Improving Regulatory Science: A Case Study of the National Ambient Air Quality Standards

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This paper explores the motivations and institutional incentives of participants involved in the development of regulation aimed at reducing health risks, with a goal of understanding and identifying solutions to what the Bipartisan Policy Center has characterized as "a tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, [that] is at the root of the stalemate and acrimony all too present in the regulatory system today." We focus our analysis with a case study of the procedures for developing National Ambient Air Quality Standards under the Clean Air Act, and attempt to identify procedural approaches that bring greater diversity (in data, expertise, experience, and accountability) into the decision process.

1. REGULATORY SCIENCE AND POLICY

Regulations intended to address public health and environmental risks depend heavily on scientific information. These regulations are often the subject of heated debate, involving accusations of "politicized science," "advocacy science," and "junk science" (see, for example, John-

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ston 2012). While it is legitimate to want to protect the integrity of scientific findings, more often than not, these policy debates center on issues that science must inform, but cannot decide.

No one is immune to the temptation to spin science to advance a predetermined policy goal. However, masquerading policy preferences as "science" can be extremely harmful. At worst, scientists and policymakers work, wittingly or unwittingly, in an unholy alliance to support harmful political preferences in the name of "science." Perhaps the most notorious example in the United States is the extent to which some scientists in the nineteenth century declared certain human races inherently "inferior." This "evidence" was, in turn, used by politicians to justify, and defend, race-based slavery (see Burnett [2008] describing the work of anthropologist Henry Hotze on behalf of the Confederate States of America). Fortunately, the costs of "politicized science" in the United States today are less severe than mass human enslavement, but they can still have significant adverse effects on public policies as well as diminish the integrity of scientific advice.

While there is extensive media coverage of "politicized science" related to public disagreements regarding regulatory issues that have a strong scientific component, such as genetically modified organisms or climate change, the examination of how science may be politicized inside federal regulatory decision-making processes has been largely limited to academia and the scientific community (see, for example, Rice 2011). In particular, while attempts by policy advocates to improperly shape science have been widely presented in the media, in everything from main stream news reports[1] to the AMC series *Mad Men*,[2] there has been much less examination of the role of scientists improperly attempting to shape policy decisions. Yet the latter problem can be just as serious. As former Assistant Administrator of the US Environmental Protection Agency, Milton Russell (1992, 108), has noted, while government scientists need to be protected from "influence over what they *find and report*, . . . policy-makers must be protected from policy analysts or scientists telling them what they should *decide*, but open to information about what the consequences of alternative decisions are likely to be."

This paper examines two types of politicized science that can infect policymaking inside regulatory agencies. The first is when scien-

[1] See, for instance, a discussion in the *New York Times* of how politicians from both major parties attempt to spin science (Stolberg 2009).

[2] See, for instance, the discussion of the manipulation of the public regarding the health effects of tobacco on behalf of tobacco companies in the episode "Smoke Get in Your Eyes" (Taylor, Alan, dir. *Mad Men* Season 1, episode 1. Aired July 19, 2007, on AMC.).

tists, intentionally or unintentionally, insert, but do not disclose, their own policy preferences in the scientific advice they provide government decision-makers. Such "hidden policy judgments" are a form of "advocacy science."[3] The second is when scientists and/or policymakers conflate scientific information and nonscientific judgments to make a policy choice, but then present that decision as being solely based on science. It is this tendency to "camouflag[e] controversial policy decisions as science" that Wagner (2009, 1617) called a "science charade," and it can be particularly pernicious. For instance, a 2009 Bipartisan Policy Center (BPC) report, *Improving the Use of Science in Regulatory Policy*, concluded that "a tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today" (BPC 2009, 11). Both of these problems, hidden policy judgments and the science charade, can be the result of officials falling prey to the "is-ought fallacy": incorrectly mixing up positive information about what "is" with normative advice about what "ought to be."

This paper focuses on the problems of hidden policy judgments and the science charade inside federal regulatory agencies. It examines why these are problems, how institutional incentives contribute to them, and possible remedies. After describing what we mean by hidden policy judgments and the science charade and describing the "is-ought fallacy," we illustrate these problems by examining the incentives and behavior of participants in the development of National Ambient Air Quality Standards (NAAQS) under the Clean Air Act (42 U.S.C. § 7408). The paper concludes with ten recommendations for changing those incentives.

2. THE POLITICIZATION OF SCIENCE

Science is rarely sufficient for making policy decisions for two reasons. First, while science is essential for understanding the positive question of *what is* or predicting what outcomes might obtain under different scenarios, it is not determinative for the normative decisions regarding what *ought to be* (see Keynes 1999, 22). Along these lines, in 1983 the National Research Council (NRC) of the National Academy of Sciences described the following conceptual framework for making regulatory decisions regarding health, safety, and environmental risks:

[3] "Advocacy science" is an elusive term and can, for instance, include the activity of scientists seeking more federal funding for research. For the purposes of this paper the term is defined as when a policy preference is presented in the form of scientific advice. For a discussion of advocacy science, see Runkle (2012, 2–3).

> Regulatory actions are based on two distinct elements, risk assessment . . . and risk management. Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. (NRC 1983, 3)[4]

In other words, regulatory decisions can be split conceptually into two phases. The risk-assessment phase provides science-based information regarding what we know about a risk (positive information regarding *what is*). However, risk assessment is necessary, but rarely sufficient, input for deciding how the government should regulate a risk. That requires a second phase, risk management, to determine what *ought to be*. Sound policy decisions regarding risk management typically need to consider a host of nonscientific factors such as economic feasibility, legal constraints, ethical considerations, and the existence of other public policies that may address, or exacerbate, the risk, to name just a few.

2.1. Hidden Policy Judgments in Risk Assessments

Unfortunately, in practice there is not a clear distinction between scientific and policy decisions in the regulatory process. First, when it comes to risk assessment, scientists will never have complete information to predict outcomes with certainty, so analysts rely on what the NRC calls "risk assessment policy"—assumptions, judgments, and rules of thumb—to guide the use of scientific information in analyses that inform policy in the face of uncertainty. The NRC (1983, 3) puts it this way:

> In each step [of the risk-assessment process], a number of decision points (components) occur where risk to human health can only be inferred from the available evidence. Both scientific judgments and policy choices may be involved in selecting from among possible inferential bridges, and we have used the term risk assessment policy to differentiate those judgments and choices from the broader social and economic policy issues that are inherent in risk management decisions.

[4] This document is also commonly known as the "Red Book."

Thus, the risk-assessment phase itself embeds judgments that need to be made to produce a result that scientists can give to policymakers, and these judgments, intentionally or not, can bias the ultimate advice provided to decision-makers and the public.

This fuzziness between science and policy choices is not unique to health and safety regulations. In 1972 Alvin Weinberg (209) pointed out, "Many of the issues which arise in the course of the interaction between science or technology and society—e.g., the deleterious side effects of technology, or the attempts to deal with social problems through the procedures of science—hang on the answers to questions which can be asked of science and yet *which cannot be answered by science*." To describe such questions, Weinberg (1972, 209, 222) coined the term "trans-science."[5] Figure 1 below illustrates the relationship between pure scientific inputs and policy decisions, and the role of "trans-science" and judgment in interpreting and presenting evidence relevant to policy. "Risk assessment policy" includes various judgments: which science is considered; how individual studies are weighed and combined; when competing theories are considered appropriately supported for inclusion; which models to use; and in general, what to do in the face of scientific uncertainty. It also guides the way in which risks are characterized and communicated (Dudley and Gray 2012).

Policymakers and the public are often unaware of the influence of these risk-assessment policy choices or the existence of alternative choices that are equally plausible. Instead, assessments often generate precise-sounding predictions that hide not only considerable uncertainty about the actual risk, but also the reliance on biased inferences and assumptions for handling that uncertainty.[6] As noted above, this is a problem of hidden policy judgments. While some judgment is necessary to translate scientific evidence into risk assessment, current risk-assessment policies are not transparent and lead to distortions in risk estimates and false precision in the presentation of scientific information.[7] These practices obscure the boundary between science and

[5] "I propose the term *trans-scientific* for these questions since, though they are, epistemologically speaking, questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science. . . . Scientists have no monopoly on wisdom where this kind of trans-science is involved" (Weinberg 1972).

[6] For example, the Environmental Protection Agency (EPA) has a "Risk Assessment Principles and Practices" document, which states: "Since EPA is a health and environmental protective agency, EPA's policy is that risk assessments should not knowingly underestimate or grossly overestimate risks. This policy position prompts risk assessments to take a more 'protective' stance given the underlying uncertainty with the risk estimates generated" (EPA 2004, 13).

[7] "[T]he problem is the EPA's use of assumptions that it claims are 'public health protective,' which err on the side of overstating risk when data are lacking. . . . Such inflated

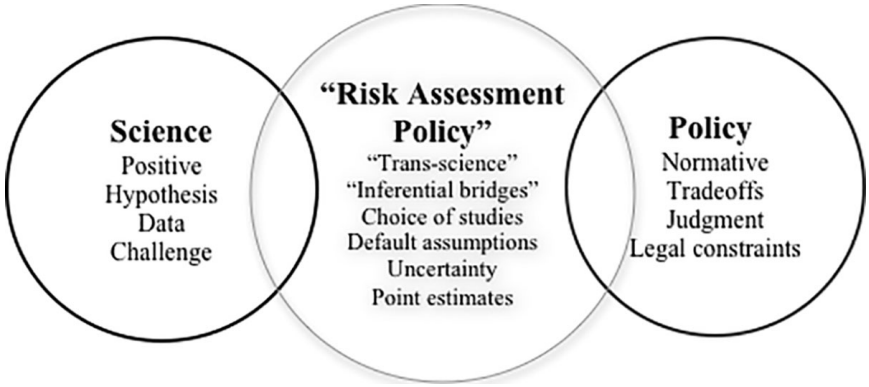

Figure 1. "Science, Policy, and Risk Assessment Policy" (based on Dudley and Gray 2012).

policy and contribute to the politicization of science through biased science advice.

Former EPA scientist Robert T. Lackey (2013, 36) cautions against this problem, which he calls "normative science":

> Science should be objective and based on the best information available. Too often, however, scientific information presented to the public and decision-makers is infused with hidden policy preferences. Such science is termed normative, and it is a corruption of the practice of good science. Normative science is defined as "information that is developed, presented or interpreted based on an assumed, usually unstated, preference for a particular policy choice."

Normative science can be masked by presentations that are not transparent. For example, in its 2011 evaluation of the EPA's Integrated Risk Information System (IRIS) assessment for formaldehyde, the National Academy of Sciences raised concerns about recurring "problems with clarity and transparency of the methods":

> In general, the committee found that the draft was not prepared in a consistent fashion; it lacks clear links to an underlying conceptual framework; and it does not contain sufficient documentation on methods and criteria for identifying evidence from epidemiologic and experimental studies, for critically evaluating individual studies, for assessing the weight of evidence, and for selecting studies for derivation of the [reference dose] RfCs and unit risk estimates. (NRC 2011, 4)

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risk estimates can lead to overly stringent regulations and can scramble agency priorities because the degree of precaution differs across chemicals" (Gray and Cohen 2012, 27).

