

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

NATURAL RESOURCES DEFENSE)
COUNCIL, INC.,)

Plaintiff,)

v.)

Civil Action No. 1:19-cv-05174-DLC
ECF Case

U.S. ENVIRONMENTAL PROTECTION)
AGENCY and ANDREW WHEELER,)
in his official capacity as)
Administrator of the U.S.)
Environmental Protection Agency,)

Defendants.)

**BRIEF OF LYNN R. GOLDMAN, BERNARD GOLDSTEIN, DAVID MICHAELS,
KENNETH OLDEN, BOB PERCIASEPE, AND TERRY YOSIE
AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF'S MEMORANDUM IN
OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AND IN SUPPORT OF
PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT**

SHAUN A. GOHO
LYNNE I. DZUBOW
Emmett Environmental Law & Policy Clinic
Harvard Law School
6 Everett Street, Suite 5116
Cambridge, MA 02138
(617) 496-5692
sgoho@law.harvard.edu

Dated: October 16, 2019

*Counsel for Amici Curiae
Lynn R. Goldman, et al.*

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INTERESTS OF AMICI CURIAE¹

Amici are former officials in the U.S. Environmental Protection Agency (“EPA”) and other federal agencies who have seen first-hand the critical role that science plays in EPA’s work and understand the importance of agencies obtaining the best possible scientific advice. They are deeply concerned that EPA’s decision to exclude recipients of its grants from its scientific advisory committees will undermine the agency’s ability to protect human health and the environment. As former federal officials who were involved in various aspects of scientific decision-making at federal agencies, including EPA’s issuance of research grants and the management of EPA’s scientific advisory committees, they collectively have decades of relevant experience and expertise to share with the Court.

Amicus Dr. Lynn R. Goldman is the Michael and Lori Milken Dean and Professor of Environmental and Occupational Health at the Milken Institute School of Public Health at George Washington University. She was previously Assistant Administrator for Toxic Substances at EPA, where she directed the Office of Chemical Safety and Pollution Prevention (1993–1998). She is a member of the National Academy of Medicine.

Amicus Dr. Bernard Goldstein is Emeritus Professor of Environmental and Occupational Health at the University of Pittsburgh. He is a physician and toxicologist who was EPA Assistant Administrator for Research and Development under President Reagan and is also former chairperson of the EPA Clean Air Scientific Advisory Committee (“CASAC”). He is a member of the National Academy of Medicine, for whom he has chaired numerous committees evaluating scientific studies.

¹ *Amici* certify that no person or entity, other than *amici* or their counsel, made a monetary contribution to the preparation or submission of this brief or authored this brief in whole or in part.

Amicus Dr. David Michaels is a Professor of Environmental and Occupational Health at the Milken Institute School of Public Health of George Washington University. From 2009 to 2017, he was Assistant Secretary of Labor for the Occupational Safety and Health Administration, the longest serving Administrator in the agency's history. From 1998 to 2001, he served as Assistant Secretary for Environment, Safety and Health in the Department of Energy.

Amicus Kenneth Olden, Ph.D., was Director of the National Center for Environmental Assessment in the Office of Research and Development at EPA between 2012 and 2016. He previously served as both Director of the National Institute of Environmental Health Sciences and Director of the National Toxicology Program within the Department of Health and Human Services between 1991 and 2005. Dr. Olden, a cell biologist and biochemist by training, has authored and co-authored more than 200 scientific papers.

Amicus Bob Perciasepe was Deputy Administrator of EPA from 2009 through 2014, as well as Acting Administrator from February 2013 through July 2013. He had previously served as Assistant Administrator for Water and Assistant Administrator for Air and Radiation in the Clinton Administration. Mr. Perciasepe has also held senior positions in the non-profit sector, state government and local government.

Amicus Dr. Terry Yosie was director of EPA's Science Advisory Board ("SAB") from 1981 to 1988. In this role, he advised EPA Administrators and Congress on the scientific basis of public health and environmental decisions, and instituted policies and procedures to improve the technical basis for EPA-wide policy decisions. He has served on numerous committees of the National Academy of Sciences/National Research Council and served in senior executive positions in the private sector. Dr. Yosie has published more than eighty articles on science, risk

assessment, and environmental policy making.

SUMMARY OF ARGUMENT

EPA’s mission is to protect human health and the environment. To fulfill this charge, the agency must address scientific questions involving sources of pollution; the transport, fate, and impacts of those pollutants; and the feasibility and cost of different pollution control technologies. Pursuant to EPA’s statutory authorities, the agency has long taken the position—and continues to assert—that its decisions must be based on the “best available science.” Over the past forty-nine years, this approach has resulted in significant net benefits for the American people.

The Directive issued by former EPA Administrator Scott Pruitt on October 31, 2017 (the “Directive”) bars scientists who hold EPA grants from serving on the agency’s scientific advisory committees. Consequently, it blocks EPA from accessing highly relevant scientific expertise, which undermines the agency’s ability to base its decisions on the best available science.

Throughout the agency’s history, independent science reviews have been essential to ensuring that EPA uses the highest quality science as a foundation for its decisions. To receive the best scientific advice possible, and to ensure that the public, industry, and elected officials have confidence in it, EPA must staff its scientific advisory committees with the most qualified scientists.

