

## Annual Review of Public Health

# Deregulation and the Assault on Science and the Environment

### Jonathan M. Samet<sup>1</sup> and Thomas A. Burke<sup>2</sup>

- <sup>1</sup>Colorado School of Public Health, University of Colorado Anschutz Medical Campus, Aurora, Colorado 80045, USA; email: jon.samet@cuanschutz.edu
- <sup>2</sup>Department of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Maryland 21205, USA; email: tburke1@jhu.edu



#### www.annualreviews.org

- Download figures
- · Navigate cited references
- Keyword search
- Explore related articles
- Share via email or social media

Annu, Rev. Public Health 2020, 41:347-61

First published as a Review in Advance on January 6, 2020

The Annual Review of Public Health is online at publhealth.annualreviews.org

https://doi.org/10.1146/annurev-publhealth-040119-094056

Copyright © 2020 by Annual Reviews. This work is licensed under a Creative Commons Attribution 4.0 International License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. See credit lines of images or other third-party material in this article for license information.

#### **Keywords**

environment, deregulation, public health

#### **Abstract**

The quality of the environment is a major determinant of the health and well-being of a population. The role of scientific evidence is central in the network of laws addressing environmental pollution in the United States and has been critical in addressing the myriad sources of environmental pollution and the burden of disease attributable to environmental factors. We address the shift away from reasoned action and science to a reliance on belief and document the efforts to separate regulation from science and to remove science-based regulations and policies intended to protect public health. We outline the general steps for moving from research to policy, show how each has been undermined, offer specific examples, and point to resources that document the enormity of the current efforts to set aside scientific evidence.



#### INTRODUCTION

One major determinant of the health and well-being of a population is the quality of the environment. In promoting public health in general, the starting point for taking action has long been the scientific evidence on the causes of problems and the implications of the causes identified for the control measures to be used. This evidence-grounded starting point has been critical in addressing the myriad sources of environmental pollution; controlling the innumerable pollutants that contaminate air, water, and food; and reducing the burden of disease attributable to environmental factors. The role of scientific evidence is central in the network of laws addressing environmental pollution in the United States (**Table 1**); in fact, the necessity of relying on reason and science in our government and laws dates to the founding of the country.

Here, we address the shift away from reasoned action and science to reliance on belief and the once insidious but now blatant efforts to separate regulation from science and to remove science-based regulations and policies intended to protect public health. We outline the general

Table 1 Major environmental laws in the United States

Acts	Regulation	Year	Description
Clean Air Act (CAA)	42 U.S.C. §7401	1970, 1977, 1990	Authorizes the Environmental Protection Agency (EPA) to establish National Ambient Air Quality Standards (NAAQS) to protect public health and welfare from hazardous air pollutants. The law regulates air emissions from stationary and mobile sources.
Occupational Safety and Health Act (OSHA)	29 U.S.C. §651	1970	Ensures worker and workplace health safety by providing a place of employment free from recognized hazards such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress, or unsanitary conditions.
Clean Water Act (CWA)	33 U.S.C. §1251	1972	Establishes the fundamental structure for regulating discharges of pollutants into US waters and quality standards for surface waters (e.g., pollution control programs such as setting wastewater standards for industry and permit programs to control discharges).
Safe Drinking Water Act (SDWA)	44 U.S.C. §300	1974, 1996	Protects the quality of drinking water—actually or potentially designed for drinking use, whether from above ground or underground sources. The EPA establishes minimum standards to protect tap water and requires all owners or operators of public water systems to comply with health-related standards.
Toxic Substances Control Act (TSCA)	15 U.S.C. §2601	1976, 2016	Provides the EPA authority to require reporting, record keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures during production, importation, use, and disposal of chemicals. Chemicals include polychlorinated biphenyls (PCBs), asbestos, radon, and lead-based paint. Other substances such as food, drugs, cosmetics, and pesticides are generally excluded.
Federal Insecticide, Rodenticide, and Fungicide Act (FIFRA)	7 U.S.C. §136	1947, 1972, 1996	Governs the registration, distribution, sale, and use of pesticides in the United States. All pesticides distributed or sold in the United States must be registered (and licensed) by the EPA. According to the statute, a pesticide is any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant or any nitrogen stabilizer.

(Continued)

Table 1 (Continued)

Acts	Regulation	Year	Description
National	42 U.S.C. §4321	1969	Assures that all branches of government give proper consideration
Environmental			to the environment prior to commencing any major federal
Policy Act			action that significantly affects the environment. The most
(NEPA)			notable NEPA requirements are the Environmental Assessments
			(EAs) and Environmental Impact Statements (EISs), which are
			assessments of the likelihood of impacts from alternative courses
			of action. Projects governed by this statute include airports,
			buildings, military complexes, highways, and parkland purchases.
Resource	42 U.S.C. §6901	1979, 1986	Gives the EPA the authority to control hazardous waste from the
Conservation			"cradle-to-grave." This involves the generation, transportation,
and Recovery			treatment, storage, and disposal of hazardous waste. The RCRA
Act (RCRA)			also sets a framework for the management of nonhazardous solid
			wastes by focusing on waste minimization and phasing out land
			disposal of hazardous waste.
Comprehensive	42 U.S.C. §9601	1980, 1986	Provides a federal superfund to clean up uncontrolled or abandoned
Environmental			hazardous-waste sites in addition to accidents, spills, and other
Response,			emergency releases of pollutants and contaminants into the
Compensation,			environment. The EPA is authorized to implement the Act in all
and Liability			50 states and US territories. The identification, monitoring, and
Act (CERCLA			response activities in superfund sites are coordinated through the
or Superfund)			state environmental protection or waste management agencies.

steps for moving from research to policy and show how each has been undermined. We offer specific examples and point to resources that document the enormity of the current efforts to set aside scientific evidence.