2.2. When Risk Management Becomes a Science Charade

While embedded policy judgments raise concerns of hidden bias in the *risk-assessment* phase of a rulemaking, policy judgments couched as "science" can raise similar problems in the *risk-management* phase.

While there should be a clear distinction in the minds of scientists and policymakers between describing what "is" and deciding what "ought to be," the two are sometimes unintentionally, or intentionally, conflated when the ultimate policy decision is presented as dictated solely by "the science." We adopt the phrase "science charade" (Wagner 1995) to describe the camouflaging of controversial policy decisions as science.

Scientists and/or policymakers create a science charade by describing a policy decision in purely scientific (or scientific sounding) terms without revealing the trans-science and policy factors that played a role in the decision. For instance, in 1982, the EPA faced a decision whether to regulate formaldehyde under the Toxic Substances Control Act. In order to regulate, the Administrator had to find "a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings" (15 U.S.C. § 2603(f)). Such a decision inherently involves policy judgments regarding the interpretation of the terms "reasonable" basis, "significant" risk, and "serious or widespread harm." Yet, in presenting the issue to the Administrator of the EPA, the Assistant Administrator for Pesticides and Toxic Substances couched the decision as a purely scientific judgment:

> (a) formaldehyde is a carcinogen in the rat by the inhalation route; (b) its carcinogenic potential appears to vary significantly with species and route; (c) under certain exposure conditions it could present some carcinogenic risk to humans; and (d) given available data the risk estimates suggest that certain populations may experience a carcinogenic risk—albeit low—due to formaldehyde exposure. However, because of the nature of the toxicology data and the unreliability in the exposure data one cannot reasonably conclude, at this time, that formaldehyde poses a significant risk among the U.S. population. (Ashford, Ryan, and Caldart [1983], 327–28, excerpting memorandum from John Todhunter to Anne Gorsuch, February 10, 1982)

Scientists can unwittingly impose, or intentionally foist, science charades on decision-makers by hijacking risk-management decisions. Policymakers can create science charades on their own (as in the example above), or scientists and policymakers may cooperate in disguising value-laden decisions as the necessary result of "the best science."

Regardless, the science charade results in similar harms as hidden policy judgments in risk assessments: the public is cheated of sound and open policymaking and the integrity of science advice is weakened.

2.3. Falling Prey to the "Is-Ought" Fallacy

As noted above, science describes what "is," but it cannot solely determine what "ought to be." Hidden policy judgments in risk assessments and science charades result from incorrectly mixing up positive information about what "is" with normative advice about what "ought to be." These errors are examples of the "is-ought fallacy."[8] This fallacy, first identified by philosophers David Hume and G. E. Moore in the eighteenth century, happens when a prescription is erroneously embedded in, or directly follows, a description, as if one automatically follows from the other. For instance, the statement "ambient carbon dioxide concentrations are increasing, and therefore we must stop burning fossil fuels" may or may not be good public policy, but the latter policy decision does not necessarily follow from the former scientific fact. As some scientists have noted, only "in the most trivial of decision contexts, where there is no immediate disagreement about relevant facts, values or decision options, can a fact dictate an action" (Sarewitz 2012, 4).

This fallacy is not unique to science. It "is common and has been the source of many mischievous errors" (Keynes 1999), confounding diverse areas of study and decision-making (see, for example, Davis 1997). However, it can be particularly pernicious when it influences government regulations that affect the lives of millions of people and the allocation of significant resources. Both scientists and policymakers may fall prey, willfully or not, to the is-ought fallacy.

Scientists and policymakers may intentionally invoke the is-ought fallacy, although for different reasons. Scientists may wish to influence policymakers by subtly absorbing nonscientific assumptions in their risk assessments or in descriptions of what "is" so that it appears there is no better risk-management alternative than the one they prefer. Likewise, decision-makers, such as political appointees, who may fear criticism of a particular decision can muddle descriptions of "is" with assumptions regarding what "ought to be" in the risk-management phase of rulemaking and claim that "science" dictated the outcome. In both cases, the fallacy allows scientists and/or policymakers to create a science charade by dressing up a policy decision and disguising it in a lab coat.

[8] This is also called the "naturalistic fallacy," the "positive-normative fallacy," Hume's Law, or Hume's Guillotine.

2.4. The Harms of Politicized Science and the Example of NAAQS

The process by which the EPA sets National Ambient Air Quality Standards (NAAQS) for "criteria pollutants"[9] under the Clean Air Act illustrates some of the perverse incentives involved in developing regulations, which can encourage biased scientific advice and a science charade. The NAAQS process is particularly worth examining because, on the one hand, it is held up by some as an ideal by which all science-based rulemaking should be developed,[10] but on the other, NAAQS decisions are among the most controversial of the EPA's policies. The last three presidents have taken the highly unusual step of publicly and personally intervening in the EPA's regulatory decisions.[11]

Biasing science advice or framing issues as resolvable solely by science threatens the credibility of the scientific process and damages the resulting regulatory policy. Many of those involved in regulatory decisions have incentives to hide rather than reveal the uncertainty in assessments of risk[12] and to dismiss and denigrate dissenting views.[13]

[9] The Clean Air Act (42 U.S.C. § 7408(a)(1)) identifies six "criteria pollutants": particulate matter, ground-level ozone, carbon monoxide, sulfur oxides, nitrogen oxides, and lead.

[10] Wagner (2013, 29) referred to the NAAQS development process as "the equivalent of a five-star process for incorporating science into regulatory policy."

[11] The EPA's 1997 standards for ozone and fine particles were debated extensively at the cabinet level, and on issuance of the final regulations, President Clinton took the unprecedented step of writing a public memorandum to the EPA Administrator to "ensure that the new standards are implemented in a common sense, cost-effective manner" (Memorandum on Implementation of Revised Air Quality Standards for Ozone and Particulate Matter, 33 Weekly Comp. of Pres. Docs. 1080 [July 18, 1997]). Fraas (2011, 81–85) gives an insider's account of the 1997 deliberations. In 2008, the EPA again faced objections from other agencies, as well as from state and local governments, when it proposed to revise the ozone standard. President George W. Bush was called in to settle the dispute, following the rarely used section 7 of Executive Order 12,866 (Exec. Order No. 12,866, 58 Fed. Reg. 51,735 [Oct. 4, 1993]) regarding the resolution of conflicts. He decided the dispute over the appropriate form of the welfare standard by directing EPA Administrator Stephen Johnson to set it at a level identical to the primary standard (Dudley 2008). In 2011, the President intervened again. The EPA was poised to revise the ozone standard amid strong objections from other parts of the government and the regulated community when President Obama took the unusual step of "request[ing] that Administrator [Lisa] Jackson withdraw the draft ozone national ambient air quality standards" from interagency review (Statement on the Ozone National Ambient Air Quality Standards, Daily Comp. of Pres. Docs. No. 201100607 [Sept. 2, 2011]). This is the only time during President Obama's administration that the White House returned a regulation to an agency.

[12] According to Wagner (1995, 1668), "It would seem that such science-based mandates not only invite, but actually compel the science charade due to the threat of reversal if an agency frankly acknowledges the inherent scientific uncertainties and its requisite retreat to economic, technological, and other policy considerations in reaching a final, quantitative standard."

[13] For example, see posts from the Center for Progressive Reform (n.d.) and the Center for Regulatory Solutions (Kerrigan 2015).

Key policy choices, disguised as science, rest with technical staff; meanwhile, political appointees charged with making hard policy decisions are able to avoid responsibility by claiming that their hands were tied by the science.

When questions involving policy judgments and values are falsely characterized as scientific, a small number of people have disproportionate influence on the information that is used and how it is characterized, leading to decisions that are not as accountable or as transparent as they should be.[14] This is exacerbated by the adversarial nature of rulemaking, by the reluctance of courts to review scientific findings, and by group dynamics that discourage differences of opinion, mask uncertainty, and give short shrift to alternative perspectives.

Using the NAAQS as a case study, the next section explores the procedures for developing regulations and the institutional incentives that may encourage the is-ought fallacy and contribute to politicized science through hidden policy judgments and the science charade.

3. PARTICIPANTS IN THE RULEMAKING PROCESS: THEIR MOTIVES AND BEHAVIOR

The development of regulation in the United States involves several steps and numerous parties. First, Congress must pass and the president must sign legislation authorizing regulation. Legislation addressing health and environmental risks generally expresses broad goals and objectives, but leaves fact-finding and the details of implementation to executive branch agencies, such as the EPA (Schoenbrod 1995). Regulatory agencies then develop draft regulations consistent with the language in the enabling legislation and according to procedures mandated by both Congress and the President (Dudley and Brito 2012). In particular, section 1 of the Administrative Procedure Act (5 U.S.C. § 551 [2012]) requires regulatory agencies to notify the public and seek comments on proposed regulations and to base final regulations on information in the rulemaking record. This notice-and-comment process guarantees interested parties (those affected by potential regulation, nongovernmental organizations, and others) an opportunity to present views and information on proposed regulations (Balla 2011). Additionally, since 1981, presidents have required agencies to conduct regulatory impact analyses (RIAs) of economically significant regulations

[14] Eisenhower (1961) warned in his farewell address, "Yet, in holding scientific research and discovery in respect, as we should, we must also be alert to the equal and opposite danger that public policy could itself become the captive of a scientific-technological elite."

and to subject them to interagency review through the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (see Improving Regulation and Regulatory Review, Exec. Order No. 13,563, 76 Fed. Reg. 13,563 [Jan. 21, 2011] and Regulatory Planning and Review, Exec. Order No. 12,866, 58 Fed. Reg. 51,735 [Oct. 4, 1993]). Congress has an opportunity to fast track a joint resolution to disapprove a final regulation after it is published (Congressional Review Act of 1996, 5 U.S.C. §§ 801–808), and regulations are also subject to judicial review (allowing affected parties to sue to have regulations overturned by the courts) (Dudley and Brito 2012). Throughout the rule development process and beyond, the media will also track and report on regulations and any controversies that may arise.

The behavior of each party in the regulatory development process is influenced by these institutional structures and constraints, and the incentives they provide, as a case study of the NAAQS development process illustrates.

3.1. Authorizing Legislation

The Clean Air Act of 1970 (Pub. L. No. 91-604, 84 Stat. 1676 [codified as amended in 42 U.S.C. ch. 85 (2012)]) directed the newly created EPA to issue NAAQS for each pollutant for which the Department of Health, Education, and Welfare had already issued air quality criteria, and for widespread air pollutants identified in the future that reasonably may be expected to endanger public health or welfare.[15]

The Act (42 U.S.C. § 7408(b)(1)) directed the EPA Administrator to set "primary," or health-based, NAAQS at levels that are "requisite to protect the public health . . . allowing an adequate margin of safety," based on "air quality criteria [that] shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities" (42 U.S.C. § 7408(a)(2)). It further required the Administrator to set "secondary" (welfare-based) standards based on these criteria at a level "requisite to protect the public welfare from any known or anticipated adverse effects" (42 U.S.C. § 7408(b)(2)).