Scientists who receive EPA grants possess expertise relevant to EPA’s scientific advisory committees. Because EPA’s grant process is very competitive, scientists who receive these grants are often leaders in their fields. Moreover, the agency directs its grant funding to research into emerging or newly-recognized environmental questions. As a result, grant recipients

become experts on highly specialized scientific issues likely to come before the agency. The Directive, then, prevents some of the most qualified scientists from serving on EPA scientific advisory committees.

Finally, the Directive tries to solve a problem that does not exist. Its stated purpose is to prevent conflicts of interest on advisory committees and remove bias towards the agency. Office of Government Ethics guidelines do not treat grant funding as a disqualifying conflict of interest; as a result, EPA scientific advisory committees have always welcomed scientists who received grant funding from either the agency or from regulated industries. An effective and detailed conflict of interest framework already governed these committees before the Directive took effect. The Directive thus undermines EPA's ability to base its decisions on the best available science while serving no countervailing purpose.

ARGUMENT

I. TO FULFILL ITS STATUTORY MANDATES TO PROTECT HUMAN HEALTH AND THE ENVIRONMENT, EPA MUST USE THE BEST AVAILABLE SCIENCE

EPA's mission is to protect human health and the environment.² While EPA is not a "science agency" in the manner of the National Institutes of Health or the National Science Foundation, "science is and always has been the backbone of EPA's decision-making."³ EPA's statutory authorities require the agency to base many of its decisions on specific types of scientific information and conform with discrete, science-based standards. More generally, the regulatory decisions that EPA must make inevitably involve scientific questions such as what

² *Our Mission and What We Do*, EPA, <https://www.epa.gov/aboutepa/our-mission-and-what-we-do> (last visited Sept. 24, 2019).

³ Press Release, EPA, EPA Administrator Gina McCarthy Testimony before House Committee on Science, Space and Technology (Nov. 14, 2013), https://archive.epa.gov/epapages/newsroom_archive/newsreleases/201f4594a4b43bad85257c22007ac270.html.

impacts various pollutants have on human health and the environment; how those pollutants interact with each other and how they move through the air, water, and soil; and the feasibility and cost of different pollution control technologies. As a result, EPA has always taken the position that its decisions should be based on the best available science—an approach that has produced immense benefits for the American people.

A. EPA’s Statutory Authorities Require Science-Based Decision-Making

Many of the statutes that EPA implements specifically require science-based decision-making. For example, one of EPA’s core duties under the Clean Air Act is to set and periodically review the National Ambient Air Quality Standards (“NAAQS”) for six common air pollutants: carbon monoxide, lead, ground-level ozone, nitrogen dioxide, particulate matter, and sulfur dioxide. 42 U.S.C. § 7409. In discharging this responsibility, EPA must use “the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects [of air pollution] on public health or welfare.” *Id.* § 7408(a)(2). Similarly, the Safe Drinking Water Act commands EPA to use “the best available, peer-reviewed science,” *id.* § 300g-1(b)(3)(A)(i), and, when deciding whether to regulate a particular contaminant, to consider the “best available public health information.” *Id.* § 300g-1(b)(1)(B)(ii)(II). The Toxic Substances Control Act requires that regulation of chemical substances be “consistent with the best available science,” 15 U.S.C. § 2625(h), and that EPA make decisions “based on the weight of the scientific evidence,” *id.* § 2625(i). The water quality criteria that EPA develops under the Clean Water Act must “accurately reflect[] the latest scientific knowledge” on a variety of factors. 33 U.S.C. § 1314(a)(1). Under all of these statutes, EPA must assess the current state of scientific knowledge on the issue in front of it before deciding whether and, if so, how to act.

More generally, EPA’s statutory authorities require that the agency make decisions about

environmental, public health, and technological issues that inevitably implicate scientific questions. For example, under the Clean Air Act, EPA must set the NAAQS at a level “requisite to protect the public health.” 42 U.S.C. § 7409(b). Under the Safe Drinking Water Act, EPA must determine whether a contaminant “may have an adverse effect on the health of persons” before deciding to regulate it. 42 U.S.C. § 300g-1(b)(1)(A)(i). These statutory standards involve questions about the exposure of populations to pollutants and about the effects of those exposures—both of which are scientific questions.

Scientific questions are also central to the decisions that EPA must make to set technology-based emission or discharge standards. Thus, for example, the Clean Air Act requires that EPA establish emission limitations for hazardous air pollutants to “require the maximum degree of reduction in emissions . . . achievable.” 42 U.S.C. § 7412(d)(2). Under the Clean Water Act, EPA must set effluent discharge limitations that embody standards such as “the best practicable control technology currently available” or “the best available technology economically achievable.” 33 U.S.C. § 1311(b)(1)(A), (b)(2)(A). These, too, are science-based determinations.