While the shift away from scientific evidence and expertise antedates the current US presidential administration, the approach of directly separating regulation and policy from scientific evidence and guidance by knowledgeable experts has been implemented widely with the Trump administration. This shift has been fueled by the false promise of relieving the economic burdens of regulation and justified by undermining or denying the scientific evidence base that provides the foundation for protecting public health. It also comes at a political moment when powerful and monied interests can play out an antiregulatory agenda (16).

We begin with a broad overview of environmental protection at the national level in the United States. Through multiple statutes, the US Environmental Protection Agency (EPA) is mandated to protect the environment (Table 1). Other agencies also have missions concerned with environmental protection (e.g., the Department of Energy and nuclear wastes, the Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry and contaminated industrial sites, and the Department of the Interior and public lands), but our focus is on the EPA and its broad mandate to fulfill its mission: "The mission of EPA is to protect human health and the environment" (https://www.epa.gov/). The agency was founded in 1970 by President Richard Nixon, a Republican, and consolidated various entities concerned with the environment. By 1970, multiple seminal events were driving the creation of a central agency to deal with the deteriorating environment in the United States: the publication of Rachel Carson's Silent Spring in 1962, the Cuyahoga River fire in 1969, the first Earth Day in 1970, and widespread and noticeable deterioration of air and water quality across the country (3, 5, 23).

Over the ensuing half century, the EPA has put into place a set of procedures to use scientific evidence of broad scope to assure that its actions are grounded in what will be effective to protect

the environment and human health. Underlying methodologies include systems to identify the most relevant scientific evidence, to integrate the evidence for decision making and policy formulation, and to track the consequences of policy changes. Quantitative risk assessment is a core methodology and involves formulating the problem, identifying hazards, assessing exposures, determining dose–response relationships, and characterizing risk (17). Cost-benefit analyses are completed under some statutes to guide risk-management decisions.

To carry out its mission, the EPA has its own research capabilities housed within the Office of Research and Development, while supporting extramural researchers as well. It also has the scientific staff needed to facilitate the translation from scientific evidence to policy and regulation; and through its Science Advisory Board and various committees, it obtains broad, multidisciplinary guidance for its activities. This core of scientists and the scientific review processes they carry out, developed over 50 years, have been dramatically eroded during the present administration. While we focus here on the EPA, science has been similarly diminished at other agencies in this administration.

#### **DEREGULATION**

The elimination or rollback of regulations has been a hallmark of the Trump administration. At the 2018 World Economic Forum in Davos, Switzerland, the president declared, "I pledged to eliminate two unnecessary regulations for every one new regulation. We have succeeded beyond our highest expectations" (40). In 2017, President Donald Trump issued Executive Order (E.O.) 13771, which directs all agencies to repeal at least two existing regulations for each new regulation issued in FY 2017 and thereafter. It also provided a directive to the agencies regarding costs such that the "total incremental costs of all regulations should be no greater than zero" in FY 2017, and guidance in subsequent years has followed this principle. For FY 2018 and beyond, the director of the Office of Management and Budget (OMB) is to provide agencies with a total amount of incremental costs that will be allowed.

E.O. 12866 continues to provide agencies with structure over regulatory planning and review. As such, OMB instructs agencies, except where prohibited by law, to continue to assess and consider both the benefits and costs of regulatory actions, including deregulatory actions, when making regulatory decisions, and issue regulations only upon a reasoned determination that benefits justify costs. (29)

This aggressive deregulation, with support of major industries including coal, oil and gas, chemicals, and industrial agriculture, has the potential to profoundly and unfavorably impact the nation's environmental quality and public health. A concerning prospect has long been amendments to the core statutes concerned with the environment that would weaken them (**Table 1**). Scenarios can be envisioned with a single party controlling the presidency and Congress that would weaken the laws that are the foundation of environmental protection. For this reason, the Clean Air Act has not been amended since 1990, largely reflecting concern that amendments could reduce the effectiveness of the regulations that it mandates. However, the Toxic Substances Control Act was successfully amended with bipartisan support in 2016 with passage of The Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Although the national statutes provide the framework for environmental protection, the agencies of the executive branch are charged with implementation and have broad authority to shape the policies, rules, and resources. From climate change to water resources, air pollution to pesticides and toxic chemicals, the Trump EPA has moved to delay, revise, and rescind regulations. These actions have been accompanied by, indeed often justified by, an assault on the scientific evidence required by the laws and that provide the essential characterization of adverse impacts,