Amendments to the Clean Air Act in 1977 (Pub L. No. 95-95, 91 Stat. 685 [codified as amended in 42 U.S.C. ch. 85]) required the Ad-

[15] For a thorough review of the history of NAAQS, see Bachmann (2007, 655), who found that "[e]ven a cursory look at the history of the NAAQS and air pollution shows that developments are subject to what is sometimes called big 'P' (i.e., partisan) and little 'p' (e.g., interagency or office) politics and all of the changing societal, economic, cultural, and other influences related to a particular time and place."

ministrator to conduct a "thorough review of the criteria . . . and promulgate such new standards as may be appropriate," at least every five years.

In 2001 the Supreme Court confirmed the EPA's interpretation that, when the EPA sets primary standards, the statutory language precludes consideration of the costs of achieving the standard (*Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 [2001]). Thus the Clean Air Act itself, at least in this reading, encourages the is-ought fallacy by implying that scientific evidence is sufficient to resolve such normative questions as what is "requisite to protect public health" or an "adequate margin of safety."[16]

According to Schoenbrod,

> The legislative history and reality made clear that EPA was not to set the ambient standards at zero. So EPA would necessarily have to leave some threat to health. The statute evaded the question of how much. The evasion was intentional. As the author of the Clean Air Act, Senator Edmund Muskie, later admitted, "[o]ur public health scientists and doctors have told us that there is no threshold, that any air pollution is harmful. The Clean Air Act is based on the assumption, although we knew at the time it was inaccurate, that there is a threshold. When we set the standards, we understood that below the standards that we set there would still be health effects." (Schoenbrod [2003, 270] citing Clean Air Act Amendments of 1977: Hearings Before the Subcommittee on Environmental Pollution of the Senate Committee on Environment and Public Works, 95th Cong. 8 [1977]),

The statutory framing makes it much more difficult to follow the Bipartisan Policy Center's (2009, 4) first recommendation that "when federal agencies are developing regulatory policies, they explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy."

While the Act left the decision for setting NAAQS to "the judgment of the [EPA] Administrator," the 1977 amendments required

[16] An amicus brief in this case, signed by a bipartisan group of forty-two prominent economists, including five Nobel Laureates, argued: "We believe that it would be imprudent for the EPA to ignore costs totally. . . . Not considering costs makes it difficult to set a defensible standard, especially when there is no threshold level below which health risks disappear" (Brief of AEI-Brookings Joint Center for Regulatory Studies et al. as Amici Curiae Supporting Cross-Petitioners, *Browner v. American Trucking Ass'n, Inc.*, 529 U.S. 1129 [2000], [No. 99-1257]). A former EPA science advisor observed regarding the EPA's position that it "is not supposed to take cost into account in promulgating standards (does any thinking person actually believe that they shouldn't, or don't?)" (Mauderly 2006).

the Administrator to create an "independent scientific review committee," now known as the Clean Air Scientific Advisory Committee (CASAC), with authority not only to review the scientific criteria developed by the EPA but to "recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate" (42 U.S.C. § 7409(b)(1), (d)(2)). By inviting scientific advisors to make normative recommendations regarding what level is appropriate, this language deliberately confused the distinction between scientific expertise and policy judgment, codifying the input of hidden policy judgment and the is-ought fallacy into the policymaking process.[17]

3.2. Environmental Protection Agency

The EPA follows a multi-step process when reviewing and setting NAAQS, as shown in Figure 2 (Jackson 2009). It begins by developing an Integrated Review Plan that identifies the science and policy issues that will be reviewed during the five-year assessment. Next, the EPA conducts extensive reviews of the available science in what is called an Integrated Science Assessment (ISA). Data on the criteria air pollutants are often extensive, with ISAs running to thousands of pages and including reviews of hundreds or thousands of studies. The EPA staff use the results of the ISA to develop a risk and exposure assessment (REA) to evaluate potential risks associated with exposures expected at the existing standard and at alternative standards. To accomplish this, agency staff interpret various studies and data to generate a single concentration-response model to predict health effects at different levels of exposure. The EPA's formulation and presentation of the studies and data necessarily involves judgments about which studies to consider and which to exclude, as well as assumptions about what models best fit the selected data and how to extrapolate between observed and predicted exposures.

Unfortunately, the many risk-assessment policy judgments embedded in these models are not transparent. The findings of the ISA and REA depend heavily on how the staff decides to answer such nonscientific questions as what effects are considered "adverse," how far to "err on the side of safety" when determining the appropriate shape of the exposure-response function, and whether observed associations are sufficient to assume causal effects, even in the absence of plausible biological evidence of causality. For example, the EPA considers

[17] The statutory role assigned CASAC makes it difficult to implement the Bipartisan Policy Center's recommendation that, "in general, scientific advisory panels should not be asked to recommend specific regulatory policies" (BPC 2009, 17).

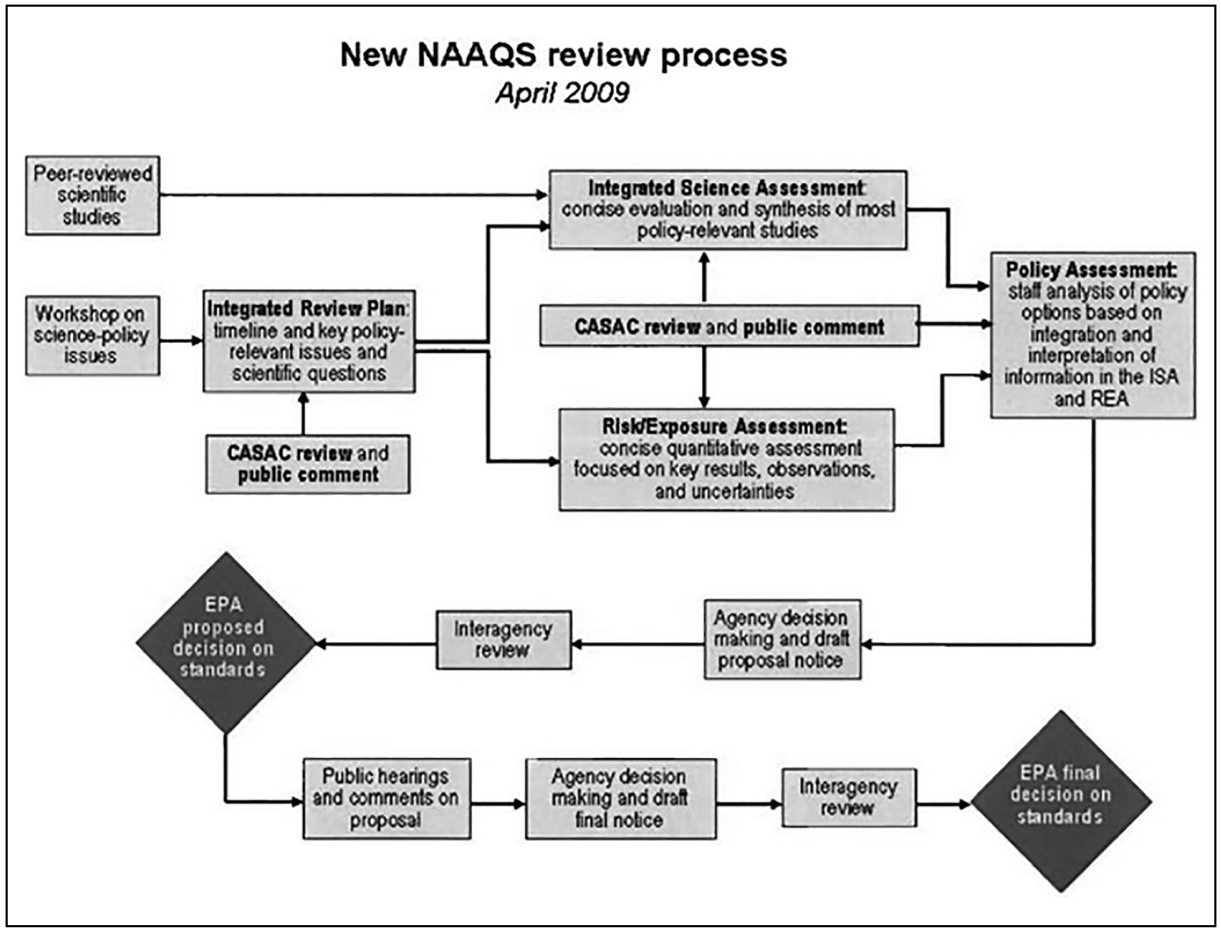
New NAAQS review process
April 2009
Peer-reviewed scientific studies
Integrated Science Assessment: concise evaluation and synthesis of most policy-relevant studies
Workshop on science-policy issues
Integrated Review Plan: timeline and key policy-relevant issues and scientific questions
CASAC review and public comment
Policy Assessment: staff analysis of policy options based on integration and interpretation of information in the ISA and REA
CASAC review and public comment
Risk/Exposure Assessment: concise quantitative assessment focused on key results, observations, and uncertainties
EPA proposed decision on standards
Interagency review
Agency decision making and draft proposal notice
Public hearings and comments on proposal
Agency decision making and draft final notice
Interagency review
EPA final decision on standards

Figure 2.

reversible, asymptomatic cellular changes and transient symptomatic effects (such as a cough) to be "adverse" which is clearly a matter of opinion, not something that can be determined solely on the basis of what "is."

3.2.1. Treatment of Uncertainty. Perhaps the most pervasive hidden policy judgments regard the treatment of uncertainty. A recent report from the Institute of Medicine (2013) observed the following:

> Uncertainty is inherent in the scientific information upon which health risk estimates are based. Uncertainties enter the health risk assessment process at every step and can be caused by the potential confounders in observational studies, by extrapolation from animal studies to human studies, by extrapolation from high to low dose exposures, by inter-individual variability, and by modeling the relationships between concentrations, human exposures, and human health responses and evaluating the effect of interventions or risk control options on public health risk.

The uncertainties inherent in these assessments can be significant. For example, one key assumption that drives estimates of the effects of exposure to fine particles ($PM_{2.5}$) is that "inhalation of fine particles is causally associated with premature death" (OIRA 2013, 19). The EPA assumes a causal relationship based on epidemiological evidence of an association between PM concentrations and mortality. However, correlation does not imply causation (*cum hoc non propter hoc*), and the EPA has not been able to identify a biological mechanism to explain the observed correlation. As Dominici, Greenstone, and Sunstein (2014) observe, "associational approaches to inferring causal relations can be highly sensitive to the choice of the statistical model and set of available covariates that are used to adjust for confounding." Further, statistical experts have raised questions as to whether the correlation that the EPA claims is real, and such experts present analysis that suggests the EPA's estimates of $PM_{2.5}$ mortalities are a product of model and data choices, rather than a real, measured correlation.[18]

Another key assumption on which EPA estimates of adverse effects hinge is that the concentration-response function for fine particles is

[18] See, for example, Cox (2012), whose statistical analysis suggests with a greater than 95 percent probability that no association exists, and that instead, the EPA's results are a product of its choice of models and selected data, rather than real measured correlation. Krstić's (2013) reanalysis shows that "the statistical significance of the correlation is lost after removing one of the metropolitan areas from the regression analysis, suggesting that the results may not be suitable for a meaningful and reliable inference."

linear within the range of ambient concentrations under consideration. Both theory and data suggest that thresholds exist below which further reductions in exposure to $PM_{2.5}$ do not yield changes in mortality response and that one should expect diminishing returns as exposures are reduced to lower and lower levels.[19] However, the EPA assumes a linear concentration-response impact function that extends to concentrations down to zero (see National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3,085 [Jan. 15, 2013]; Primary National Ambient Air Quality Standards for Nitrogen Dioxide, 75 Fed. Reg. 6,473 [Feb. 9, 2010]; National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. 16,435 [Mar. 27, 2008]).