EPA also relies on scientific information to set regulatory priorities. The relative magnitude of two different risks is fundamentally a scientific question. “In the absence of sound scientific information, high-risk problems might not be adequately addressed, while high-profile but lower-risk problems might be targeted wastefully.”⁴

B. EPA’s Longstanding Approach of Relying on the Best Available Science Has Produced Immense Benefits for the Nation

EPA has long taken the position that all of its decisions must be based on the best

⁴ NATIONAL RESEARCH COUNCIL, STRENGTHENING SCIENCE AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY: RESEARCH-MANAGEMENT AND PEER-REVIEW PRACTICES 24 (2000).

available science. For example, the agency’s 1997 strategic plan provided that one of EPA’s seven overall purposes was to ensure that “efforts to reduce environmental risk are based on the best available scientific information.”⁵ As indicated above, the Safe Drinking Water Act requires that EPA use “the best available, peer-reviewed science.” 42 U.S.C. § 300g-1(b)(3)(A)(i). In 2002, the agency issued Information Quality Guidelines in which it took the position that this standard should apply to all of its risk assessments.⁶ In April 2018, EPA reiterated in a notice of proposed rulemaking that “[t]he best available science must serve as the foundation of EPA’s regulatory actions.”⁷

In fact, the need for a centralized, scientific approach to environmental regulation was one of the main reasons President Nixon created EPA in the first place. In April 1969, President Nixon appointed an advisory council to provide advice on the organization of the executive branch.⁸ The council recommended “that key anti-pollution programs be merged into an Environmental Protection Administration, a new independent agency of the Executive Branch.”⁹ Among the reasons it cited in support of creating the agency were that “[w]e must know that standards are soundly based; thus, a research capability is necessary.”¹⁰ When President Nixon announced the new agency to Congress, he identified one of its main functions as “[t]he conduct of research on the adverse effects of pollution and on methods and equipment for controlling

⁵ EPA, EPA/190-R-97-002, EPA STRATEGIC PLAN 16 (1997).

⁶ EPA, GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY THE ENVIRONMENTAL PROTECTION AGENCY 21-23 (2002), <https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf>.

⁷ Strengthening Transparency in Regulatory Science (Proposed Rule), 83 Fed. Reg. 18,768, 18,769 (Apr. 30, 2018).

⁸ *President’s Advisory Council on Executive Organization*, RICHARD NIXON PRESIDENTIAL LIBRARY AND MUSEUM, <https://www.nixonlibrary.gov/finding-aids/presidents-advisory-council-executive-organization-white-house-central-files-staff> (last visited Sept. 24, 2019).

⁹ Memorandum from the President’s Advisory Council on Executive Organization to Richard Nixon, President of the United States (Apr. 29, 1970), <https://archive.epa.gov/epa/aboutepa/ash-council-memo.html>.

¹⁰ *Id.*

it.”¹¹ This research function remains a central one for the agency, and “[d]oing the right science and the science right is the foundation of EPA’s work to protect public health and the environment.”¹²

By following a science-based approach, EPA has achieved substantial benefits for the American people over the last forty-nine years. To take air pollution as an example, between 1970 and 2017 emissions of the six criteria air pollutants declined by an average of seventy-three percent, resulting in 160,000 fewer premature deaths per year, even as gross domestic product increased by 324%.¹³ Regulation under the Clean Air Act has also achieved significant reductions in emissions of hazardous air pollutants, reduced acid rain, and helped reverse the destruction of the ozone layer.¹⁴ As summarized last year by William Ruckelshaus, the first EPA Administrator, “[t]he environment is far healthier today than it was forty-seven years ago, when the E.P.A. was created, precisely because of the science-based standards that the agency implemented.”¹⁵

¹¹ Richard Nixon, President of the United States, Reorganization Plan No. 3 of 1970, Special Message from the President to the Congress About Reorganization Plans to Establish the Environmental Protection Agency and the National Oceanic and Atmospheric Administration (July 9, 1970), <https://archive.epa.gov/epa/aboutepa/reorganization-plan-no-3-1970.html>. It was not inevitable that environmental science and technology would be included administratively within EPA. The Occupational Safety and Health Administration was also created in 1970, but its scientific arm, the National Institute for Occupational Safety and Health, was established in what is now the Department of Health and Human Services. The arguably greater impact and effectiveness of EPA is at least partially due to its closer direct working relationship with the scientific community. See Jonathan M. Samet et al., *The Trump Administration and the Environment—Heed the Science*, 376 NEW ENG. J. MED. 1182, 1186 (2017). This effective working relationship is imperiled by the Directive.

¹² Press Release, EPA, EPA Administrator Appoints Advisors to Lead Science Panels (Oct. 15, 2004), https://archive.epa.gov/epapages/newsroom_archive/newsreleases/dfd5bca479cbd06085256f2e00581b94.html.

¹³ *Progress Cleaning the Air and Improving People’s Health*, EPA, <https://www.epa.gov/clean-air-act-overview/progress-cleaning-air-and-improving-peoples-health> (last visited Sept. 24, 2019).

¹⁴ Samet et al., *supra* note 11, at 1184.

¹⁵ William D. Ruckelshaus, Letter to the Editor, NEW YORKER, Apr. 16, 2018, at 5.

II. EPA'S INDEPENDENT SCIENTIFIC ADVISORY COMMITTEES PLAY A KEY ROLE IN THE AGENCY'S DECISION-MAKING

EPA oversees twenty-two federal advisory committees.¹⁶ Among these are several scientific advisory committees—including SAB, CASAC, and the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel—that “review scientific research and . . . provide advice and expertise from outside the agency.”¹⁷

The scientific advisory committees perform multiple functions. For example, by “review[ing] EPA’s research strategies and plans,” these committees “provide critical, early input to the Agency at the planning stage as it establishes its research priorities.”¹⁸ Advisory committees also respond to specific research requests to advise the agency on developing situations. Furthermore, they review EPA’s scientific conclusions in a process analogous to peer review that includes significant opportunities for public input.