Table 2 Deregulation: assaulting the science

Action	Links				
Rolled back, rescinded, or revised policies and rules					
Paris Agreement Clean Power Plan Waters of the United States Chlorpyrifos ban reversal	https://www.whitehouse.gov/briefings-statements/statement-president-trump-paris-climate-accord/ https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-year-regulatory-reform-environmental-protection-epa/ https://www.epa.gov/wotus-rule/step-one-repeal https://www.epa.gov/newsreleases/epa-administrator-pruitt-denies-petition-ban-widely-used-pesticide-0				
Research cuts					
Climate change research Chemical safety and sustainability Science and technology budget Elimination of Science to Achieve Results Program	https://budget.house.gov/publications/report/president-trump-s-2020-budget-dangerous-exercise-ignoring-reality-and-threat https://www.epa.gov/planandbudget/fy-2020-epa-budget-brief https://www.epa.gov/sites/production/files/2019-04/documents/fy20-cj-03-science-technology.pdf				
Scientific peer review					
Dismissal of Board of Scientific Counselors Science Advisory Board changes Clean Air Science Advisory realignment	https://www.sciencemag.org/news/2017/06/epa-axes-38-more-science-advisers-cancels-panel-meetings https://www.sciencemag.org/news/2017/11/epa-unveils-new-industry-friendlier-science-advisory-boards https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee				
Limiting the evidence base	, , , , , , , , , , , , , , , , , , ,				
Restrict scientific findings supporting regulation Exclude historical epidemiologic data Narrow focus of evidence reviews and exposure assessments for chemical hazards	https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations https://www.epa.gov/sites/production/files/2018-06/documents/ final_application_of_sr_in_tsca_05-31-18.pdf				
Revising scientific methods					
Less protective risk assessment promoting threshold assumption Revision of guidelines for cancer and noncancer effects Limited scope of benefit cost analysis	https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations https://yosemite.epa.gov/sab/sabproduct.nsf/ LookupWebReportsARsLastMonthBOARD/ E7CB10891C8CAD8F852582B3006EFAF7/ \$File/EPA-SAB-18-002_Response.pdf https://www.epa.gov/newsreleases/epa-administrator-wheeler-sends-cost-benefit-analysis-memo-assistant-administrators				

health risks and benefits of control, and costs of regulation. **Table 2** provides a broad classification of these actions; **Supplemental Table 1** provides a more exhaustive compilation assembled as this article was written in 2019. As a further resource, *The New York Times* is tracking the weakening of environmental regulations (21).

Supplemental Material >

# PATHWAYS TO REDUCING THE IMPACT OF SCIENTIFIC EVIDENCE ON ENVIRONMENTAL PROTECTION

Former EPA Administrator Lisa Jackson declared that science is "the backbone" of EPA (14). Science is essential to decision making throughout the agency, from the highest levels of national

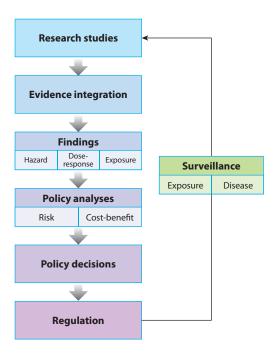


Figure 1
Path from research to action to protect the environment and human health.

policies to the routine staff-level decisions on permitting and rule compliance. **Figure 1** provides an admittedly simplified representation of the path from research to action to protect the environment and human health. Some examples do follow such a sequential approach, e.g., the process for reviewing whether new scientific evidence warrants a revision of the National Ambient Air Quality Standards (NAAQS). This stepwise process includes a public workshop to identify new scientific evidence; an integrated science plan to review the science in light of the statutory mandates to protect public health; an integrated science assessment to review the science; a risk and exposure assessment; and a policy assessment to provide the scientific basis for alternative policy options. Scientific peer review of the various elements of the process is fundamental to the quality, integrity, and credibility of the process. We use this general framework (**Figure 1**) to anchor our discussion of the separation of decision making from a scientific foundation.

The starting point of environmental protection is the scientific research that addresses the determinants of risk. Such research comes from multiple domains of investigation: in vitro toxicology to explore mechanisms and pathways of injury, animal and sometimes human exposure studies to screen for adverse effects and to quantify risks, and epidemiological studies that capture the effects of exposures as naturally experienced in the population. A next step in decision making is to integrate the evidence for the purpose of policy formulation. Investigators ask one initial question: Does the agent pose a hazard? This determination constitutes a causal judgment, one made with a weight-of-evidence expert judgment, comparable to that used for decades in identifying the adverse consequences of tobacco products. Over time, the EPA has elaborated a number of weight-of-evidence frameworks that have become embedded into its decision-making processes (28, 35).

Depending on the regulatory jurisdiction, the determination that an agent causes a hazard may be followed by estimation of the concentration—/exposure—/dose—response relationship for

the purpose of quantifying risk. The data for this purpose may come from toxicological or epidemiological studies, either considered individually or pooled. Complementary information on the distribution of exposure in the population and on those exposed is needed to fully characterize risk at the population level and to assess how different regulatory scenarios would reduce risk. This last step, risk characterization, also identifies critical points of uncertainty as they relate to decision making.