3.2.2. Hidden Biases. Based on its policy-related assumptions of a causal, linear, no-threshold relationship between $PM_{2.5}$ exposure and premature mortality, the EPA quantifies a number of premature mortalities that will be avoided when concentrations of $PM_{2.5}$ decline as a result of regulation. If any of these assumptions are false (in other words, if no association exists, if the relationship is not causal, or if the concentration-response relationship is not linear at low doses), then the effects of reducing $PM_{2.5}$ would be significantly less than the EPA's assessments estimate, including zero.

The assumptions of EPA scientists are not necessarily wrong, but each assumption in the face of uncertainty represents a decision based on policy considerations, not science. The extent to which a resulting standard should err on the side of safety reflects public values that the statute puts in the hands of the EPA Administrator and should be transparent to the public. Yet these uncertainties are not presented in the ranges of risks reported. Cox's (2015) review of the EPA's ozone NAAQS proposed in December 2014 finds as follows:

> EPA has not quantified crucial model uncertainties. Therefore, confidence intervals calculated assuming that the models used are correct are misleadingly narrow and EPA has provided policy makers with no basis for confident predictions about how different changes in the ozone standard would probably affect public health.

One former EPA science advisor called for "a more explicit characterization of uncertainty in estimates of causality and exposure-response

[19] See, for example, Texas Commission on Environmental Quality (2013), which noted that "extrapolations [to current exposure levels] can be contrary to the basic principles of toxicology where the biological threshold (a level below which no effect is apparent) is a key concept."

relationships . . . for both primary and secondary standards," noting the following:

> At present, assessments of "uncertainty" are almost completely focused on the mathematical uncertainty of effects estimates (i.e., confidence intervals on measurements of exposures and effects). This is important of course, but I would like to see a more rigorous discussion of "certainty" in a broader sense. For example, how do the magnitudes of health effects of air pollution rank in comparison to other voluntary and involuntary health risks? Because air pollutants seldom, if ever, exert novel effects, what portion of the total public health effect is plausibly attributable to a pollutant (or to pollution)? What do we know about the relative benefits, and cost-benefit relationships, of different approaches to reducing health burdens that are exerted in part by air pollution? I care not that these issues might not fall within many folks' definition of "scientific information," or that EPA is not supposed to take cost into account in promulgating standards (does any thinking person actually believe that they shouldn't, or don't?). We delude ourselves and miss opportunities to inform policy makers and promote a rational public understanding of risk if we continue to view the "uncertainty" issue as solely one of statistical methodology and data quality, while advocating for the special importance of the particular effects . . . by which we make our living. (Mauderly 2006)

These uncertainties are further hidden from policymakers when, after the ISA and REA are completed, EPA staff prepare a Policy Assessment (formerly called the Staff Paper) that "bridges the gap" between the ISA and REA, and develop a set of policy options to present to the Administrator. The Policy Assessment "presents staff conclusions regarding the adequacy of the current suite of PM standards as well as potential alternative standards for [the Administrator's] consideration" (EPA Office of Air Quality Planning and Standards 2011). This presentation of staff's judgment (informed by CASAC) regarding what is "requisite to protect public health" further obfuscates the line between science and policy judgment and virtually compels staff to fall prey to the is-ought fallacy.[20] The Policy Assessment presents policy options framed with vague but portentous language, such as "the weight of the evidence" and "a consensus among scientific advisors"

[20] A committee charged with identifying PM research needs did not look at the adequacy of scientific basis for a NAAQS standard "because the process of setting such standards also involves legal requirements and policy choices that the present committee was neither charged nor constituted to address" (NRC 1998).

(EPA Office of Air Quality Planning and Standards 2011). Uncertainty at lower levels of exposure is typically discussed vaguely and qualitatively to justify setting levels greater than zero.[21] As a result, the policy options presented by EPA staff, which clearly include nonscientific judgments, attempt to constrain the ultimate decision of the Administrator, who is the accountable decision-maker under the Clean Air Act. The staff recommendations, shrouded in scientific language, create a science charade.

One would have difficulty discerning the large impact of nonscientific decisions just by reading the recommendations. For example, the Policy Assessment that EPA staff prepared for the fine particle standards set in December 2012 states:

> Taking into account both evidence-based and risk-based considerations, staff concludes that consideration should be given to revising the current annual $PM_{2.5}$ standard level of 15 $\mu g/m^3$ to a level within the range of 13 to 11 $\mu g/m^3$. Staff further concludes that the evidence most strongly supports consideration of an alternative annual standard level in the range of 12 to 11 $\mu g/m^3$. (EPA Office of Air Quality and Planning Standards 2011)

3.2.3. Public Communication. Documents prepared to support executive requirements for economic analysis and to communicate with the public also suffer from a science charade. The EPA staff prepares a Regulatory Impact Analysis (RIA), and publicly releases it concurrently with proposed and final determinations. RIAs are required by executive order to "assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating" (Exec. Order No. 12,866, § 1(a), 58 Fed. Reg. 51,735 [Oct. 4, 1993]). This document is not depicted on the decision diagram (shown above), and the EPA is explicit that "the RIA is done for informational purposes only, and the final decisions on the NAAQS . . . are not in any way based on consideration of the information or analyses in the RIA" (see National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3,086, 3,089 [Jan. 15, 2013]). The results of the RIA feature prominently in EPA press releases, however. For the December 2012 $PM_{2.5}$ NAAQS, the EPA announced that meeting the Administrator's selected standard of 12.0 $\mu g/m^3$ standard would avoid between 460 and 1,000 premature deaths per year. However, the RIA also indicated that further

[21] For example, the December 2014 ozone proposal argued that "setting a standard below 0.065 ppm, down to 0.060 ppm, would inappropriately place very little weight on the uncertainties in the health effects evidence and exposure/risk information" (National Ambient Air Quality Standards for Ozone, 78 Fed. Reg. 75,233 [proposed Dec. 17, 2014]).

tightening—going from a standard of 12 μg/m^3 to 11 μg/m^3—would yield additional life savings of 1,040 to 2,300 mortalities per year.

Given that these two data points suggest the incremental life savings associated with a reduction from 12 μg/m^3 to 11 μg/m^3 are greater than those associated with a reduction from 13 μg/m^3 to 12 μg/m^3, it is curious that the Policy Assessment did not recommend, or at least examine, standards below 11 μg/m^3. Neither the Policy Assessment nor the RIA explains this, nor does the Administrator's decision to set a standard of 12 μg/m^3, which, as these documents suggest, leaves between 580 and 1,300 lives unprotected.

Instead, the RIA justifies the standards as follows:

> This action provides increased protection for children, older adults, persons with pre-existing heart and lung disease, and other at-risk populations against an array of $PM_{2.5}$-related adverse health effects that include premature mortality, increased hospital admissions and emergency department visits, and development of chronic respiratory disease. . . .
>
> . . . The revised suite of $PM_{2.5}$ standards also reflects consideration of a quantitative risk assessment that estimates public health risks likely to remain upon just meeting the current and various alternative standards. Based on this information, the Administrator concludes that the current primary $PM_{2.5}$ standards are not requisite to protect public health with an adequate margin of safety, as required by the Clean Air Act, and that these revisions are warranted to provide the appropriate degree of increased public health protection. (National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3,086, 3,088–89 [Jan. 15, 2013]).

As a former senior EPA air office official observed about the 1997 standard,

> Nuance and uncertainty were also lacking in EPA's public communications after proposal. The agency's sound bite was that the science demanded the revisions. Although it was true that EPA's assessment of the science found a need to tighten the standards, the *particular* standards proposed were obviously not wholly determined by science. (Bachmann 2007, 687)

The statutory language forces EPA staff to present vague justifications that carefully avoid expressing consideration of economic tradeoffs. Yet because there is no threshold below which models do not predict health effects—short of eliminating these criteria pollutants altogether—science alone cannot identify what standard along the modeled linear no-threshold dose-response function would be "requisite

to protect public health." And yet, all involved regularly participate in a science charade in which the EPA sets standards at non-zero levels and justifies the decision based solely on arguments that are characterized as strictly scientific.

3.3. Clean Air Scientific Advisory Committee

The Clean Air Scientific Advisory Committee is a seven-member committee the Clean Air Act established "to provide advice and recommendations to EPA" (EPA 2015). Members are chosen on the basis of their scientific expertise, generally serve for two consecutive three-year terms, and meet twelve to fifteen times a year. Their expertise is often supplemented by panels of twenty or more experts on the health and environmental effects of the specific pollutants that are under review. As Figure 2 shows, these CASAC panels are involved at all stages of the NAAQS development process.

As recent reports from the Keystone Center and BPC have observed, scientific advisory panels can provide valuable input to agency decision-making. However, they caution that "in general, scientific advisory panels should not be asked to recommend specific regulatory policies" (BPC 2009, 5) or "to answer questions that go beyond matters of scientific judgment" (Keystone Center 2012, 8). As noted above, the Clean Air Act authorizes CASAC to recommend "new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate" (EPA 2015). Similar to the problem discussed above with respect to EPA staff, this allows CASAC to make hidden policy judgments couched in scientific terms and attempt to influence the Administrator's final policy decision. Note that the Act does not go so far as to require CASAC's *approval* of the Administrator's policy choice, and a Congressional Research Service (CRS) review of the history of CASAC observed that, until recently, committees eschewed the role of approver:

> CASAC panels have a nearly 30-year history of working quietly in the background, advising the agency's staff on NAAQS reviews, and issuing what were called "closure letters" on the agency documents that summarize the science and the policy options behind the NAAQS. Closure letters have been used by CASAC panels to indicate a consensus that the agency staff's work provides an adequate scientific basis for regulatory decisions. The science and policy documents, written by EPA staff, generally have gone through several iterations before the scientists were satisfied, but, with the issuance of a closure letter, CASAC has in past years removed itself from the process, leaving the formal

> proposal and final choice of standards to the Administrator. (McCarthy 2007, 2)

This CASAC behavior of detaching itself from the final policy process was consistent with Weinberg's recommendation in his landmark paper on "trans-science," in which he observed:

> Though the scientist cannot provide definite answers to trans-scientific questions any more than can the lawyer, the politician or a member of the lay public, he does have one crucially important role: to make clear where science ends and trans-science begins. (Weinberg 1972)

3.3.1. Recent CASAC Panels Take Forceful Policy Positions. Going beyond the subtler hidden policy judgment asked of CASAC in the statute, recent committees have been more aggressive at advocating their public policy decisions and have openly criticized administrators who deviate from their recommendations. For instance, in 2006, after the EPA Administrator issued standards outside the range recommended by CASAC, the committee took the unprecedented action of writing to the Administrator that the standard "does not provide an 'adequate margin of safety . . . requisite to protect the public health' (as required by the Clean Air Act)" (Henderson et al. 2006, ellipsis in original).