Some statutes mandate that EPA consult with a committee before taking action. For example, the Safe Drinking Water Act requires that EPA consult with SAB when identifying drinking water contaminants that may require regulation. 42 U.S.C. § 300g-1(b)(1)(B)(i)(I). SAB must also review all criteria documents developed under the Clean Air Act, as well as any “standard, limitation, or regulation” promulgated under several environmental statutes. *Id.* § 4365(c)(1). CASAC’s duties include reviewing criteria documents and the NAAQS every five years, *id.* § 7409(d)(2)(B), as well as advising the Administrator on “areas in which additional

¹⁶ *All Federal Advisory Committees at EPA*, EPA, <https://www.epa.gov/faca/all-federal-advisory-committees-epa> (last updated Sept. 18, 2019).

¹⁷ NATIONAL RESEARCH COUNCIL, SCIENCE FOR ENVIRONMENTAL PROTECTION: THE ROAD AHEAD 180 (2012).

¹⁸ Statement of Paul Gilman, Assistant Administrator for Research and Development and EPA Science Advisor, EPA, Before the House Committee on Transportation and Infrastructure, Subcommittee on Water Resources and the Environment 2 (Mar. 5, 2003), https://archive.epa.gov/ocir/hearings/testimony/108_2003_2004/web/pdf/2003_0305_pg.pdf.

knowledge is required to appraise the adequacy and basis of existing, new, or revised” NAAQS and “describ[ing] the research efforts necessary to provide” this information, *id.* § 7409(d)(2)(C). The Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel provides comments on proposed Federal Insecticide, Fungicide, and Rodenticide Act regulations and decisions whether to cancel the registration of a pesticide or change its classification. 7 U.S.C. § 136w(d)(1).

CASAC offers a good example of how advisory committees fit into EPA decision-making. As mentioned above, under the Clean Air Act, CASAC must review the NAAQS every five years and recommend any new standards or revisions “as may be appropriate.” 42 U.S.C. § 7409(d)(2)(B). When proposing to issue new NAAQS or revise existing ones, EPA must “set forth or summarize . . . any pertinent findings, recommendations, and comments by [CASAC]” and explain any “important” departures from those recommendations. 42 U.S.C. § 7607(d)(3). If it disagrees with CASAC’s scientific analysis, “EPA must give a sound scientific reason for its disagreement” in order to “preserve the integrity of CASAC’s scientific role.” *Mississippi v. EPA*, 744 F.3d 1334, 1355 (D.C. Cir. 2013). If, instead, EPA accepts CASAC’s scientific analysis, but departs from its recommendation because of policy considerations, it must only show that it made its decision “in a manner calculated to negate the dangers of arbitrariness and irrationality.” *Id.* CASAC is thus the primary independent body that reviews the scientific basis of the NAAQS.

As CASAC’s role demonstrates, the agency’s scientific advisory committees provide the scientific input that makes informed environmental policymaking possible. EPA regularly relies on this advice, making it especially important that the committees include the most qualified scientists. For example, in 1989 “SAB estimated that 50% of EPA’s major activities in one form

or another are debated, reviewed, or influenced by SAB.”¹⁹ More recently, SAB’s Research Strategies Advisory Committee studied the impact of peer review on three EPA guidance documents. It reported that SAB “peer reviews had substantial effects on” all three documents,²⁰ which then-Assistant Administrator for Research and Development Paul Gilman understood to “demonstrate the value that peer review provides to all our scientific and technical work products.”²¹

Scientific advisory committee input also helps the agency properly understand risks to public health and decide how best to address them. For example, SAB peer review changed EPA’s characterization of the risks posed to drinking water by hydraulic fracturing. In 2015, the agency published a draft report, which concluded that there was “no[] . . . evidence that [hydraulic fracturing] ha[s] led to widespread, systemic impacts on drinking water resources in the United States.”²² On review, SAB expressed “particular concern” with this statement, and found that EPA “did not support quantitatively its conclusion.”²³ It requested that the agency “revise the major statements of findings . . . to clearly link these statements to evidence” provided elsewhere in the report.²⁴ After reviewing SAB’s comments, EPA “concluded that [its earlier statement] could not be quantitatively supported given the existing data gaps and

¹⁹ MARK POWELL, SCIENCE AT EPA 40 (1999).

²⁰ RESEARCH STRATEGIES ADVISORY COMM., SCI. ADVISORY BD., EPA, IMPLEMENTATION OF THE ENVIRONMENTAL PROTECTION AGENCY’S PEER REVIEW PROGRAM: AN SAB EVALUATION OF THREE REVIEWS 8 (2001).

²¹ Statement of Paul Gilman, *supra* note 18, at 9.

²² OFFICE OF RESEARCH & DEV., EPA, ASSESSMENT OF THE POTENTIAL IMPACTS OF HYDRAULIC FRACTURING FOR OIL AND GAS ON DRINKING WATER RESOURCES, at ES-23 (2015).

²³ OFFICE OF RESEARCH & DEV., EPA, RESPONSE TO THE U.S. ENVIRONMENTAL PROTECTION AGENCY’S SCIENCE ADVISORY BOARD REVIEW OF THE DRAFT REPORT: ASSESSMENT OF THE POTENTIAL IMPACTS OF HYDRAULIC FRACTURING FOR OIL AND GAS ON DRINKING WATER RESOURCES 6 (2017).