What is being eroded during the current administration? **Table 2** presents examples of regulatory rollbacks and the accompanying assault on the EPA's scientific capacity, including research cuts, manipulation of peer review, limitations on the evidence base, and revision of established scientific methods.

#### CUTTING AND ELIMINATING RESEARCH

Various national laws require the EPA to act when the scientific evidence reveals threats to our environment and public health. Simply put, no new evidence means no need for regulations or tightening of regulations. In fact, reducing or eliminating the advancement of research is a short-sighted but effective means to deregulate. Without new evidence, new regulations are not needed. One enacted strategy has been to slow or end research intramurally and extramurally through executive decisions and budget cuts.

The Trump administration has continually recommended reducing the total EPA budget (30, 31, 34). The EPA's Science and Technology budget has been particularly hard hit, with recommended reductions of 37%. Within the Office of Research and Development, key programs on climate change and energy have been cut or eliminated (see **Table 2**). In addition, research to support key science assessments of hazardous chemicals and air pollutants has been cut and delayed by shifting administration priorities (36).

EPA extramural funding provides needed support for academic research across the nation to address critical gaps in the scientific foundation for protecting human health from environmental threats. The highly competitive Science to Achieve Results (STAR) program has supported extramural researchers carrying out targeted projects to support the EPA's mission. STAR fellowships supported the education and training of emerging environmental science leaders. This program has been eliminated in the 2020 budget (34). The EPA has also discontinued funding for 13 Children's Environmental Health and Disease Prevention Research Centers. These centers have studied the impacts of environmental exposure on childhood development, including long-term developmental impacts of exposures to neurotoxicants such as lead and pesticides. Research conducted by one of these centers was pivotal to the EPA's proposed ban of the pesticide chlorpyrifos. The pesticide industry has challenged these findings and former EPA Administrator Scott Pruitt rejected the plan to move ahead with the ban (12).

#### **Manipulating Peer Review**

At various points throughout rulemaking processes, stakeholders are given the opportunity for input as are other agencies and branches of government, including the executive branch through the OMB. Stakeholders include a broad range of interests, ranging from environmental and public health organizations to trade associations and businesses affected by regulatory policies. Comments are made publicly, whether at open hearings or through publicly accessible dockets. Stakeholder review and comment have traditionally focused on the identification of concerns about the impacts of policies. However, businesses are increasingly following the lead of the tobacco industry in attacking or denying the scientific evidence supporting regulation.

Scientific peer review involves the careful assessment of the data, methods, and conclusions of studies that provide the evidence base for policy. Independent and transparent peer review has long been embedded in the agencies' processes, with thousands of external and internal scientists contributing over the decades of the EPA's existence. The EPA expects peer review of all scientific information intended to inform agency decisions. For scientific reports supporting major policies or highly influential scientific assessments, independent external peer review is the expected procedure (for example, 24, 25). The credibility of the science depends on independent review by experts who are highly knowledgeable in the disciplines most relevant to the evidence base. In addition, the EPA has considered and balanced potential biases in the reviewers and eliminates any reviewers who may have conflicts of interest. High-level peer reviews at EPA are conducted primarily through the EPA's Science Advisory Board, program-specific federal advisory committees, and committees of the National Academies of Science, Engineering, and Medicine.

One policy advanced by former EPA Administrator Pruitt with broad implications for the credibility of peer review excludes EPA-funded scientists from Science Advisory Board membership while easing restrictions on membership in the EPA committees by industry scientists (10). A net result could be a shift in the balance of committees from having the most knowledgeable participants to including more members with potential bias and conflicts of interest, whether disclosed or undisclosed. The current membership of the Science Advisory Board is widely viewed as tilted away from the protection of public health when compared with membership during prior administrations. A 2019 report from the Government Accountability Office (GAO) documents the changes in the composition of the Science Advisory Board and other EPA advisory committees (38). Under the Trump administration, the proportion of academic members of the Science Advisory Board dropped sharply with increases in industry and consultant members.

#### Limiting the Evidence Base

Another step, long supported by certain industrial stakeholders, has been the attempted exclusion of some evidence from consideration in decision making. Epidemiological studies have been a specific focus of this effort, owing to the weight given to epidemiological findings in decision making as addressing real-world exposures. The strategy originated with the 1997 revision of the NAAQS for airborne particulate matter (PM). In revising the PM NAAQS, the EPA relied on the results of two epidemiological cohort studies [the Harvard Six Cities study and the American Cancer Society's Cancer Prevention Study II (CPS II)], both showing that exposure to PM pollution increased risk of dying over the long term, implying that the association of air pollution with daily mortality observed in many studies of daily mortality was not merely a slight shortening of life span (2, 4). At the time of the review of the PM NAAQS, there were claims (27) that the investigators leading the two cohort studies had selectively modeled the data to produce positive results, that confounding was not controlled, and that the data were flawed. These claims were addressed with a congressionally mandated reanalysis done through the Health Effects Institute, which found the data to be valid and replicated the findings of the original investigators (15).

The Republican Congress responded quickly to the controversy around the findings of the studies. The 1998 Shelby Amendment to OMB's Circular A-110, which governs federally funded research, required the release of study data used to support any agency action that has the force of law (6). Under the Shelby Amendment, the investigators are required to release data in response to requests made under the Freedom of Information Act.