In an excellent example of a science charade, CASAC's ozone review panel stated in a 2008 letter to the EPA that its members

> *do not endorse the new primary ozone standard as being sufficiently protective of public health*. The CASAC—as the Agency's statutorily-established science advisory committee for advising you on the national ambient air quality standards—*unanimously recommended* decreasing the primary standard to within the range of 0.060–0.070 ppm. It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations. (Henderson 2008, italics in original)[22]

The CRS report observes that CASAC's recent advocacy deviates from its past practice of refraining from objecting to policy decisions that differed from its recommendations. It points to two examples where

[22] This may be one of the best examples of a nonscientific recommendation being couched as purely scientific opinion.

EPA administrators took no action to revise standards, despite staff and CASAC recommendations that the standards be tightened: in 1990, with regard to the lead NAAQS, and in 1996, with regard to the sulfur dioxide NAAQS. CASAC did not object in either case (McCarthy 2007, 9). In a more recent case, CASAC did not publicly object to Administrator Lisa Jackson's decision not to revise the primary standard for coarse particles (PM_{10}) in 2012, despite its conclusion that "it is clear that the current PM_{10} standard is not adequate to protect the public health" (Samet 2010a) and its recommendation "that the primary standard for PM_{10} should be revised downwards" (Samet 2010b).

3.3.2. Distinction between Science and Policy Blurred. The more activist stance of recent committees clearly crosses the line between science and policy. In response to an EPA workgroup effort to improve the NAAQS process, several former CASAC members expressed concerns about CASAC's ability to distinguish between science and policy recommendations.

Former CASAC member, Dr. Ellis Cowling (2006), cautioned:

> The responsibility of scientists, engineers, and policy analysts is to understand and clearly communicate the scientific facts and uncertainties and to describe expected outcomes objectively. Deciding what to do involves questions of societal values where scientists, engineers, and policy analysts have no special authority.

Former chairman, Bernard D. Goldstein, M.D. (2006), reflected on his experience:

> I found a sense among several CASAC members that the CASAC is responsible for approving the proposed standards rather than giving advice and recommendations. The Agency should make clear to CASAC what they require in terms of scientific advice and what they consider to be policy issues, on which they do not need advice. The line between science and policy is not always apparent, and this difference should be made clear in the charge questions given to CASAC.

Dr. George T. Wolff (2006) made a similar point:

> The selection of a particular level for a standard is a policy judgment. CASAC's job is to insure that the range, form and averaging time recommended in the Staff Paper have a scientific basis. In questioning the recommendations in the January 17, 2006 NPRM, CASAC has clearly overstepped their boundaries and ventured into the policy arena.

Former CASAC chairman Dr. Joe Mauderly (2006) observed:

> Neither scientists nor policy makers want to draw the line [between science and policy], or to define it or admit to it. CASAC meetings are rife with discussions about how its pronouncements will affect policy, and scientist advocates (on CASAC and its panels, as well as others) game the system to achieve their ideological policy goals. When EPA proposes or promulgates standards, it is reluctant to state clearly how science and policy enter into the decision—it wants to portray that all is based on science. These behaviors are absolutely understandable—most scientists are convinced that they know what's best for the country, and EPA Administrators don't want to admit to any motive other than the "best science."

The bald consideration of nonscientific factors by CASAC in making its recommendations is illustrated in the committee's deliberations on the 2007 lead NAAQS. Members objected to the standard the Administrator was considering because "it wouldn't create any pressure on any person producing lead in the environment today from reducing because it doesn't leave any more exceedances than the current standard" (EPA 2007a, 15). They presented various nonscientific arguments in support of their preferred, more stringent, policy option, including the "need to regulate it at a level that causes public attention to come to the problem," and that "causes the most severe polluters to have to put in additional controls" (EPA 2007a, 15–16).

The committee discussions appear to suffer from the symptoms identified in the organizational behavior literature regarding group behavior, including

> close-mindedness, involving a collective effort "to rationalize" so as to discount warnings or information that might lead to reconsideration, and stereotyped views of enemies, as too evil to warrant efforts at negotiation or "too weak and stupid to counter" the group's . . . choices. (Sunstein 2009, 86)

Transcripts of CASAC's 2007 meetings on the lead NAAQS decisions, for example, reveal that its members had few real disagreements with each other or with EPA staff. This means the committee likely lacked the value of independent analysis and challenge that is so essential to the scientific method. The discussions appear to exhibit the "asymmetrical trust" symptomatic of insular group dynamics that perpetuates an "us vs. them" mindset (Sunstein 2009). While committee members treat each other and EPA staff, with whom they often have a close working relationship, with respect, their comments reflect a "stereotyped view of enemies," including policy officials, other agency

staff, and the public (EPA 2007b, 145). For example, committee members objected strongly to providing the broader public an opportunity to comment on issues not preapproved by the committee, and members expressed the view that anyone not part of the committee likely had a conflict of interest (EPA 2007b, 33).[23]

3.3.3. CASAC Panels May Lack Diversity. Former CASAC chair George Wolff has raised concerns that EPA's selection of panel members exacerbates this problem. He noted several differences between the panel reviewing the 1997 fine particle NAAQS and the 2006 standard, including a change in the composition of the panels:

> In the 1994–96 review, there were a number of Panel members who were skeptical that the epidemiology studies demonstrated cause and effect including one biostatistician and one epidemiologist who were not authors of the studies that found statistical links between PM and health endpoints. As a result, the Panel expressed "a diversity of opinion."
>
> When the new Panel was formed, most of the Panel members who supported a causal role in 1996 were invited back to be on the new panel. Most of the skeptics were not. Instead they were replaced by individuals that, on the balance, were more supportive of the Agency's position. In fact, by the time the Panel concluded the review, seven out of 22 members had been authors of papers that purport causality. No epidemiologist or statistician who questioned causality was a member of the Panel. This lack of balance on the Panel predetermined the outcome of the review. (Wolff 2006)

Former CASAC chair Roger McClellan (2011) expressed concern that CASAC panel "membership has been excessively dominated by scientists that to a large extent have developed the scientific information contained in the documents [they are charged with reviewing]," noting that "[i]n some cases, the individuals have already offered opinions as to how the science should be used to set . . . a more stringent standard based on their science." According to a congressional investigation, sixteen of the twenty members of the CASAC panel charged with reviewing the science in support of the 2015 ozone NAAQS had conducted studies they were supposed to evaluate, and fourteen of the twenty members had been principal or co-investigators for EPA grants totaling more than $120 million (Smith 2014).

[23] Members objected to seeking public comment on issues because that put commenters "on an equal basis with the CASAC," and constituted "taking a group that has a clear conflict of interest and treating them as though they are equal to CASAC" (EPA 2007b).

3.3.4. CASAC's Treatment of Uncertainty. The unabashed crossing of the line between science and policy is also evident in the treatment of uncertainty and risk communication. Although the members of CASAC recognize the uncertainty inherent in supporting analyses, the drive for a narrow range of policy options may limit their willingness to quantify the full uncertainty range or to explore the quantitative implications of alternative science policy choices. For example, the 2007 lead NAAQS transcript reveals that CASAC members were initially critical of an EPA method for measuring health effects on the grounds that it was oversimplified and did not rely on current data and modeling techniques. When EPA staff pointed out that, compared to the more sophisticated method, this simplified method would more likely lead policymakers to a level already preferred by CASAC, CASAC members dropped their objections (EPA 2007b).

CASAC's position on how to manage uncertainty is another example of a hidden policy decision. The strongly worded letter objecting to the Administrator's policy decision on the 2006 $PM_{2.5}$ NAAQS, states that "while there is uncertainty associated with the risk assessment for the $PM_{2.5}$ standard, this very uncertainty suggests a need for a prudent approach to providing an adequate margin of safety" (Henderson et al. 2006).

Yet this assertion that uncertainty demands a "prudent" policy decision stands in contrast to the statement of former chairman, Bernard Goldstein (2006), who told the EPA:

> How one deals with the uncertainties is a policy issue. One can say that a lot of uncertainty suggests being more conservative to be sure we are "safe." Another policy might be that a large amount of uncertainties means that we cannot select appropriate levels until we have more information. In any case, the amount of uncertainty should be fully addressed and central estimates should be given as well as the upper and lower confidence limits. Again, the policy decisions made should be explicit and clearly stated in public.

As this discussion has shown, CASAC members' views of their role has evolved over time to be increasingly involved in the policy decision as to the level at which the standard should be set, yet still present such a recommendation as "science." This may be due, in part, to the individuals that the EPA staff select to serve on the committee and panels (Wolff 2006), and the charge the EPA gives them.[24]

[24] As Rogene Henderson (2006) observed, the EPA "should make clear to CASAC what they require in terms of scientific advice and what they consider to be policy issues, on which they do not need advice."

As discussed further below, members' views constrain policy officials and the courts, and influence public opinion. When differences of opinion about policies are cast as scientific disagreements, accusations of politicized science arise. However, as the BPC (2009) noted, "some disputes over the 'politicization' of science actually arise over differences about policy choices that science can inform, but not determine." The role of CASAC in setting NAAQS illustrates processes that both perpetuate hidden policy judgments and science charades, inviting use of the is-ought fallacy.

3.5. Policy Officials

Under the Clean Air Act, it is the EPA Administrator (and thus the president at whose pleasure she serves) who is ultimately responsible for issuing primary NAAQS, "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health" (42 U.S.C. § 7409(b)(1)). Similarly the Act requires the Administrator to set secondary NAAQS at a level which, in her judgment, "is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air" (42 U.S.C. § 7409(b)(2)). Though EPA staff prepare a regulatory impact analysis, including an assessment of the likely costs and benefits of achieving different standards, the Administrator does not consider it, and staff do not present it to her.[25]

As discussed above, in choosing the level of the standard, the Administrator faces pressure from EPA staff and CASAC members. In addition, outside groups, including state and local governments (which are responsible for implementing and achieving the standard), potentially regulated parties, nongovernmental organizations (NGOs), and Congress attempt to influence the Administrator's decision. Also, other administration officials (who often are responsible for implementing competing policy goals and may also be hearing from constituencies outside the government) may seek to sway the Administrator's determination.

The Administrator deviates from the recommendations of the Policy Assessment and CASAC at her peril (Henderson et al. 2006). If she

[25] According to the Regulatory Impact Analysis conducted in association with the final particulate matter standard set in December 2012, "[i]n NAAQS rulemaking, the RIA is done for informational purposes only, and the final decisions on the NAAQS in this rulemaking are not in any way based on consideration of the information or analyses in the RIA" (National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3,085 [Jan.15, 2013]).

makes a decision outside of the staff's and CASAC's recommendations presented to her, the Administrator runs the risk that NGOs will file suit to overturn her decision (possibly with support from EPA staff, who may even work with the Justice Department to make sure that the Administrator loses the lawsuit) (see, for instance, Haynes 2015). Particularly in the context of a science charade, public disagreement also puts policy officials at a public relations disadvantage when exercising policy judgment is characterized as going against science (see, for example, Union of Concerned Scientists, n.d.). For instance, both Presidents Obama and Bush were accused of politicizing science when they chose not to regulate ozone at the levels recommended by CASAC and the staff's Policy Assessment (see Walke 2011). Particularly when it comes to environmental and health experts, "it is difficult for political executives to reject their recommendations" (Melnick 1983, 295).

