent science be represented. Despite epidemiology being the central discipline for interpreting the data relevant to standard setting for most air pollutants, no one with primary expertise in epidemiology was chosen for the seven-member CASAC committee. Wheeler is quoted as saying that the group of CASAC members had "a diverse set of skills in fields like toxicology, engineering, medicine, ecology and atmospheric science." Epidemiology is notably absent from this list. [125]

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it has become traditional that an ecologist is one of the seven CASAC members. To the best of my recollection there previously has never been more than one member from a state or local agency. 42 U.S.C. § 7409(d)(2) (2018).

122. John Balmes, *Don't Let a Killer Pollutant Loose,* N.Y. TIMES (Apr. 14, 2019), https://www.nytimes.com/2019/04/14/opinion/air-pollution-trump.html?partner=IFTTT [https://perma.cc/BC6N-Q2DD]; GOLDMAN & DOMINICI, *supra* note 6.

123. Tony Cox, *The EPA's Next Economic Chokehold,* WALL ST. J. (Sept. 1, 2015, 7:19 PM), https://www.wsj.com/articles/the-epas-next-big-economic-chokehold-1441149571 [https://perma.cc/G943-PQEE].

124. This opinion is based on my experience chairing CASAC and about a dozen NAS committees, many requested by the EPA. I have chaired other EPA and federal, state and local scientific consensus committees, as well as for the Health Effects Institute, the World Health Organization, the United Nations Environmental Program and the Scientific Committee on Problems of the Environment.

125. Dino Grandoni & Juliet Elperin, *EPA Scraps Pair of Air Pollution Panels*, WASH. POST (Oct. 13, 2018), https://www.washingtonpost.com/energy-environment/2018/10/14/epa-scraps-pair-air-pollution-science-panels/ [https://perma.cc/X4PB-5HJM]. The only medical professional on CASAC is Mark Frampton, MD, a pulmonary physician who would be expected to have at least modest training and working experience in epidemiology. He submitted a minority opinion arguing that the evidence

(4) Because there is such a breadth of disciplines involved in evaluating the health effects of NAAQS pollutants, it has long been recognized that pollutant-specific CASAC subcommittees are also needed.[126] The particulate subcommittee had already begun its deliberations when it was peremptorily fired and plans for the ozone subcommittee were aborted.[127]

(5) After receiving much criticism about the discharge of the subcommittees from CASAC members and others, the Administrator's office chose individual external scientists to, in essence, be made available for CASAC members to question – once again without a deliberative process.[128]

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required a more stringent annual particulate standard rather than EPA's proposal to retain the existing standard.

126. I served on two such subcommittees in the early 1980s. These subcommittees have tended to increase in size, due to the increasing number and breadth of relevant published papers and due to advances in environmental epidemiology and in exposure science.

127. *Id at 126.* EPA's rationale was the need to speed up the NAAQS review process to meet the five year statutory deadline. *See* Memorandum from E. Scott Pruitt, Administrator, U.S. Environmental Protection Agency, to Assistant Administrators; *Back-to-Basics Processes for Reviewing National Ambient Air Quality Standards,* U.S. ENV'TL PROT. AGENCY (May 9, 2018) https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf [https://perma.cc/ES5V-HXGU]. This is specious. If that were the true reason then it would make sense to begin with the health-based standard that was most out of date, that of carbon monoxide. *See NAAQS Table*, EPA, https://www.epa.gov/criteria-air-pollutants/naaqs-table [https://perma.cc/JA33-Z7B8]. My conclusion is that the reason Mr. Pruitt and Mr. Wheeler began with ozone and particulates and short circuited the process is that these were the two NAAQS pollutants for which accumulating science frightened the fossil fuel industry into believing that the standards might be made more stringent unless acted on in the first term of the Trump Administration. See also Gretchen Goldman, et al., *We Put Science Back into EPA Air Pollution Standards, But . . .* , SCI. AM.: OBSERVATIONS (Apr. 15, 2020), https://blogs.scientificamerican.com/observations/we-put-science-back-into-epa-air-pollution-standards-but/ [https://perma.cc/NE5R-MDJC]. The particulate standard subcommittee continued to meet on their own and, in contrast to CASAC, recommended more stringent standards. Independent Particulate Review Panel, *The Need for a Tighter Particulate Matter Air Quality Standard.* 360NEW ENGL. J. MEDICINE 680-683 (Aug. 13, 2020).