The effort to advance laws demanding data access for critical studies has continued. The House Committee on Science, Space, and Technology, when the House of Representatives was led by a Republican majority (2012–2018), proposed a number of measures best exemplified by the Secret

Science Reform Act (26). The premises of the act are that researchers are covering up deficiencies in their data and conducting selective analyses and that the resulting misleading findings could be addressed by unrestricted data access so that data quality could be examined and independent analyses conducted. However, epidemiological researchers have been reluctant to make data generally available, adhering to commitments made to research participants to maintain privacy and confidentiality. The most recent tactic related to data access comes from the EPA in the form of its 2018 rule, Strengthening Transparency in Regulatory Science, which calls for access to data and also to the code underlying analyses (22). In 2019, as this article is being completed, the administration is moving forward to implement the rule (8). Such transparency has become state-of-practice in some fields as part of the move to assure rigor and reproducibility. However, in a rulemaking context, data access could readily lead to conflicting findings from the same data sets if skilled analysts seek to push results toward or away from the null. Additionally, the logistics, processes, and funding for such data sharing have yet to be addressed. The underlying strategy has been labeled as "weaponized transparency" (7).

#### **Revising the Scientific Methods**

The national laws and the mission of the EPA require "the protection of the environment and public health" (33). EPA has been an international leader in developing methods to identify environmental and health risks, to characterize the magnitude of those risks, and to present the benefits and costs of risk management policies. These methods have been subject to extensive peer review, including major studies by the National Academies of Science, Engineering, and Medicine (17). The EPA risk assessment methods, including carcinogen risk assessment, noncancer risk assessment, exposure assessment, children's health risk assessment, and ecological risk assessment, are presented in a series of guideline documents (37).

Because risk assessments are the basis for so many EPA policies and standards, they have long been challenged by both regulated industries and environmentalists for being either too protective or not protective enough. Because there are inherent uncertainties in risk assessment (e.g., Do animal results predict human health effects?), the assessments depend on the use of evidence-informed assumptions and judgments called defaults. One notable default is the application of the assumption that there is no threshold for potential effects from exposure to carcinogens. That is, any exposure to a genotoxic carcinogen results in some degree of increased cancer risk in a population. The EPA employs a linear no-threshold approach to cancer risk assessment. That approach has been reviewed and supported by the National Academies, yet it is extremely contentious with industry representatives because, with this default, a determination that a chemical or product is carcinogenic implies that there is no safe level of exposure, a finding that may trigger regulatory action (17).

Cost-benefit analysis is another essential assessment tool used by the EPA to quantify and compare the environmental and health benefits of a regulation to the costs of implementation. An ideal outcome might be when the costs of regulating a risk are very small compared with the benefits; i.e., the benefits outweigh the costs. The ratio of benefits to costs of compliance are clearly dependent on the range of benefits and costs included in the calculation.

EPA Administrator Andrew Wheeler has initiated moves to examine and change the established methods for both risk assessment and cost-benefit analysis. The proposed rule Strengthening Transparency in Regulatory Science will require the application of alternative approaches to the no-threshold model for cancer-causing pollutants. In addition, Wheeler has requested that his industry-friendly Science Advisory Board examine guidelines for risk assessment. Wheeler has also directed the political appointees leading the agency programs to reform how costs and benefits are considered in the rulemaking process (39).

The general framework (**Figure 1**) points to another point for separating science from decision making: changing the processes for evidence integration. The current chair of EPA's Clean Air Scientific Advisory Committee (CASAC), which provides peer review and guidance to the EPA as it considers revision of the NAAQS, has brought forth ideas concerning causal inference that threaten well-established and accepted weight-of-evidence approaches (see below), although these ideas have not yet been systematically executed. An overall consequence of the methodologies advanced by the CASAC chair would be the exclusion of findings of some epidemiological studies. To date, the in-progress review of the PM NAAQS has been slowed by the interjections of the CASAC chair (9, 18).

#### CASE STUDIES

#### The National Ambient Air Quality Standards

Here, we use the example of the Clean Air Act and the current review of the PM NAAQS to show how these strategies are being played out in a way that could threaten the protection of public health afforded by the NAAQS (32). The original Clean Air Act dates from 1970 during the presidency of Richard Nixon. Under the act, a committee, the CASAC, provides guidance to the agency for the establishment of the NAAQS under Sections 108 and 109. For the six current pollutants covered under these sections, evidence-based standards are to be set by the administrator with "an adequate margin of safety."