It is important to point out that hidden policy judgments by scientists not only discourage policymakers from setting standards higher than those recommended by staff, but lower ones as well. At one point in the development of the 2008 lead NAAQS, consideration was given to seeking public comment on whether zero was appropriate as the lower end of the range at which to set the standard. Given the lack of a threshold in health effects, and CASAC's unanimous and vocal opinion that lead remained a very serious public health risk, some policy officials questioned the justification for setting any standard above zero (authors' pers. comms. in NAAQS discussions as OIRA administrator and deputy administrator of the EPA). Available data and modeling made it difficult for the Administrator to conclude that a lead ambient air quality standard of 0.15 ug/m^3 was "requisite" to protect public health with an "adequate margin of safety," but 0.5 ug/m^3 or 0 ug/m^3 was not. The EPA Air Office staff (perhaps correctly) perceived this as an effort to expose the inherent contradictions in the NAAQS provisions of the Clean Air Act, and they strongly objected to it. In the face of staff opposition, Administrator Johnson chose not to present the wider range for public comment. It is much safer, from a political and staff management viewpoint, for Administrators to stay inside the policy box that EPA staff and CASAC have created for them.[26]

Sometimes the influence of the staff and CASAC is so strong that the decision requires an explicit and public policy judgment to be made above the Administrator and carefully explained to the public. In 2008, during the interagency review of the EPA's ozone NAAQS, disagreement over the form of the secondary "welfare" standard was

[26] Mauderly (2006) notes, "[M]ost scientists are convinced that they know what's best for the country, and EPA Administrators don't want to admit to any motive other than the 'best science.'"

so contentious that President Bush ultimately had to step in to resolve it.[27] Deliberations within the executive are generally not public, but in this case the Administrator was very reluctant to select a form different from that recommended by staff (Authors' pers. comms. in NAAQS discussions as OIRA administrator and deputy administrator of the EPA). Out of respect for his concern, the agencies' websites publically shared correspondence between the OIRA Administrator and Deputy Administrator of EPA (Dudley 2008), and the final preamble to the rule acknowledged the disagreement and that it was the president who concluded what the appropriate form of the standard should be (National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. 16,435, 16,497 [Mar. 27, 2008]).

3.6. States

States have a great interest in the level of the NAAQS. Under the Act, the EPA establishes the allowable concentration of each pollutant in the ambient air, but the burden falls on states to develop implementation plans that achieve those levels. Under the statute, areas not in attainment with the standard face restrictions on economic growth (Greenstone, List, and Syverson 2012). If a state fails to develop a plan that meets the EPA's standards, the agency may impose a more restrictive (and possibly punitive) Federal Implementation Plan; the federal government can also withhold federal highway funding from states chronically out of attainment, although it has not yet done so. By imposing the obligation of NAAQS attainment on the states, the EPA effectively commandeers, not only the considerable state resources that are needed to carry out the program, but also the much broader array of police powers that states enjoy. State Implementation Plans may include land use controls and other regulatory options that are not available to the EPA under the Constitution, let alone the Clean Air Act.

And yet, it may not be enough. Since the EPA Administrator cannot consider the feasibility of achieving a standard when revising it, the NAAQS for several criteria pollutants have put large geographic areas out of attainment, particularly the more densely populated urban areas of the Northeast and Pacific coast, with no realistic options for successful implementation. Los Angeles and surrounding areas, for example, cannot comply with the 0.08 ppm ozone NAAQS set in the 1990s, to say nothing of the tighter 0.075 ppm standards established

[27] The rarely used section 7 of Executive Order 12,866 says, "[C]onflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President" (58 Fed. Reg. 51,735 [Oct. 4, 1993]).

in 2008 or the even tighter 0.070 ppm standard set in 2015 (National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. 65,291 [Oct. 26, 2015]).[28]

Ironically, the states unable to comply with current standards are typically more supportive of stricter standards than the states that are in attainment. Eight of the fifteen states that filed comments in support of tightening the ozone NAAQS set in 2008 were unable to meet the existing standard and would certainly not be able to comply with a tighter standard. Not only do nonattainment states file comments on proposed standards, but several also have sued the EPA for failure to issue more stringent standards (see Hicks 2017). In contrast, of the six states that filed comments in opposition to tightening the ozone NAAQS, four were in "maintenance," meaning they had recently achieved compliance.

This may not be as surprising as it initially appears. Nonattainment areas have trouble attracting new businesses, and their citizens suffer (or move) when potential job-creating industries settle in other states. Greenstone, List, and Syverson (2012) have quantified the economic losses associated with nonattainment status, finding that

> total factor productivity (TFP) among plants that emit the targeted pollutants . . . declines by 4.8 percent for polluting plants in nonattainment counties. This corresponds to an annual economic cost from the regulation of manufacturing plants of roughly $21 billion in 2010 dollars. This translates into a loss of more than $450 billion over the studied period [1972 to 1993].

From the perspective of nonattainment areas, strict standards that throw areas in other states out of attainment "level the playing field." Areas that are already out of attainment have little to lose from stricter standards, but they gain relative to competing states, which will have nonattainment conditions imposed on them. Even though parts of California have been unable to meet the ozone NAAQS set in the 1990s, California legislators were the most vocal proponents of the more stringent ozone standards in 2008, accusing the EPA of considering factors other than public health in setting the NAAQS (*Wall Street Journal* 2008).

Absent a federal mandate, states would be expected to compete with each other in providing environmental quality, as well as economic prosperity. State officials know that voters demand environmental quality, and they also know that it affects property values—

[28] The EPA, in an archived map, shows the areas of the country that had not attained the 2008 ozone standards (https://archive.epa.gov/ozonedesignations/web/html/finalmap.html).

which in turn affect the state tax base, including funding for local governments and school districts. The overlay of mandatory federal NAAQS, however, suppresses and redirects this virtuous interstate competition. The EPA's oversight of NAAQS attainment acts in much the same way that economic regulation affects an otherwise competitive industry (see OMB [2003] for a discussion of the "presumption against economic regulation"). Instead of competing in the provision of air quality, states may be motivated to direct their energies to lobbying the regulator, seeking lenient treatment for themselves while advocating economically stifling restrictions on their competitors. State politicians present themselves to the voters as high-minded, if ineffectual, champions of environmental quality.[29]

3.7. Courts

As noted earlier, the United States Supreme Court confirmed the EPA's statutory interpretation that it cannot consider costs when setting NAAQS (*Am. Trucking Ass'ns*, 531 U.S. at 465–72, 475–76). The EPA notes, however, that the Act "does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels . . . but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety" (National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3,085 [Jan. 15, 2013]).

States supporting more stringent standards are joined by NGOs, such as the American Lung Association and the Natural Resources Defense Council, in seeking a remand of EPA standards on the grounds that they are not adequately protective according to statutory criteria (see, for example, Final Opening Brief of State Petitioners, *Mississippi v. EPA*, 744 F.3d 1334 [D.C. Cir. 2013] [No. 08-1200], arguing that the EPA's 2008 ozone NAAQS be remanded "on grounds that the primary NAAQS does not protect public health with an adequate margin of safety and the secondary NAAQS does not protect public welfare, as required under the Act"; see also Proof Brief For Environmental Petitioners, *Mississippi*, 744 F.3d 1334). States supporting less stringent standards sued the EPA seeking to have NAAQS vacated because the agency did not establish that the standards are requisite to protect health and welfare under the meaning of the Act. These states are supported by industry litigants (such as the US Chamber of Commerce, the Utility Air Regulatory Group, and the National Association of Home

[29] This behavior is consistent with economic theory regarding regulation, particularly the colorfully named "bootlegger and Baptist" theory (Smith and Yandle 2014).

Builders) (see, for example, Joint Opening Brief Of Petitioner State Of Mississippi and Industry Petitioners, *Mississippi*, 744 F.3d 1334). Given the statutory construction, none of the litigants openly express policy arguments for preferring one standard over another, but rather, they couch their legal arguments in terms of science—highlighting differences between CASAC's recommended levels and the Administrator's choice, and debating what science is needed to determine what levels are "requisite" to protect public health and welfare and what qualifies as an "adequate margin of safety."[30]

Lower courts also help enforce the Act's requirement for reviews of the standards every five years. In response to litigation over missed statutory deadlines, the government will enter into consent decrees that impose judicial deadlines for issuing standards.[31] Particularly given the steps involved in preparing the regulatory record in NAAQS proceedings, these deadlines constrain the opportunity for meaningful public consultation and interagency review (Fraas 2011, 86). The EPA often submits draft regulations to OIRA for interagency review just days before such deadlines.[32]

Even as the courts drive the NAAQS process forward and enforce the Clean Air Act's procedural requirements, they avoid questioning anything in the administrative record that is characterized as science. This understandable deference to agency fact-finding has a curious result: it tends to limit the EPA Administrator's ability to exercise the policy discretion that the Congress has entrusted to her. If the Administrator makes a policy decision that conflicts with the policy preferences of EPA staff or science advisors, there will be a conflict in the administrative record, falsely framed as a policy choice inconsistent with the "science." Judges find it easy to vacate administrative decisions in such circumstances. Whatever doubts the Administrator may have about the merits of the options given, the safest thing for the Administrator to do is simply acquiesce to the staff recommendations. The deference that courts properly owe to the political branches is cap-

[30] Bachmann (2007, 687) notes that "in the pre-proposal period, [interest] groups tried to influence the scientific basis for EPA's decisions," while "during the post-proposal period, the emphasis shifted to providing Congress, local elected officials, the media, and the public with 'spin' on the science . . . with results distilled to the 'sound bite.'"

[31] For example, the EPA faced a judicial deadline to issue final ozone NAAQS by October 15, 2015 (Order Granting Plaintiffs' Motion for Summary Judgment and Denying Defendant's Motion for Summary Judgment, Sierra Club v. EPA, No.: 13-cv-2809-YGR [N.D. Cal. Apr. 30, 2014]).

[32] Since the mid-1990s, the average interagency review time for NAAQS rules subject to deadlines has been less than twenty days, compared to an average review time of more than seventy days for all EPA rules over the same period. Statistics can be derived from data available at OIRA's website on regulatory information (www.RegInfo.gov).

tured, instead, by an unelected bureaucracy and outside science advisors due to the science charade.

3.8. Summary

The NAAQS process exemplifies the incentives at work that compel every party to the regulation to engage in hidden policy judgment and the science charade. Congress directs the EPA to set the standards to achieve noble goals, but encourages the politicization of science by restricting the agency from openly considering relevant nonscientific factors. Combined with tight deadlines, the statutory language permits Congress to take credit for laudable public goals while blaming the executive branch's execution for any undesirable outcomes. The courts have reinforced a limited interpretation of the Act, as well as the tight deadlines for issuing revised standards. Executive branch career and appointed officials respond by hiding policy judgments and creating a science charade, developing scientific-sounding explanations to justify one standard over another, and public interveners vigorously defend alternative standards based on their own interpretation of the "science."

Scientists argue for the primacy of their data; analysts have an incentive to downplay rather than reveal uncertainties regarding their predictions or the implications of key risk assessment policy choices; and decision-makers point to science as either requiring a new standard or as determining that existing standards are adequate.