²⁴ *Id.*

uncertainties.”²⁵ Its final report stated that hydraulic fracturing “can impact drinking water resources under some circumstances” and that “[i]mpacts can range in frequency and severity, depending on the” circumstances.²⁶

By grounding these decisions in science, the scientific advisory committees also ensure that EPA does not *over*-regulate. For example, refusals by SAB to support the designation of perchloroethylene—a chemical used in commercial dry cleaning—as a carcinogen in 1987²⁷ and 1991²⁸ dissuaded the agency from regulating the chemical.²⁹ In 1997, EPA set the Ozone NAAQS at 0.08 ppm, despite numerous public comments calling for a more stringent standard. *See Am. Trucking Ass’ns v. EPA*, 283 F.3d 355, 377, 379 (D.C. Cir. 2002). It based its decision, in part, on the fact that no CASAC member at the time “supported a standard set lower than 0.08 ppm, specifically after considering a range of alternative standards that included 0.07 ppm.” *Id.* at 377 (citation and internal quotation marks omitted). Similarly, in 2012, EPA refused to issue a combined NO_x-SO_x standard upon CASAC’s recommendation. *See Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079, 1086 nn.11 & 13 (D.C. Cir. 2014).

Scientific advisory committees are not a one-way ratchet in support of more stringent

²⁵ *Id.* at 7.

²⁶ OFFICE OF RESEARCH & DEV., EPA, HYDRAULIC FRACTURING FOR OIL AND GAS: IMPACTS FROM THE HYDRAULIC FRACTURING WATER CYCLE ON DRINKING WATER RESOURCES IN THE UNITED STATES, at ES-3 (2016).

²⁷ *See* EPA, EPA-SAB-EHC-87-018, REPORT OF THE HALOGENATED ORGANICS SUBCOMMITTEE OF THE ENVIRONMENTAL HEALTH COMMITTEE ON A DRAFT ADDENDUM TO THE HEALTH ASSESSMENT DOCUMENT FOR TETRACHLOROETHYLENE (PERCHLOROETHYLENE) (1987), [https://yosemite.epa.gov/sab/sabproduct.nsf/14374A2A3BAF0F9A852573280068C57E/\\$File/PERCHLOROETHYLENE+++++EHC-87-018_87018_5-23-1995_309.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/14374A2A3BAF0F9A852573280068C57E/$File/PERCHLOROETHYLENE+++++EHC-87-018_87018_5-23-1995_309.pdf).

²⁸ *See* EPA, EPA-SAB-EHC-91-013, HEALTH EFFECTS ASSESSMENT OF PERCHLOROETHYLENE: REVIEW OF THE OFFICE OF RESEARCH AND DEVELOPMENT’S DRAFT DOCUMENT “RESPONSE TO ISSUES AND DATA SUBMISSIONS ON THE CARCINOGENICITY OF PERCHLOROETHYLENE (EPA/600/6-91/002A) BY THE ENVIRONMENTAL HEALTH COMMITTEE” (1991), [https://yosemite.epa.gov/sab/sabproduct.nsf/8D3F55B7C594202385257325004AD957/\\$File/PERCHLOROETHYLENE+++++EHC-91-013_91013_5-11-1995_169.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/8D3F55B7C594202385257325004AD957/$File/PERCHLOROETHYLENE+++++EHC-91-013_91013_5-11-1995_169.pdf).

²⁹ Terry F. Yosie, *The EPA Science Advisory Board: A Case Study in Institutional History and Public Policy*, 27 ENVTL. SCI. & TECH. 1476, 1478 (1993).

regulation, but instead guide EPA toward whatever decision is most strongly supported by scientific evidence. They are “critical in ensuring that EPA’s best available scientific knowledge has been independently reviewed by leading scientists in the field.”³⁰ The scientific advisory committees can continue to play this role effectively, however, only as long as they continue to be made up of leading independent scientists. As explained in a National Research Council report, EPA’s scientific advisory committees “will remain a valuable resource for the agency *assuming the members of these bodies continue to be chosen based on the virtue of their expertise and experience.*”³¹

III. THE DIRECTIVE UNDERMINES THE EFFICACY OF EPA’S SCIENTIFIC ADVISORY COMMITTEES

On October 31, 2017, former Administrator Pruitt issued a directive entitled “Strengthening and Improving Membership on EPA Federal Advisory Committees,” which, among other things, included a requirement that “no member of an EPA federal advisory committee be currently in receipt of EPA grants.”³² The Directive will harm EPA’s scientific advisory committees—and therefore harm EPA’s ability to base its decisions on the best available science—because it excludes qualified scientists from sitting on those committees while producing no countervailing benefits.

Congress clearly intended that EPA select the members of these committees based on their possession of relevant scientific expertise. For example, the statute that authorizes SAB provides that the committee’s members “shall be qualified by education, training, and experience

³⁰ Press Release, EPA, Science Advisory Board (Nov. 4, 2003), https://archive.epa.gov/epapages/newsroom_archive/newsreleases/ebffb3e52764e85256dd4007b73d4.html.

³¹ NATIONAL RESEARCH COUNCIL, *supra* note 17, at 181 (emphasis added).