The EPA has put in place a process for moving from evidence to NAAQS revisions that has proved effective over the last decade (**Figure 2**). The process includes the development of a plan

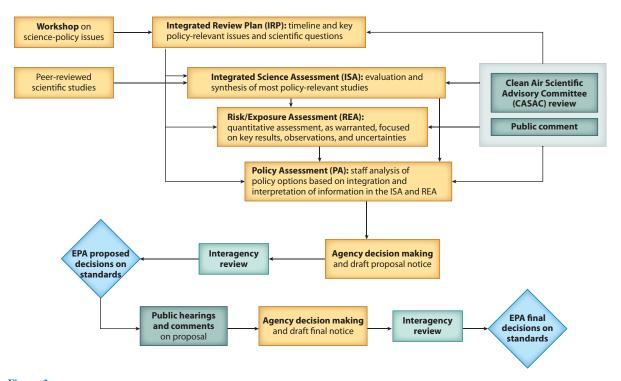


Figure 2

The NAAQS: changing the game. Schematic of the key steps in review of the National Ambient Air Quality Standards.

for review, the completion of a literature review that focuses on advances over the five years since the prior assessment (the integrated science assessment, or ISA), a risk assessment comparing impacts of various regulatory scenarios (the risk/exposure assessment, or REA), and finally the policy assessment (PA), which sets out policy options for the administrator.

Critical steps in that sequence are now threatened: the generation of evidence, as the EPA has eliminated its grants program and reduced the scope of its scientific enterprise; proposals to restrict the evidence considered under the proposed transparency rule; and limitations on appointees to CASAC and other committees that remove some of the most knowledgeable scientists while allowing industry scientists. Further issues have emerged during the currently ongoing review of the PM ISA, including the dismissal of 17 experts appointed to complement the seven chartered CASAC members appointed under the CAA and introduction of approaches to evidence evaluation and synthesis by the CASAC chair that sharply depart from those already and successfully in place (Figure 2). The proposed approach moves away from the long-established guidelines of the 1964 Surgeon General's Report and Sir Austin Bradford Hill toward emphasizing studies that address manipulations in exposures by policy or source changes. Emphasis is also given to effect estimates from causal modeling. Overall, this approach is untested and not the state of practice. The reach of these changes across the full process is alarming.

#### Climate Change and the Denial of Science

Perhaps no other issue demonstrates more plainly the assault on science in the name of deregulation than the reversal of EPA climate change policies. Led by the president who has called climate change a "hoax," EPA leadership has supported the US withdrawal from the Paris Agreement and moved to rescind or roll back the key regulations aimed at reducing greenhouse gas emissions and promoting renewable noncarbon-based energy sources. At the same time, the Intergovermental Panel on Climate Change continues to warn that the adverse consequences of global warming are already evident and that preventing the dire consequences of warming to 1.5° centigrade will require "rapid and far reaching" actions (13).

While working to rescind and replace the Clean Power Plan, the EPA froze the vehicle fuel economy rules and initiated widespread rollbacks to deregulate and promote the fossil fuel industry (see **Supplemental Table 1**). Ignoring the work of agency career professionals and scientists, plans were made by the Trump administration's EPA to convene a panel of climate change deniers to challenge the established evidence. Research programs were refocused away from tracking and researching the impacts of climate change.

From extreme weather events to droughts and wildfires, the EPA has broad responsibility to protect the environment and public health. Yet, in the face of undeniable evidence of the reality of global warming, the administration continues to assault the science and promote energy policies that pose unfathomable risks to the global environment and human health.

#### CLOSING COMMENTS

Over the almost five decades since the EPA was established and laws were passed to support its efforts to reduce environmental contamination, progress has been made in curbing environmental pollution. The benefits are clear: cleaner waters and clearer skies and documented health benefits that have been achieved in a cost-effective manner. Yet, environmental problems that need to be regulated persist, and new contaminants continue to be identified that pose risks to human and ecosystem health. Most worrisome is the global threat posed by climate change, a consequence of our exceeding the capacity of the planet to handle the load of greenhouse gases. National

Supplemental Material >

survey data continue to show that most Americans want to maintain environmental quality and are concerned about climate change (1).

But environmental protection has become politicized such that the present administration has set out systematically to (a) displace scientific evidence as the foundation for regulations to control environmental threats to human and ecosystem health, (b) distance scientific expertise from decision-making processes, (c) weaken or eliminate rules and regulations that are intended to control environmental pollution, and (d) diminish the role of the EPA in protecting the environment. We cite numerous examples that document this characterization of how the administration has proceeded. Cynically, some stakeholders, particularly the fossil fuel and chemical industry sectors, have pushed for less regulation without consideration of the external costs of their actions. Short-term corporate profits are being made at the sacrifice of common goods: environmental quality and human health. The "tragedy of the commons" is being played out too quickly as the societal principles underlying regulation have been abandoned (11). The actions taken with regard to deregulation cannot readily be fit nor explained by conceptual frameworks or regulation. The interests of industrial stakeholders are dominating policy.

Here, we have described the strategies used to undermine the numerous processes that undergird the rules and regulations coming from the EPA that protect the environment. In the end, all strategies aim to sever the connection between scientific evidence and decision making. The scope and comprehensiveness of the strategies in play are alarming, and their effects are becoming evident. We are hopeful that there will be a rebuilding of what has been destroyed, but fixing the loss of scientific expertise from government agencies, rebuilding research, and restoring the links between science and environmental protection will not happen quickly.

We are also concerned that the activities lumped here as deregulation have motivated little public outcry. Members of the scientific community have spoken out, but their voices have little reach beyond those scientists and politicians who are already aware. For the public generally, the subtleties of what is being done by the administration cloak their impact. And, there is a general turn by the public away from trust in science and scientists and rising emphasis on personal belief over expertise (19, 20).