This has evolved into an adversarial process, characterized by harsh rhetoric in which each party claims the science supports its preferred policy outcome, and each party questions opponents' credibility and motives, rather than constructively discussing appropriate data, assumptions, and normative decisions. The real reasons for selecting a particular standard may not even be discussed. This harms the credibility of scientific advice and results in poorer decision-making.

4. RECOMMENDATIONS

Despite the National Research Council's (NRC) guidance over thirty years ago, controversy remains surrounding regulatory actions aimed at reducing risk, leading to accusations of "politicized science," "advocacy science," or "junk science." What the NRC in 1983 identified as "a blurring of the distinction between risk assessment policy and risk management policy" is enabled by the is-ought fallacy and leads to hidden policy judgments and science charades that harm policy outcomes and can damage faith in science itself.

In thinking about reforms to improve how science is used in developing regulations, clarifying which aspects of the decision are matters of science and which are matters of policy is essential to avoid both hidden policy judgments and the science charade. When people condemn the "politicization" of science (Mooney 2006), the problem may really be that we ask too much of science in addressing policy problems. The Clean Air Act succumbs to the is-ought fallacy and does not permit transparent consideration of relevant policy factors when developing regulations. Other statutes, particularly those dealing with health, safety, and the environment are vulnerable to the same problem. As the BPC (2009, 4) recommended, a focus of reform should be on devising regulatory processes that "in as many situations as possible, . . . help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy." This would not only help address the is-ought fallacy, but also the problem of hidden policy judgments, in which the effect of risk-assessment policy judgments on estimates of outcomes are not acknowledged. "This transparency would both help force values debates into the open and could limit spurious claims about, and attacks on, science " (BPC 2009, 5).

Numerous experts have offered specific recommendations for improving the conduct of regulatory science. The following recommendations attempt to alter the incentives of the parties to the rulemaking process. The first category would address behavior contributing to the is-ought fallacy, and the second would specifically address the problem of hidden policy judgments, and the third would improve incentives generally.

4.1. Is-Ought Fallacy

The is-ought fallacy is the pretense that normative policy decisions regarding what "ought to be" can be determined exclusively by positive scientific information that describes what "is." This mistake can lead to both hidden policy judgments in risk assessments and a science charade in justifying policy decisions. The first two recommendations aim to reduce incentives to succumb to the is-ought fallacy.

1. Legislators must be more forthright in recognizing that "science" is a positive discipline that can inform, but not decide, appropriate policy. It would be challenging to convince legislators to avoid the is-ought fallacy and resist delegating decisions to agencies on the pretense that science alone can make the normative determination of what policy ought to be. This includes asking science advisors to rec-

ommend policy judgments they are typically ill suited to provide. For legislators to make the effort to elevate the debate above simple rhetoric, they must have different incentives and expectations of rewards than exist now. Currently, there is no feedback loop to reward a politician for tackling these issues openly and seriously.

Comparing the effectiveness of different statutes can be illuminating, however. Some statutes directed at health, safety, and environmental risks have facilitated more rational regulatory policy than others by recognizing that risk management requires normative judgments that consider tradeoffs. For example, the Safe Drinking Water Act requires the EPA to consider the costs as well as the benefits of requiring local water authorities to install controls for specific substances. Perhaps that is one reason why the debates over drinking water standards are generally less acrimonious than debates over ambient air quality standards. Since the statute allows explicit consideration of tradeoffs when setting standards, the full burden of decision-making is not vested in the risk assessment. As a result, policymakers and interested parties may have less incentive to embed policy preferences in the risk-assessment portion of the analysis because they can debate them openly and transparently in the risk-management discussion (Dudley and Gray 2012).

Codifying current executive requirements for performing regulatory impact analyses, including benefit-cost analyses, could provide a "supermandate" that would require agencies to explicitly present uncertainties and tradeoffs and to justify decisions in a transparent manner (Dudley 2015).

2. Legislators and policymakers must clarify the appropriate role for scientific advisors. The engagement of scientific advisory panels can provide a necessary and valuable source of information and peer review for agency science, but greater efforts should be made to restrict their advice to matters of science and to not ask them to recommend regulatory policies. When asked to advise on policy choices, as is the case with CASAC, it is impossible for members not to be tempted to wrap their policy views in a lab coat and present them as scientific recommendations.[33]

[33] See, for instance, the recommendation of former CASAC member Morton Lippman regarding changing the Clean Air Act. Lippman (2006, A-22) noted, "CASAC's role must be limited to highlighting the issues at the science-policy interface and the scientific knowledge that informs these issues."

As a former EPA scientist observed,

> Scientific information must remain a cornerstone of public policy decisions, but I offer cautionary guidance to scientists: get involved in policy deliberations, but play the appropriate role. Provide facts, probabilities, and analysis, but avoid normative science. Scientists have much to offer the public and decision-makers, but also have much to lose when they practice stealth policy advocacy. (Lackey 2013)

Cox (2015) observes:

> Experts, like other people, typically have high confidence in their own judgments, even when these lack objective validity. But subjective confidence in subjective judgments should not be used in place of sound, objective scientific methods. To do so, as in EPA's risk assessment for ozone, replaces sound science with potentially arbitrary, biased, and mistaken judgments.

Legislators should be clear when establishing committees like CASAC, to limit the role of scientific advisory panels to advising on science. Executive branch policy officials should also be very clear in drafting charge questions for advisory committees to solicit their scientific expertise without encouraging them to blur the lines between scientific expertise and policy judgment.[34] As both the BPC (2009, 5) and Keystone Center (2012, 8) reports emphasized, the questions posed to such panels "should be clearly articulated, and 'explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics, and other matters of policy.'" Experts with formal training and experience in policy analysis, economics, law, and other disciplines are much better equipped to provide advice on these latter questions.

4.2. Hidden Policy Judgments

Risk assessment necessarily involves assumptions and judgments as well as pure scientific inputs, yet it often generates precise-sounding predictions that hide not only considerable uncertainty about the actual risk, but hidden policy judgments. When scientists, intentionally or unintentionally, insert, but do not disclose, their own policy preferences in the scientific advice they provide government decision-

[34] Several former CASAC officials encouraged EPA to be clearer in its charge questions to distinguish between science and policy (see generally EPA, n.d.).

makers, it harms the credibility of science advice and results in poorer policy decisions.

3. The executive branch must establish procedures and incentives to make more transparent the effect different credible risk assessment inputs and assumptions have on the range of plausible outcomes. This proposal reiterates the recommendations of expert reports issued over the last three decades, including recent recommendations from the Institute of Medicine[35] and BPC. One way to make the risk-assessment policy choices more transparent to decision-makers and the public would be for agency scientists to calculate and present multiple risk estimates based on a variety of scientifically plausible data sets, endpoints, models, and the like (Dudley and Gray 2012). This would be in stark contrast to the current practice where agencies embed multiple risk-assessment policy choices in a single assessment, which facilitates what one former EPA scientist calls "stealth advocacy . . . because the average person reading or listening to such scientific statements is likely unaware of the underlying advocacy [and] . . . hidden policy preferences" (Lackey 2013). It is telling that currently, despite the fact the NAAQS level must "err on the side of safety," the EPA currently cannot (or will not) produce a quantitative estimate of just how prudent NAAQS levels are compared to more likely estimates of health risks.

Once a range of plausible risk outcomes were identified based on different, scientifically plausible inputs, agencies would be able to transparently identify which set of inputs, models, and outcomes comported with its preferred risk-assessment policy choice. Policy officials would choose specific numerical values from a range of scientifically plausible risk estimates and publicly defend the risk-assessment policy choices that support that choice. This would provide a serious incentive for policy officials to look into estimates of risk, consult with a broad variety of experts to understand the range of scientific views, and explicitly articulate the policy preferences informing their decisions.

Greater transparency regarding the assumptions and policy rationales for choosing one set of assumptions or models over another would encourage more openness and constructive discussion about science and policy, improving the ultimate policy decision and probably engendering greater acceptance of that policy choice (Dudley and Gray 2012).

[35] See, for instance, recommendation 8.1 that "U.S. Environmental Protection Agency senior managers should be transparent in communicating the basis of its decisions, including the extent to which uncertainty may have influenced decisions" (Institute of Medicine 2013, 225).

4. The executive branch should institutionalize reforms that encourage greater feedback and challenge of risk-assessment practices and policy choices. Greater transparency in the models, assumptions, and risk-assessment policy choices could encourage more open, constructive debate on those choices (see, for example, Obama Whitehouse Archives, n.d.). The scientific method depends on falsifiable hypotheses, data gathering, replication, dissent, and challenge to ensure objective analysis to minimize bias in the interpretation of results.

No one is truly objective. We all approach problems with our own prior views and perceptions, and, particularly when faced with new or incomplete information, we tend to look to others in whom we trust to help form our opinions and make decisions. Research suggests that individuals form more extreme views when surrounded by others with similar perspectives (Sunstein 2009). Institutional reforms that intentionally engage, rather than avoid, competing views, could go a long way to improve the clarity of the risk assessment process and the decisions that depend on scientific input.

President Obama built on his predecessors' efforts to provide for interagency review of different aspects of regulatory decisions, including the underlying science. He directed agencies to encourage an "open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, . . . including relevant scientific and technical findings" (Exec. Order No. 13,563, 76 Fed. Reg. 3,822 [Jan. 18, 2011]).

Successful reforms might involve pre-rulemaking disclosure of risk-assessment information to engage broad public comment on the proper choice of studies, models, and assumptions, long before any policy decisions are framed and "positions" established. Advanced notices of proposed rulemaking could be used effectively to gather such input (Balla and Dudley 2014).

5. Scientific advisory panels should be required to represent a diversity of perspectives, disciplines, expertise, and experience. The 2012 Keystone Center report offers a series of recommendations on "the composition of committees that are empaneled to review the science behind a regulatory decision." Acknowledging the importance of choosing panelists that "have the knowledge, training, and experience needed to address the charge to the panel" (Keystone Center 2012, 14), it admonished agencies "to recognize that all potential panelists will have conscious and unconscious biases," and said that "the panel selection process requires review of the disclosed information and a judgment as to the ability of each prospective panelist to participate in

open discussion and to consider other perspectives" (Keystone Center 2012, 15).

The report goes on to recommend:

> Because biases exist, an agency should strive to engage a wide range of perspectives of qualified scientific experts. We endorse the BPC report's statement that, "Agencies should not shy away from including scientists on a panel who are considered 'outliers' on the question(s) under consideration, provided that the scientist is a respected practitioner in a relevant field and the committee as a whole fairly represents the mainstream." (Keystone Center 2012, 15, quoting BPC 2009, 24)

Former CASAC Chair George Wolff's (2006) observations, quoted above—that the lack of balance among the individuals that the EPA empaneled to review the PM standards published in 2006 "predetermined the outcome of the review"—illustrates how not engaging a range of perspectives affects policy.

4.3. Improving Incentives for Feedback: Learning and Experimentation

The scientific method involves forming a hypothesis, making predictions based on that hypothesis, and data gathering and empirical testing, followed by revisions to the hypothesis and predictions based on results. It represents a systems approach whereby feedback and challenge inform action and encourage learning. The recommendations that follow would improve incentives for feedback, learning, and experimentation.