³² Directive from EPA Administrator E. Scott Pruitt, Strengthening and Improving Membership on EPA Federal Advisory Committees (Oct. 31, 2017), https://www.epa.gov/sites/production/files/2017-10/documents/final_draft_fac_directive-10.31.2017.pdf.

to evaluate scientific and technical information on matters referred to the Board.” 42 U.S.C. § 4365(b). CASAC must be “composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.” *Id.* § 7409(d)(2)(A). The Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel:

shall consist of 7 members appointed by the Administrator from a list of 12 nominees, 6 nominated by the National Institutes of Health and 6 by the National Science Foundation. . . . Members of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation from the disciplines of toxicology, pathology, environmental biology, and related sciences.

7 U.S.C. § 136w(d)(1). In each case, the possession of relevant scientific expertise is a critical consideration in selecting committee members.

Far from being an indication that a scientist should be disqualified from serving on EPA scientific advisory committees, a scientist’s receipt of EPA research grants demonstrates that she is likely to have precisely the kind of expertise that Congress wanted committee members to possess. Scientists in academia rely on grants for their research funding. The nature of this arrangement makes grants competitive and means that highly-qualified scientists generally get the most grants.

EPA grants are especially competitive, making leading scientists more likely to receive them. For example, under the Science to Achieve Results grant program—EPA’s largest extramural grants program—only sixteen percent of applicants receive grants.³³ In 2017, the National Academy of Sciences found that this low award rate is “notable for its competitiveness”

³³ NATIONAL ACADEMY OF SCIENCES, A REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY’S SCIENCE TO ACHIEVE RESULTS RESEARCH PROGRAM 29 (2017) (measured from 2013-2014). For the annual grant award rate, *see id.* at 29, fig. 2-1.

and “is a measure of the vitality of a sponsored-research program.”³⁴

These grants fund high-impact research, further demonstrating the qualifications of the grantees. For example, between 2002 and 2017, Science to Achieve Results-funded research resulted in 5,760 publications.³⁵ Some of these studies are very highly cited—a proxy for scientific importance. The National Academy of Sciences identified sixty-three such publications since 2000 that have been cited more than 100 times,³⁶ nearly ten times more than the average number of citations for scientific papers during a similar period.³⁷ A review of one category of Science to Achieve Results grants (the Safe and Sustainable Water Resources program) found that “half the grants analyzed had at least one publication that was among the most highly cited publications in their field.”³⁸

Moreover, as a result of the targeted nature of the program, recipients often become experts in regulatory matters that come before EPA. Therefore, the Directive turns away scientists with expertise in areas *specifically relevant* to the committees’ work. The operation of the Science to Achieve Results grant program demonstrates why this is the case. EPA issues these grants to answer emerging research questions related to the Office of Research and Development’s four national programs: Air, Climate, and Energy; Chemical Safety for Sustainability; Safe and Sustainable Water Resources; and Sustainable and Healthy

³⁴ *Id.* at 31 (citations omitted).

³⁵ *See id.* at 35.

³⁶ *Id.* at 37. For a list of the highest-cited Science to Achieve Results-grantee publications, *see id.* at 40 tbl. 3-1, 42 tbl. 3-2.

³⁷ *See Citation Averages, 2000-2010, by Fields and Years*, TIMES HIGHER EDUCATION WORLD UNIVERSITY RANKINGS, <https://www.timeshighereducation.com/news/citation-averages-2000-2010-by-fields-and-years/415643.article> (last visited Sept. 24, 2019).

³⁸ NATIONAL ACADEMY OF SCIENCES, *supra* note 33, at 35.

Communities.³⁹ The national director for each program develops a four-year strategic research action plan, which identifies pressing research needs and important scientific questions in the relevant area.⁴⁰ EPA then publicly announces individual requests for applications for grants to address these needs.⁴¹

The effect of this process is that grantees develop expertise relevant to new and emerging regulatory issues. While American industrial innovation produces many benefits, new technologies and practices can potentially have harmful environmental impacts. EPA's grant funding often addresses such cutting-edge environmental and public health issues. For example, between 2003 and 2015, EPA awarded seventy-eight Science to Achieve Results grants to evaluate the environmental impacts of engineered nanoparticles.⁴² Nanoparticles are microscopic materials that have become increasingly easy to develop and manipulate.⁴³ Although they present opportunities for technological advances, little was known about their effect on human health and the environment when EPA started funding this research.⁴⁴

Research funded and directed by Science to Achieve Results grants has also been the basis for EPA decision-making. For example, EPA prohibited the use of azinphos-methyl, an organophosphate insecticide, after a Science to Achieve Results grant-funded study showed increased exposure levels among child farmworkers.⁴⁵ EPA also strengthened the NAAQS for

³⁹ *Id.* at 24.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.* at 57.

⁴³ See OFFICE OF RESEARCH & DEV., EPA, NANOTECHNOLOGY & NANOMATERIALS RESEARCH (2013), <https://www.epa.gov/sites/production/files/2013-12/documents/nanotechnology-fact-sheet.pdf>.