128. For a succinct overview of the many changes made in the CASAC process see H. Christopher Frey, *A Rush to Judgment: The Trump Administration is Taking Science Out of Air Quality Standards,* THE CONVERSATION (as A comprehensive review can be found in a letter to the Chair of Casac: H. Christopher Frey, et al. *Letter to CASAC from former members of 2009–2014 CASAC Ozone Review Panel, Nov. 26, 2018,* https://yosemite.epa.gov/sab/

(6) The SAB was not consulted about the wisdom of excluding scientists who receive EPA grants from advisory processes, or issues related to changing the CASAC processes described above.

(7) For the proposed transparency rule, EPA leadership initially only gave SAB the task of recommending a way to deal with technical issues related to meeting personal privacy concerns.[129] They did not ask SAB for advice on whether the proposal was a good idea, or even whether there was a problem requiring this drastic new approach. This is equivalent to treating SAB as a mechanic whose job is to fix a flat tire, but not asking for advice on whether this was the appropriate destination or the route to be traveling.[130]

(8) The SAB did hold a hearing after the EPA published a Supplemental Notice of Proposed Rulemaking on Transparency in Regulatory Science. The SAB pointed out numerous problems that needed to be corrected, including lack of clear definitions of terms.[131]

(9) EPA's transparency proposal alters the selection of scientific studies to be considered in ways that remain unclear and appears

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sabproduct.nsf/0AC9E8672B0CA54985258351005BE54F/$File/Ozone+Letter+181126+Submitted-rev2.pdf [https://perma.cc/J6PX-BXBZ]. Gretchen Goldman, et al., *We Put Science Back into EPA Air Pollution Standards, But . . .* , SCI. AM.: OBSERVATIONS (Apr. 15, 2020), *See also* H. Christopher Frey, *EPA decides to reject the latest science, endanger public health and ignore the law by keeping an outdated fine particle air pollution standard,* THE CONVERSATION (May 1, 2020), https://theconversation.com/epa-decides-to-reject-the-latest-science-endanger-public-health-and-ignore-the-law-by-keeping-an-outdated-fine-particle-air-pollution-standard-136226 [https://perma.cc/YH49-AFG3].

129. The subject line from the letter of Sept. 30, 2019 from Michael Honeycutt, Chair of SAB to Andrew Wheeler clearly states the narrow subject. Michael Honeycutt, *Subject: Consultation on Mechanisms for Secure Access to Personally Identifying Information (PII) and Confidential Business Information (CBI) Under the Proposed Rule, Strengthening Transparency in Regulatory Science*, OFF. OF THE ADMIN. SCI. ADVISORY BOARD (Sept. 30, 2019), https://yosemite.epa.gov/sab/sabproduct.nsf/41042C652229CA39852584850059545 8/$File/EPA-SAB-19-005.pdf [https://perma.cc/X2EG-Z4XF].

130. *See* Wendy E. Wagner & Rena Steinzor, *A Real, Not Faux, Transparency Proposal for Regulatory Science*, THE REG. REV. (July 31, 2018), https://www.theregreview.org/2018/07/31/wagner-steinzor-real-not-faux-transparency-proposal/ [https://perma.cc/Z6M8-ZWXH] (pointing out the lack of a problem statement as a central failing for all of the EPA proposed changes in their advisory processes).

131. Honeycutt, *supra* note 83.

> to provide the Administrator, as the judge, with a major role in deciding which studies are applicable to the regulatory issue.[132]
>
> (10) At their meeting concerning the data privacy issues in the transparency proposal, much to the evident surprise of the SAB members, SAB members were told to put their individual comments in writing and submit them to EPA with no further committee deliberations. This approach allows supporters of EPA's transparency proposal to pick and choose from among these individual comments, which again is contradictory to a deliberative consensus process.[133] But it would be in keeping with a lawyer summing up their case in front of a judge or jury.

The transparency proposal provides another particularly glaring example of the failure to ask a question – in this case whether the proposal can feasibly be carried out. Proponents of the approach embodied in EPA's proposal have had many years to find out whether anyone but industry and their consultants would turn over their working data to the EPA.

Before a study involving human subjects can be performed it must be approved by the organization's Institutional Review Board (IRB). For any already published study, or a new study for which it was considered likely that the data would be pertinent to EPA's regulatory activities, the investigators would need to get approval from the IRB to release the data to EPA.

Briefly, the key unanswered questions are:[134]

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132. *See* discussion of Daubert rule *infra* Part II.F.