Is there a solution for this turn away from science and scientific evidence? With regard to the deregulatory processes at EPA, and elsewhere in the federal government, a shift of views among politicians is needed and the distressing politicization of science needs to be undone. How can the interpretation of scientific evidence be based on political party? Many have written about the public's dismissal of scientific evidence and expertise, even when the consequences can be dire, e.g., measles outbreaks in the United States and elsewhere. The proposed solutions make sense—increasing scientific literacy and better and more far-reaching communications through social media, as examples—but implementation challenges remain. Who is responsible for taking action?

There is a basis for some optimism. In the face of deregulation at the national level, some states and cities are taking action on climate change, and we are hopeful that the public will respond if environmental gains are lost. In California, for example, Assembly Bill 32 (California Global Warming Solutions Act) addresses climate change, and some major cities have committed to emissions reductions that would have been targets for the United States under the Paris Agreement. Research continues to deepen our understanding of how the environment can damage human health, and new tools, whether citizen science or -omics, are making research more informative for decision making. Strengthening the scientific foundation for action should continue, while awaiting a future of greater receptivity to science by government and the public at large.

#### **DISCLOSURE STATEMENT**

T.A.B. served as EPA Science Advisor and Deputy Assistant Administrator for Research and Development (2015–2017) and received grant support from the Environmental Defense Fund for research on assessing the health risks of toxic chemicals (funding was not related to the writing of this article and was awarded after the writing was complete).

#### **ACKNOWLEDGMENTS**

We thank Meghan Buran, MPH (Department of Epidemiology, Colorado School of Public Health), for her assistance in documenting deregulation policies discussed in this work.

#### LITERATURE CITED

- Anderson M. 2017. For Earth Day, bere's how Americans view environmental issues. Pew Res. Cent., Fact Tank, April 20. https://www.pewresearch.org/fact-tank/2017/04/20/for-earth-day-heres-how-americans-view-environmental-issues/
- Pope CA III, Thun MJ, Namboodiri MM, Dockery DW, Evans JS, et al. 1995. Particulate air pollution
  as a predictor of mortality in a prospective study of U.S. adults. Am. J. Respir. Crit. Care Med. 151:669–74
- 3. Carson R. 1962. Silent Spring. New York: Houghton Mifflin
- Dockery DW, Pope CA III, Xu X, Spengler JD, Ware JH, et al. 1993. An association between air pollution and mortality in six U.S. cities. N. Engl. 7. Med. 329:1753–59
- Earth Day Netw. 2019. The history of Earth Day. Earth Day Network. https://www.earthday.org/about/ the-history-of-earth-day/
- Fischer EA. 2013. Public access to data from federally funded research: provisions in OMB Circular A-110. Rep., Congr. Res. Serv., Washington, DC. https://fas.org/sgp/crs/secrecy/R42983.pdf
- Friedman L. 2018. The E.P.A. says it wants research transparency. Scientists see an attack on science. New York Times, March 26. https://www.nytimes.com/2018/03/26/climate/epa-scientific-transparency-honest-act.html
- Friedman L. 2019. E.P.A. to limit science used to write public health rules. New York Times, Nov. 11. https://www.nytimes.com/2019/11/11/climate/epa-science-trump.html
- Goldman GT, Dominici F. 2019. Don't abandon evidence and process on air pollution policy. Science 363:1398–400
- Halpern M. 2017. The EPA Science Advisory Board is being compromised. Here's why it matters. Union of Concerned Scientists Blog, Oct. 30. https://blog.ucsusa.org/michael-halpern/the-epa-science-advisory-board-is-being-compromised-heres-why-that-matters
- 11. Hardin G. 1968. The tragedy of the commons. Science 162:1243–48
- Hiar C, Wittenberg A. 2019. EPA plan to end funding for children's health research leaves scientists scrambling. Science, May 20. https://www.sciencemag.org/news/2019/05/epa-plan-end-fundingchildren-s-health-research-leaves-scientists-scrambling
- 13. IPCC (Intergov. Panel Clim. Change). 2018. Global Warming of 1.5°C. An IPCC Special Report on the Impacts of Global Warming of 1.5°C Above Pre-Industrial Levels and Related Global Greenhouse Gas Emission Pathways, in the Context of Strengthening the Global Response to the Threat of Climate Change, Sustainable Development, and Efforts to Eradicate Poverty. Geneva: IPCC-World Meteorol. Organ.
- Jackson LP. 2010. Scientific integrity in federal government. Email, Off. Adm. Environ. Prot. Agency, Washington, DC. https://www.peer.org/wp-content/uploads/attachments/1\_24\_11\_Lisa\_Jackson\_ science\_integrity\_message.pdf
- 15. Krewski D, Burnett RT, Goldberg MS, Hoover K, Siemiatycki J, et al. 2000. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality. Investigators' reports parts I and II. Spec. Rep., Health Effects Inst., Cambridge, MA. https://www.healtheffects.org/ system/files/HEI-Reanalysis-2000.pdf