⁴⁴ See *id.*

⁴⁵ See EPA, FINAL DECISIONS FOR THE REMAINING USES OF AZINPHOS-METHYL (2006), https://archive.epa.gov/pesticides/reregistration/web/pdf/azm_remaining_uses.pdf; for the study, see Cynthia Curl et al., *Evaluation of Take-*

small particulate matter (PM_{2.5}) from 15 to 12 µg/m³ in 2012 after a Science to Achieve Results grant-funded study established that the risk of cardiovascular harm was lower with reduced exposure to PM_{2.5}.⁴⁶

In sum, EPA grants fund research into current and emerging risks to public health and the environment. Therefore, the recipients of EPA grants typically have expertise in the very issues that EPA’s scientific advisory committees address. Barring these scientists from membership on advisory committees makes those committees less able to furnish EPA with the “best available scientific knowledge” necessary for it to make informed policy decisions.⁴⁷

Finally, the Directive may make even scientists who do not currently hold EPA grants less willing to join the agency’s scientific advisory committees. For example, scientists may decline to serve on an advisory committee because they do not want to be precluded from competing for future EPA grants. More generally, however, one factor in scientists’ decisions about whether to join advisory committees is the agency’s receptiveness to scientific input. The Directive sends the message that EPA does not value qualified expertise, and may have priorities other than regulation based on the “best available scientific knowledge.”⁴⁸ This sort of messaging may dissuade even qualified experts who are not barred by the Directive from seeking

Home Organophosphorus Pesticide Exposure Among Agricultural Workers and their Children, 110 ENVTL. HEALTH PERSP. 787 (2002).

⁴⁶ See 78 Fed. Reg. 3086, 3106–07 (Jan. 15, 2013); *id.* at 3120 (“In considering whether the suite of primary PM_{2.5} standards should be revised, the Administrator places primary consideration on the evidence obtained from the epidemiological studies.”); *id.* at 3157 (adopting 12 µg/m³ as the primary annual PM_{2.5} NAAQS). For the study, see Francine Laden, et al., *Reduction in Fine Particulate Air Pollution and Mortality*, 173 AM. J. RESPIRATORY & CRITICAL CARE MED. 667 (2006).

⁴⁷ Prior to the Directive, EPA grant recipients often sat on the agency’s advisory committees. Indeed, six of seven CASAC members at the time the Directive went into effect had received EPA grants. Amena H. Saiyid, *Scientists Getting EPA Grants Can’t Advise Agency, Pruitt Says*, BLOOMBERG ENERGY & ENV’T REP. (Oct. 17, 2017), <https://bna.com/environment-and-energy/scientists-getting-epa-grants-cant-advise-agency-pruitt-says>.

⁴⁸ See, e.g., Editorial, *President Trump’s War on Science*, N.Y. TIMES (Sept. 9, 2017), <https://www.nytimes.com/2017/09/09/opinion/sunday/trump-epa-pruitt-science.html>.

positions on advisory committees.

IV. THE DIRECTIVE IS UNNECESSARY BECAUSE EPA SCIENTIFIC ADVISORY COMMITTEES ALREADY HAVE ADEQUATE MECHANISMS FOR ADDRESSING CONFLICTS OF INTEREST

The Directive aims to solve a problem that does not exist. EPA scientific advisory committees already had sufficient mechanisms to address conflicts of interest prior to the Directive. Conflicts checks, strict adherence to Office of Government Ethics guidelines, and recusal protocols governed this process. Moreover, the very nature of consensus-based decision-making on advisory committees discourages bias on the part of individual scientists. Notably, former Administrator Pruitt, in announcing the rationale for the policy, did not cite any examples of EPA acting on misleading advice from an advisory committee because of the presence of an EPA-funded scientist on the committee.

All of EPA's advisory committees are subject to the Federal Advisory Committee Act and members of these committees are considered "special government employees" subject to the ethics rules developed by the Office of Government Ethics. The Federal Advisory Committee Act requires that an advisory committee's advice and recommendations not be "inappropriately influenced by the appointing authority or any special interest, but . . . instead be the result of the advisory committee's independent judgment." 5 U.S.C. App. II, § 5(b)(3). The General Services Administration has promulgated regulations to implement the statute, under which the fact that someone has received an agency grant does not disqualify that person from serving on an advisory committee. The Directive is inconsistent with these uniform federal standards.

Office of Government Ethics regulations provide that a special government employee cannot participate in any "particular matter" in which she will have "a direct and predictable effect on that [financial] interest." 5 C.F.R. § 2635.402(c). Such "particular matters" include

permit applications or criminal charges; they do not include “the consideration or adoption of broad policy options that are directed to the interests of a large and diverse group of persons.” *Id.* § 2635.402(b)(3). With regard to advisory committees in particular, the regulations state that a committee member “may participate in any particular matter of general applicability where the disqualifying financial interest arises from his non-Federal employment . . . , provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class.” *Id.* § 2640.203(g).

Under this scheme, the possession of an EPA research grant was not, prior to the Directive, considered a basis for excluding scientists from EPA’s scientific advisory committees. A recent report by EPA’s Inspector General noted that the agency “d[id] not consider a prospective or current member’s receipt of an agency or other federal research grant to create the basis for a financial conflict of interest.”⁴⁹ The report explained that this approach was “consistent with other federal guidance in the area” and cited an Office of Management and Budget bulletin stating that “when a scientist is awarded a government research grant . . . there generally should be no question as to that scientist’s ability to offer independent scientific advice to the agency on other projects.”⁵⁰ Similarly, the Fifth Circuit Court of Appeals found, in a case involving a National Institute for Occupational Safety and Health advisory committee, that scientists’ possession of agency grants “does not in itself render them susceptible to improper influence.” *Cargill, Inc. v. United States*, 173 F.3d 323, 339 (5th Cir. 1999). The court

⁴⁹ OFFICE OF INSPECTOR GENERAL, EPA, REPORT NO. 13-P-0387, EPA CAN BETTER DOCUMENT RESOLUTION OF ETHICS AND PARTIALITY CONCERNS IN MANAGING CLEAN AIR FEDERAL ADVISORY COMMITTEES 9 (2013).