133. The Chair of the SAB, Michael Honeycutt, in the first sentence of the third paragraph of his September 30, 2019 letter to Andrew Wheeler summarizing the SAB response, pointedly states "No consensus report is provided to the EPA because no consensus advice is given." Honeycutt, *supra* note 129.

134. The data, in italics, come from my sampling of references cited by EPA in its own cardiovascular health effects chapter of the Particulate Matter Integrated Scientific Assessment. The standard way of deciding what influences a decision in both science and law is to look at the references cited. Even under the vague definitions given by EPA, pivotal science would be cited by EPA in scientific documents underpinning decisions. I sampled the 34-page reference section of Chapter 6, Cardiovascular Effects, of the Integrated Scientific Assessment for Particulate Matter in EPA, INTEGRATED SCIENCE ASSESSMENT FOR PARTICULAR MATTER 331–344 (2019). The sample was randomized by choosing to review the first and last reference on each page – in essence randomization by page break. This provided 68 references. I excluded seven studies for which the data were likely to be already available to the EPA as they were by EPA investigators, or were multi-author reviews with no new data by organizations (e.g., American Heart Association), and an HEI Review Committee report - which left 61 studies. In considering the number of institutions that might be involved in permitting the data to be shared, I lumped together multiple institutions of the same organization, e.g., a

(1) Would the author or co-authors of EPA-relevant papers want to turn over their data?

(2) If so, would the IRB require unanimous consent of all co-authors? *(average number of co-authors per paper cited by EPA in my sample was 9.9).*

(3) To protect itself from potential scandal which could harm its ability to recruit subjects for any clinical studies, would the institution in which the study was performed insist on making its own rules related to turning over study data?

(4) What about the large majority of studies with multiple institutions involved? (aver*age of 4.2 institutions per paper in my sample*). Would they all need to agree? Would each IRB or institution have their own rules?

(5) Who would pay for any de-identification required by IRB or institutional rules?

(6) Would IRBs refuse to consider turning data over to EPA because of environmental justice issues? IRBs have the power to disapprove activities that inherently can have a biased outcome.[135] Would the fact that industry has more money to reanalyze studies than does a potentially affected disadvantaged community convince IRBs not to permit the data to be turned over to EPA?

(7) In my sample of EPA-referenced publications, a large percentage of EPA's cited references came from countries outside of the U.S. (*Only 26 of the 61 papers were solely from the U.S.; 17 had U.S. and non-U.S. institutions listed for their authors; and 18 had solely non-U.S. institutions*). In many countries, including particularly in the EU, there are more stringent privacy rules than in the U.S. – and California is now more stringent than the rest of the U.S. Will this pose difficulties in obtaining the data for secondary analyses required in EPA's proposal?[136] Would non-

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study that had authors from the Harvard School of Public Health, Harvard Medical School and a Harvard-affiliated hospital were counted as just one organization rather than three.

135. For example, a study comparing performance on a standardized intelligence test of males versus females in which one gender was disproportionately selected from community colleges and the other from Ivy League universities.

136. Deven McGraw, a private industry lawyer, speaking at a 2019 NAS Workshop on "Virtual Clinical Trials"; Alper et al., *Virtual Clinical Trials,* NAT'L ACADS. OF SCI. 51 (2019), https://www.nap.edu/catalog/25502/virtual-clinical-trials-challenges-and-opportunities-proceedings-of-a-workshop [https://perma.cc/S72P-KNSC], was quoted by the NAS Workshop rapporteurs as stating that new developments in

U.S. scientists agree to subject themselves to potentially hostile re-analysis when this is not required by their own country to base its regulatory decisions? When there are scientists from multiple institutions involved, it is not unusual for IRBs to defer to those from other reputable locations. Would EU IRBs be willing to defer to the U.S., or California IRBs to other states?

(8) What about HEI Review Committee products which EPA is partially funding?[137] Would the reviewers be restricted in their influential analyses to cite only to studies for which raw data were available? If not, then how can EPA continue to cite these HEI analyses in their regulatory documents?