- Mayer J. 2016. Dark Money: The Hidden History of the Billionaires Behind the Rise of the Radical Right. New York: Penguin Random House
- Natl. Res. Counc. 2009. Science and Decisions: Advancing Risk Assessment. Washington, DC: Natl. Acad. Press
- 18. Nature. 2019. Stop denying the risks of air pollution. Nature 568:433
- Nichols T. 2017. The Death of Expertise: The Campaign Against Established Knowledge and Why It Matters. New York: Oxford Univ. Press
- Otto SL. 2016. The War on Science: Who's Waging It, Why It Matters, What We Can Do About It. Minneapolis, MN: Milkweed
- Popovich N, Albeck-Ripka L, Pierre-Louis K. 2019. 95 environmental rules being rolled back under Trump. New York Times, updated Dec. 21. https://www.nytimes.com/interactive/2019/climate/trump-environment-rollbacks.html
- Progr. OSA (Off. Sci. Advis.). 2018. Strengthening transparency in regulatory science. Proposed Rule, Environ. Prot. Agency, Washington, DC. https://www.epa.gov/osa/strengthening-transparency-regulatory-science
- Rotman M. 2010. Cuyahoga River Fire. Cleveland Historical. https://clevelandhistorical.org/items/ show/63
- Sci. Policy Counc., US EPA (Environ. Prot. Agency). 2006. U.S. Environmental Protection Agency Peer Review Handbook. Washington, DC: US EPA
- Sci. Policy Counc., US EPA (Environ. Prot. Agency). 2015. U.S. Environmental Protection Agency Peer Review Handbook. Washington, DC: US EPA. 4th ed.
- Sneed A. 2017. House science committee may soon try to weaken the EPA. Scientific American, Feb. 8. https://www.scientificamerican.com/article/house-science-committee-may-soon-try-to-weaken-the-epa/
- US EPA (Environ. Prot. Agency). 1996. Responses to significant comments on the 1996 proposed rule on the National Ambient Air Quality Standards for Particulate Matter. Docket A-95-54, US EPA, Washington, DC. https://www3.epa.gov/ttn/naaqs/standards/pm/data/rtc\_pm.pdf
- US EPA (Environ. Prot. Agency). 2005. Guidelines for carcinogen risk assessment. EPA/630/P-03/001B, EPA, Washington, DC. https://www3.epa.gov/airtoxics/cancer\_guidelines\_final\_3-25-05.pdf
- US EPA (Environ. Prot. Agency). 2017. Executive Order 13771—Reducing regulation and controlling regulatory costs. US Environmental Protection Agency Laws & Regulations. https://www.epa.gov/lawsregulations/executive-order-13771-reducing-regulation-and-controlling-regulatory-costs
- US EPA (Environ. Prot. Agency). 2017. FY 2018 EPA budget in brief. EPA-190-K-17-001, US EPA, Washington, DC. https://www.epa.gov/sites/production/files/2017-05/documents/fy-2018-budget-in-brief.pdf
- US EPA (Environ. Prot. Agency). 2018. FY 2019 EPA budget in brief. EPA-190-R-18-002, US EPA, Washington, DC. https://www.epa.gov/sites/production/files/2018-02/documents/fy-2019-epabib.pdf
- 32. US EPA (Environ. Prot. Agency). 2018. Integrated Science Assessment (ISA) for particulate matter (external review draft). EPA/600/R-18/179, US EPA, Washington, DC
- US EPA (Environ. Prot. Agency). 2018. Our mission and what we do. US Environmental Protection Agency. https://www.epa.gov/aboutepa/our-mission-and-what-we-do
- US EPA (Environ. Prot. Agency). 2019. FY 2020 EPA budget in brief. EPA-190-R-19-001, US EPA, Washington, DC. https://www.epa.gov/sites/production/files/2019-03/documents/fy-2020-epa-bib.pdf
- US EPA (Environ. Prot. Agency). 2019. Integrated Risk Information System (IRIS) glossary. Vocab. Cat., Off. Res. Dev./Natl. Cent. Environ. Assess./Integr. Risk Inf. Syst., Washington, DC, updated Aug. 31, 2011
- US EPA (Environ. Prot. Agency). 2019. A message from the IRIS program. Integr. Risk Inf. Syst. (IRIS) Update, April, US EPA, Washington, DC. https://www.epa.gov/sites/production/files/2019-04/documents/iris\_program\_outlook\_apr2019.pdf
- US EPA (Environ. Prot. Agency). 2019. Risk assessment guidelines. US Environmental Protection Agency. https://www.epa.gov/risk/risk-assessment-guidelines

- US GPO (Gov. Account. Off.). 2019. EPA advisory committees: improvements needed for the member appointment process. Rep. GAO-19-280, Congr. Req., Washington, DC. https://www.eenews.net/assets/2019/07/15/document\_gw\_05.pdf
- Wheeler AR. 2019. Increasing consistency and transparency in considering costs and benefits in the rulemaking process. Memo., Off. Adm. US Environ. Prot. Agency, Washington, DC. https://www.epa.gov/ environmental-economics/increasing-consistency-and-transparency-considering-costs-andbenefits
- White House. 2018. Remarks by President Trump to the World Economic Forum. History Musings, Jan. 26. https://historymusings.wordpress.com/category/us-political-news-topics/economy/