⁵⁰ *Id.* at 9–10 (citing Office of Management & Budget, Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2669 (Jan. 14, 2005); *see also* EPA, PEER REVIEW HANDBOOK 77 (4th ed. 2015) (noting that “when a scientist is awarded an EPA research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist’s ability to offer independent scientific advice to the Agency on other projects”).

explained:

[The National Institute for Occupational Health and Safety] is the major sponsor of occupational safety and health research, and it is therefore not surprising that [the advisory committee], whose members are selected because they are experts in that field, would include some persons who had . . . received a grant from [the Department of Health and Human Services (“HHS”)] [R]eceiving a grant from HHS . . . does not impair a scientist’s ability to provide technical, scientific peer review of a study sponsored by HHS or one of its agencies. Moreover, if HHS were required to exclude from peer review committees all scientists who somehow had been affiliated with the department, it would have to eliminate many of those most qualified to give advice.

Id. The same reasoning applies to EPA’s scientific advisory committees.

The Inspector General’s report acknowledged that a potential conflict existed when the committee on which a grantee sits “plans to address work performed under [her] research grant.”⁵¹ However, it concluded that EPA adequately dealt with that issue by requiring all committee members to report any grants received in the two years prior to their service, and recuse themselves from any consideration of the research produced under those grants.⁵² Thus, to the extent that the possession of a research grant presented a conflict in a particular matter, EPA already had adequate methods of dealing with those conflicts.

In addition, the nature of the scientific advisory committee process—and of the scientific process itself—reduces the risk that the receipt of EPA grants will influence the role played by a committee member. Scientific advisory committees work as a team and provide a space within which experts consult with each other to arrive at rational, scientifically-supported conclusion. Through this deliberative process, the committee will arrive at “the most likely estimation of truth as perceived by expert scientists.”⁵³

⁵¹ OFFICE OF INSPECTOR GENERAL, *supra* note 49, at 10.

⁵² *Id.*

⁵³ Bernard D. Goldstein, *Risk Assessment and the Interface between Science and Law*, 14 COLUM. J. ENVTL. L. 343, 345 (1989).

Moreover, the scientific advisory committees' consensus-based approach already disincentivizes the type of biased decision-making that the Directive claims to prevent. It is a knowledge-driven process, not a viewpoint-driven one. The structure of the academic scientific community further includes a heavy reliance on reputation to achieve success in receiving peer-reviewed competitive grants from the National Institutes of Health and National Science Foundation. Because of this dynamic, committee members are unlikely to jeopardize their reputations to advance an ideological agenda—the type of conduct envisioned by the Directive. In practice, as the above-mentioned examples of advisory committee recommendations that did not support EPA proposals underscore, *see supra* pp. 10-13, the scientists on these committees do not feel beholden to the agency.

Finally, if committee members' sources of funding did present a disqualifying conflict of interest, then the Directive adopts a partial and biased solution to that problem. It bars only scientists who receive EPA grants. These scientists will generally be based at universities. The Directive does not, however, bar scientists who receive funding from regulated industries that will be affected by EPA regulatory decisions. Nothing in the Directive provides any justification for treating one source of funding as disqualifying and the other as acceptable. Instead, ironically, the practical effect of the Directive has been to make the scientific advisory committees less independent by increasing the representation of industry scientists.⁵⁴

⁵⁴ See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO 19-280, EPA ADVISORY COMMITTEES: IMPROVEMENTS NEEDED FOR THE MEMBER APPOINTMENT PROCESS 22 (2019) (reporting “a notable decrease in the percentage of members affiliated with academic institutions on the SAB and EPA Board of Scientific Counselors . . . committees after January 2017”), <https://www.gao.gov/assets/710/700171.pdf>. In a further irony, the report found that from 2017-2018, “EPA did not consistently ensure that 74 [special government employees] appointed or reappointed to serve on EPA advisory committees met federal financial-disclosure requirements.” *Id.* at 19. In other words, at the same time it was issuing a Directive purportedly aimed at addressing financial conflicts of interest, EPA was violating Office of Government Ethics regulations.

CONCLUSION

For the foregoing reasons, *amici* respectfully request that this Court deny Defendants' Motion to Dismiss or for Summary Judgment and grant Plaintiff's Cross-motion for Summary Judgment.

Dated: October 16, 2019

Respectfully submitted,

/s/ Shaun A. Goho

Shaun A. Goho (Admitted Pro Hac Vice)

MA BBO No. 652287

Lynne I. Dzubow

Emmett Environmental Law & Policy Clinic⁵⁵

Harvard Law School

6 Everett Street, Suite 5116

Cambridge, MA 02138

(617) 496-5692 (office)

(617) 384-7633 (fax)

sgoho@law.harvard.edu

Counsel for Amici Curiae

Lynn R. Goldman, et al.

⁵⁵ The Clinic would like to acknowledge the contributions of Erik Federman (JD '18) to this brief.

CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of October, 2019, I electronically filed with the Clerk of the United States District Court for the Southern District of New York via the CM/ECF System the foregoing Amicus Brief. All participants in the case are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

Dated: October 16, 2019

/s/ Shaun A. Goho
Shaun A. Goho