(9) Am I right in believing there are few if any academic scientists who, even if sympathetic to the idea of transparency in considering scientific issues among their colleagues, would welcome what is highly likely to be hostile industry consultant reanalysis that will just divert the academic scientist's time in having to respond? [138]

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privacy laws, such as in California and the EU "set a higher bar for data to be 'de-identified,'" and that this is particularly of concern "for onward secondary uses, *such as replication of results and reanalysis.*" (emphasis added). Note my careful language in ascribing this quote to the NAS workshop rapporteurs. Misleadingly, EPA in its Supplemental Notice of Proposed Rulemaking on Scientific Transparency repetitively cited out of context language from an NAS Workshop on Principles and Obstacles for Sharing Data from Environmental Health Research, Workshop Summary that made it seem as if their proposed approach had NAS support. In contrast to committee reports, NAS workshop reports routinely contain a disclaimer that the information within the document represent individual opinions "and are not necessarily endorsed or verified by the (NAS) and should not be construed as reflecting any group consensus". (*See* Bernard D. Goldstein; Comments on Supplemental Notice of Proposed Rulemaking on Science Transparency; Docket # EPA-HQ-OA-2018-0259; May 18, 2020, https://www.environmentalprotectionnetwork.org/wp-content/uploads/2020/05/Comments-on-Supplementary-Notice-of-Proposed-Rulemaking-on-Science-Transparency-Final.docx-2.pdf [https://perma.cc/P2VT-QP93]). The failure to attribute the quotes from the NAS workshop to Lynn Goldman was further evidence that EPA was being intentionally misleading as Goldman had been emphatic in her opposition to the transparency in science initiative, including testimony to the SAB and a publication in a scientific journal. GOLDMAN & SILBERGELD, *supra* note 72.

137. For description of HEI and its relation to EPA, *see supra* notes 119–21.

138. EPA avoided providing an estimate of how many existing studies would fall under its requirement for full disclosure of underlying data and models to be considered in rule-making. Perhaps indicative of the intended impact is a statement in the Congressional Budget Office (CBO) analysis of the failed congressional bill, the HONEST Act of 2017, on which the EPA transparency proposal was based. "EPA officials have explained to CBO that . . . [their] approach to implementing the legislation would

There is an obvious approach to answering these questions. *Just ask.* Survey the scientific community. Ask the SAB for a thorough analysis. Or the questions could have been posed to IRB directors, or VPs for Research at major universities,[139] or to samples of experts in the scientific community contributing to EPA's decision making.

Notably, these questions should have been posed to the NAS, which has been particularly active on data privacy issues. Putting "Date Privacy" into the National Academy Press search engine came up with 723 titles.

A final question: will the web of environmental health science underlying the EPA's regulations be destroyed because almost no peer-reviewed studies will be available for analysis?

CONCLUSION

Thanks largely to the election results and to the probing questions of Case Western reviewers and the comments of colleagues, I greatly revised the conclusions of this paper to focus on where to go from here. From the beginning of the Trump administration it has been clear that the scientific basis of EPA's many positive environmental achievements were at risk. [140] These fears were not understated. Some of what I describe is the bending or breaking of the laws mandating the involvement of CASAC and the SAB in facilitating a robust scientific basis for EPA's regulatory activities. To the extent that they are not changed by the incoming Biden Administration, the staying power of many but not all of the alterations will depend on court decisions.

But I believe more important than arguably violating the law, the EPA under the Trump administration has changed the norms that have evolved at the EPA in the last half century. As just one example, allowing a consensus committee considering a controversial issue to be chaired by a known advocate of one extreme is not specifically forbidden by the laws establishing EPA advisory processes. Nor am I aware that

significantly reduce the number of studies that the agency relies on when issuing or proposing covered actions for the first few years following enactment of the legislation." U.S. CONG. BUDGET OFF., COST EST.: H.R. 1430, HONEST AND OPEN NEW EPA SCIENCE TREATMENT (HONEST) ACT OF 2017 (2017).

139. I cannot imagine that my university's Vice Chancellor for Research, with $500 million of annual NIH funding, would risk an inadvertent disclosure event that could decrease the likelihood of patients volunteering for future clinical research (nor would reassurance of an infallible confidentiality process from either the University of Pittsburgh faculty member or a U.S. government agency likely affect the Vice Chancellor's decision).

140. Jonathan M. Samet et al., *The Trump Administration and the Environment – Heed the Science*, 376 NEW ENG. J. MED 1182–83, 1186 (2017); David Guston et. al., *Endangering the Health of All: Destroying a Half Century of Health Leadership Along With America's Environment*, 110 AMER. J. PUB. HEALTH 284–85 (2020).

the value of having an unbiased CASAC chair has been considered in judicial reviews. But, along with many other of the changes, it is a norm that is central to eliciting the consensus position of the scientific community.