6. The legislative and executive branches should institutionalize feedback through retrospective review of regulatory outcomes. Regulatory programs are rarely subjected to rigorous evaluation and feedback. Most regulatory analyses rely on models and assumptions to make predictions about the risk reduction benefits that will accrue from a specific intervention. Institutionalizing a requirement to evaluate whether the predicted effects of the regulation were realized would provide an incentive to improve the use of science for predicting the benefits of interventions.

President Obama's executive orders directing agencies to review their regulations "to determine whether [they] should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives" (Exec. Order No. 13,563, 76 Fed. Reg. 3,822 [Jan. 18, 2011]; see also Exec. Order No. 12,866, 58 Fed. Reg. 51,735 [Oct. 4, 1993]) could

facilitate better retrospective analysis. However, these and previous retrospective review guidelines have been met with limited success, largely because they did not change underlying incentives (Dudley 2013). For example, section 812 of the Clean Air Act Amendments of 1990 requires the EPA to periodically assess the benefits and costs of the Act (EPA Office of Air and Radiation 2011), but the EPA's assessment under this provision has relied on the same modeling it used for ex-ante analysis, so it has not provided information necessary to validate estimates or underlying risk-assessment assumptions and procedures.

A useful evaluation would measure population changes with respect to the predicted outcomes following the regulatory intervention. For example, actual reductions in cancer rates would be compared to predicted reductions to determine if actual experience corroborates or challenges the hypothetical benefits. Cox (2015) offers concrete recommendations for applying statistical tools to test "how changes in inputs (such as exposure) propagate through a network of validated causal mechanisms to cause resulting changes in outputs (such as health effects)."

Agencies should be required to include in proposed regulations a framework for empirical testing of assumptions and hypothesized outcomes. To incentivize more robust evaluation along the lines identified above, agencies could be required to test the validity of risk-reduction predictions before commencing a new regulation that relies on models. The five-year NAAQS reviews, for example, could be required to apply quasi-experimental techniques to gather and analyze epidemiology data and health outcome trends in different regions of the country and compare them against predictions (Cox 2015; Dominici, Greenstone, and Sunstein 2014).

Congress and OMB should reallocate resources from ex-ante analysis to allow agencies to gather the information and evaluation tools necessary to validate ex-ante predictions. Shifting resources from ex-ante analysis to ex-post review would not only help with evaluation, but would improve our ex-ante hypotheses of regulatory effects. Whether President Trump's requirement that agencies identify existing regulations to remove or modify before issuing new ones will lead to a shift in resources and motivate better retrospective analysis remains to be seen (see Exec. Order No. 13,771, 82 Fed. Reg. 9,339 [Jan. 30, 2017]).

Retrospective review should not be left exclusively to regulatory agencies, which have little incentive to find fault with their regulations, but should be subject to third-party evaluation.[36] And mechanisms such as sunset provisions or offsets (as applied in other countries)

[36] As Greenstone (2015) observed, "the process of self-evaluation is challenging for all organizations, as it requires complete objectivity. Indeed, history is unkind to organizations that fail to get outside reviews of their work."

could provide incentives for objective evaluation of regulations' effects (Dudley 2016).

7. Regulations should be designed to facilitate natural experimentation and learning. Designing regulations from the outset in ways that allow variation in compliance is essential if we are to go beyond observing mere associations and gather data necessary to test hypotheses of the relationship between regulatory actions, hazards, and risks. Quasi-experiments (QE) relying on differences in treatments (such as differences in attainment status with NAAQS) can inform risk assessments going forward.

> QE evaluation techniques provide an opportunity to improve understanding of the relation between human health and particulates air pollution. In a QE evaluation, the researcher compares outcomes between a treatment group and a control group, just as in a classical experiment; but treatment status is determined by politics, an accident, a regulatory action, or some other action beyond the researcher's control. The key difference with an observational study in this setting is that the QE approach is devoted to identifying treatment-induced variation in particulates that plausibly mitigates confounding or omitted variables bias in the estimated relation between human health and particulates, rather than relying on the variation presented by nature and optimizing agents. Despite the "nonrandom" assignment of treatment status, it is possible to draw causal inferences from the differences in outcomes (by "outcomes," we refer to both air pollution levels and human health) between the treatment and control groups in a quasi- or natural experiment, provided certain assumptions are met. (Dominici, Greenstone, and Sunstein 2014, 258)

Agencies could conduct pilot studies or "deploy different regulations where empirical evaluations of such differences will help resolve disputed issues of regulatory policy" (McGinnis 2012, 311).

8. Greater weight should be placed on scientific studies that were subject to peer review and whose results are reproducible. Peer review is often considered a fundamental component of the scientific process. Concerns over the extent and rigor of review of important scientific analyses led OMB in 2004 to issue a memorandum establishing guidelines for the use of external peer review at all federal agencies and departments (Bolten 2004). OMB has also directed agencies to issue information quality guidelines to, among other things, ensure the objectivity of information, including "a high degree of transparency about data and methods to facilitate the reproducibility of such information

by qualified third parties" (Guidelines for Ensuring and Maximizing the Quality, Objectivity, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8,451 [Feb. 22, 2002]). These guidelines did not, however, require reproducibility, observing that "reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (i.e., a new experiment, test, or sample) shall not be required prior to each dissemination" (67 Fed. Reg. 8,451).

Scientific publishing is focusing more on the sharing of data and experimental transparency (Achenbach 2015). The journal *Science*, for example, has undertaken "initiatives to increase transparency and promote reproducibility in the published research literature. . . . Connected to that progress, and an essential element to its success, an additional focus will be on making data more open, easier to access, more discoverable, and more thoroughly documented" (McNutt 2015, 7). As the *Science* editors observe, "When the greatest number of creative and insightful minds can find, access, and understand the essential features that led to the collection of a data set, the data reach their highest potential" (McNutt 2015, 7). A greater emphasis on reproducibility can encourage challenge and validation so important to the scientific method.

9. Legislation should recognize that states have a core interest in environmental quality, and that experimentation and competition among states can be a powerful force for improving environmental outcomes and our practical knowledge of what works. Many environmental statutes are structured, appropriately, with a prominent federalist framework. Much of the on-the-ground work is left to states, which makes sense because pollution is primarily a problem of local externalities, and also because local knowledge and local experimentation can be brought to bear on problems that are not susceptible to one-size-fits-all federal rules. As implemented, however, the NAAQS process assigns to EPA staff an artificial scientific determination, isolated from any practical considerations, and assigns to the states all of the implementation problems, while depriving them of the policy discretion that might allow them to solve those problems. The resulting dynamic channels competitive energy in unproductive directions.

Perhaps a better division of responsibility would be for the federal government to conduct basic risk-assessment research and share information on environmental damages but defer to states or regional associations on decisions regarding the risk-management policies appropriate for their situations. This would offer several advantages. First, it would help distinguish risk assessment from risk management, especially if combined with other recommendations aimed at avoiding

the is-ought fallacy. Second, it would encourage risk-management decisions to be made where they can best reflect the circumstances and preferences of affected citizens.[37] Third, the nation as a whole would gain from experimentation regarding how different policy measures work in practice, without imposing untried systems on the entire nation.[38] Such an approach would provide the natural experimental framework and data needed for more QE evaluation.

10. Agencies should engage in collaborative tools to generate knowledge. Nobel laureate Friedrich von Hayek (1945) identified the central problem facing public policy as "the unavoidable imperfection of man's knowledge and the consequent need for a process by which knowledge is constantly communicated and acquired." Hayek's focus was on economic planning and he showed that decentralized markets focus dispersed information—information that no one individual can obtain—and convey it efficiently to market participants. Many of the risks of concern to regulatory agencies may not be accounted for in market transactions, however. In these cases, we may require a different solution to address Hayek's observation that relevant facts are never possessed by a single mind, to take advantage of knowledge "that is dispersed among many people."

New media may provide a vehicle for stimulating a broader exchange of ideas and expanding our knowledge by reducing transaction costs, significantly lowering the costs of gathering and aggregating information, and removing obstacles to collaboration across a wide spectrum of individuals (Shirky 2008). E-rulemaking provides a platform for following and commenting on federal regulations, but to date, it has mainly served to facilitate traditional notice and comment, and has not generated interactive, iterative engagement (Dudley and Gray 2012; Balla and Dudley 2014).

[37] For pollutants that cross state borders, regional governance structures may be appropriate.

[38] Where there are large national economies of scope, such as the development of vehicle emission standards, the risk management could be done at the national level. Absent such economies, greater discretion on risk management should remain with the states. Wallace E. Oates (2009) suggests that "the introduction in the 1970s and 1980s of a variety of emissions trading systems at the state level demonstrated the feasibility of such systems and some of their very appealing properties—as well as certain pitfalls." He suggests that this state-level experimentation with innovative solutions to emissions problems led to the successful introduction of the national system of tradable sulfur allowances under the 1990 Clean Air Act Amendments (Oates 2009).

To harness the wisdom of dispersed knowledge, agencies or outside parties might experiment with a collaborative "wiki" approach to public comment where, rather than each individual or group filing comments in parallel and the agency responding to those comments individually, there would be a forum for diverse individuals to build on each other's information, adding, editing, updating, and correcting to engage the wisdom of dispersed knowledge on issues where no one person has complete information (Dudley and Gray 2012). Larry Sanger (2006), founder of Wikipedia, calls this "distributed knowledge collaboration."

One big advantage of a wiki approach is what Shirky (2008) calls its "publish-then-filter" model, where editing is done after something is posted, rather than before. Participants do not need to worry that their post is incomplete or may have inaccuracies because other participants can expand or correct it.

> In a system where anyone is free to get something started, however badly, a short, uninformative article can be the anchor for the good article that will eventually appear. Its very inadequacy motivates people to improve it; many more people are willing to make a bad article better than are willing to start a good article from scratch. (Shirky 2008, 122)

Engaging public input through a wiki is an intriguing possibility that holds the potential to revolutionize how agencies gather information on which to base public policies.

5. CONCLUSIONS

Institutional arrangements in the regulatory development process tend to aggravate two contributors to the politicization of science: "hidden policy judgments" (not acknowledging the policy judgments inherent in risk assessment) and "science charades" (camouflaging policy decisions as science). Both of these problems threaten the credibility of the scientific process and harm regulatory policy. Many of those involved in regulatory decisions have incentives to hide policy preferences, such as how to deal with the uncertainty in assessments of risk, and to dismiss and denigrate dissenting views. In many cases, politicization is the result of officials falling prey to the "is-ought fallacy" (incorrectly mixing up positive information about what "is" with normative advice about what "ought to be"). Key policy choices, disguised as science, too often rest with technical staff; meanwhile, policymakers charged with making hard policy decisions are able to avoid responsibility by claiming that their hands were tied by "the science."

As a case study, this paper has examined the process by which the EPA sets NAAQS under the Clean Air Act to illustrate some of the perverse incentives involved in developing regulations, and offered ten mechanisms to improve those incentives and resulting policy.

Effective environmental policy that focuses resources on addressing real threats to public health and the environment depends on reliable scientific information and transparent policy choices. The mechanisms offered here could reduce acrimony and improve the debate over environmental policy by helping distinguish between risk assessment and risk management, avoid the is-ought fallacy, and make more transparent previously hidden policy judgments. This will improve not only environmental outcomes, but also the integrity of scientific advice.

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