I began this paper with a description of the norms governing neighborhood basketball. Steven Levitsky and Daniel Ziblatt, in their book "How Democracies Die," point out examples of where democracies have failed despite having seemingly appropriate constitutional protections, a failing which they attribute to the loss of policy norms. Their prescient New York Times op ed written after the election but before Trump took office, contains a similar use of street basketball as a metaphor: "[l]ike a pickup basketball game without a referee, democracies work best when unwritten rules of the game, known and respected by all players, ensure a minimum of civility and cooperation. Norms serve as the soft guardrails of democracy, preventing political competition from spiraling into a chaotic, no-holds-barred conflict."[141]

Norms also serve as the guardrails protecting the scientific basis of EPA's regulations. But EPA leadership under Donald Trump has taught us that these guardrails need strengthening. One approach would be by adding adherence to consensus processes to the laws governing EPA's advisory committees. Just as lessons learned from the Trump administration may lead to developments of further laws governing transition of Executive Branch power, the public availability of candidates' tax information, or the process for confirming Supreme Court Justices, the norms governing scientific consensus processes can be further codified. For example, to the specific Congressional language in the Clean Air Act about the composition of CASAC could be added statements that the Chair of CASAC must be free of the taint of bias. Such language conceivably would have prevented the choice of the chair chosen by Administrator Pruitt, or at least given greater weight to the court arguments of those looking to overturn the recent particulate and ozone NAAQS standards. Amendments to ERDAA could state that the choice of EPA's external advisory committee members and their deliberative processes should generally conform to the consensus processes used by the National Academies of Science or similar organizations.

Note that I have chosen my words carefully to avoid asking for imposition of a one-size-fits-all legal requirement for achieving scientific consensus. What I hope for is congressional language and judicial

141. Steven Levitsky & Daniel Ziblatt, *Is Donald Trump a Threat to Democracy?*, N.Y. TIMES (Dec. 16, 2016), https://www.nytimes.com/2016/12/16/opinion/sunday/is-donald-trump-a-threat-to-democracy.html [https://perma.cc/245G-MBK3]. The authors have expanded on their thesis in a book describing how democratic governance has been lost in various countries around the world. Science is hardly mentioned. *See generally* STEVEN LEVITSKY & DANIEL ZIBLATT, HOW DEMOCRACIES DIE (2018).

decisions that strongly inhibit the substitution of advocacy for consensus, that facilitate the use of processes that achieve the strong scientific base needed by EPA, and other science-based regulatory agencies, to achieve the mission given them by the American public.

The standard governmental approach to scientific issues that are unfamiliar to most elected leaders is to establish a commission that would report their findings and recommendations. This would be welcome, as would asking the NAS to look at the issue. Ideally this commission would be asked for by Congress to whom its report would be given. At the least, it should be established by the new EPA leadership as an early signal to the internal and external environmental science communities of their recognition of the importance of the issue.

EPA can of course do much internally to change how science has been distorted, such as restoring previous processes for the selection of advisory committee members and their deliberation.

Another way for the new administration to signal their intention to restore EPA's scientific norms will be to give priority to the early nomination of a highly respected scientist to head EPA's Office of Research and Development, and to be willing to fight for that individual's confirmation by the Senate.[142]

There is so much that the new team at the EPA will need to do on the regulatory side that I am not optimistic that reversion to the baseline scientific processes will occur quickly and am concerned that quick fixes may lose sight of what the Trump administration has taught us about the vulnerability of scientific norms to those who have made their policy decisions in advance. It would be wise not to relax defense of science at the EPA just because Trump was not re-elected. His return, or the election of a president with similar anti-science and anti-environmental beliefs, is far from impossible. Further, the potential threat to the EPA's science-based regulatory approaches does not come from just one side of the political spectrum. Those on the left include many who are post-modernists, who would deconstruct science by arguing that reality cannot be proven, and that scientific truth does not exist. When they have their turn, and it is likely that sooner or later that they will, conservatives may greatly regret having provided the template for the long-term destruction of EPA's scientific consensus processes.

I certainly do not advocate changing the essential differences between lawyers and scientists. But I do advocate that we understand and credit these differences. As we each participate in the process toward achieving the common goal of effective science-based regulatory

142. The incoming EPA leadership of a new administration usually focuses on policy issues. Not surprisingly, the head of ORD has usually been among the last to be nominated. *See* Bernard D. Goldstein, *EPA at 40: Reflections on the Office of Research and Development*, 21 DUKE ENV'T L. & POL'Y F. 295, 297 n. 5 (2010).

activities, we need to acknowledge that different parts of the process need to play by different local rules. So as a final recommendation let me suggest that a major lesson of the Trump administration for the scientific community is that we need to work harder to educate our government colleagues, as well as policy makers and the general public, about the value of adhering to the norms of science.