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Regulatory Science and Policy

A Case Study of the National Ambient Air Quality Standards

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ABSTRACT

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.

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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." 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 can inform, but not decide.

No one is immune to the temptation to put a spin on science to advance a policy goal, therefore, it is useful to distinguish between two distinct types of problems leading to controversy over science as it is used in the regulatory process. Problems arise when political decision-makers attempt to distort what scientific studies conclude (we call this "politicization of science"), but problems also arise when scientists and others attempt to exert influence on policy decisions by selectively presenting, or even distorting, scientific findings (we call this "scientization of policy").

While media coverage of issues ranging from genetically-modified organisms to climate change decries the first problem, the Bipartisan Policy Center's (BPC) 2009 report, *Improving the Use of Science in Regulatory Policy*, emphasized the latter, observing 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."[3]

This tendency has contributed to what Wendy Wagner has called the "science charade," where regulatory agencies "camouflag[e] controversial policy decisions as science."[4]

This paper focuses on the scientization of policy and examines why it is a problem, the institutional incentives that contribute to it, and possible remedies. We begin by describing what we mean by the scientization of policy, and illustrate this with a case study of the incentives and

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[3] Bipartisan Policy Center. Improving the Use of Science in Regulatory Policy. Washington (DC): Bipartisan Policy Center; 2009;10. Available at: http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf "BPC"

[4] Wagner, W.E. The Science Charade in Toxic Risk Regulation. Columbia Law Review. 1995 Nov;95(7): 1614; 29.

behavior of the participants in the development of national ambient air quality standards (NAAQS) under the Clean Air Act.[5] We conclude with recommendations for changing those incentives.

1. THE SCIENTIZATION OF POLICY

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 (policy) decisions regarding what *should be*. In the context of health, safety, and environmental regulation, in 1983 the National Research Council (NRC) of the National Academy of Sciences described the following conceptual framework:

> 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.[6]

Risk assessment is necessary, but rarely sufficient, for establishing effective policy to address identified risks. Sound policy decisions must also weigh other factors, such as those related to economics, engineering, ethics, law, and politics. Failure to recognize this is what we will call the "positive-normative fallacy."

Second, even in the risk assessment phase of an analysis, scientists will never have complete information to predict outcomes with certainty, so analysts rely on what the NRC called "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.

> 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

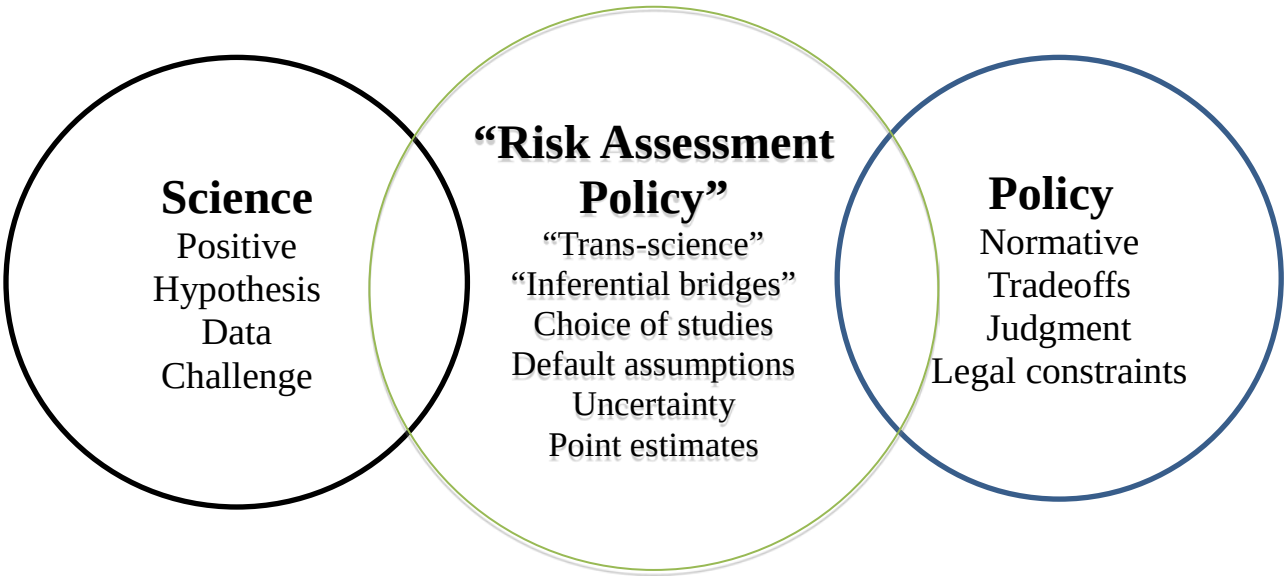
[5] The CLEAN AIR ACT, 42 U.S.C. § 7408 Available at: http://www.gpo.gov/fdsys/pkg/USCODE-2008-title42/pdf/USCODE-2008-title42-chap85.pdf

[6] National Research Council and the Committee on the Institutional Means for Assessment of Risks to Public Health. Risk Assessment in the Federal Government: Managing the Process. 1983. Washington D.C.: National Academies Press. "NAS Red Book"

> *risk assessment policy* to differentiate those judgments and choices from the broader social and economic policy issues that are inherent in risk management decisions.[7]

Figure 1 illustrates the relationship between pure scientific inputs and policy decisions, and the role of "trans-science"[8] and judgment in interpreting and presenting evidence relevant to policy. "Risk assessment policy" includes various judgments, including: judgments about 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.[9]

Figure 1. Science, Policy, and "Risk Assessment Policy"



Based on Dudley and Gray, "Improving the Use of Science to Inform Environmental Regulation," in *Institutions and Incentives in Regulatory Science,* Lexington Books, Jason Johnston ed. (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

[7] NAS Red Book ,1983.

[8] Weinberg, Alvin M. "Science and Trans-science." *Minerva* 1972, 10(2), 209-222. "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..."

[9] Dudley, SE & Gray, GM. "Improving the Use of Science to Inform Environmental Regulation," in *Institutions and Incentives in Regulatory Science,* Lexington Books, Jason Johnston ed. (2012)

often generate precise-sounding predictions that hide not only considerable uncertainty about the actual risk, but the reliance on biased inferences and assumptions for handling that uncertainty.[10] In this paper, we term this "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.[11] These practices obscure the boundary between science and policy, and contribute to the scientization of policy.

Former EPA scientist Robert T. Lackey 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."[12]

In its 2011 evaluation of 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.[13]

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[10] For example, EPA's "Risk Assessment Principles and Practices" document states: "[s]ince 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." (USEPA 2004, 13-14)

[11] Gray, G. & Cohen, J. "Rethink Chemical Risk Assessment." *Nature*. 2012 Sep; 489. P. 27.:"the 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 risk estimates can lead to overly stringent regulations and can scramble agency priorities because the degree of precaution differs across chemicals."

[12] Lackey, Robert T. "Normative Science." *Terra Magazine*. Oregon State University. 2013;8(2).

[13] Committee to Review EPA's Draft IRIS Assessment of Formaldehyde; National Research Council. *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*. Washington (DC): National Academy of Sciences; 2011: 4. Available at: http://www.nap.edu/catalog.php?record_id=13142

Institutional arrangements in the regulatory development process tend to aggravate these two contributors to the scientization of policy: the "positive-normative fallacy" (not acknowledging that science alone is insufficient to resolve normative policy questions) and "hidden policy judgments" (not acknowledging the policy judgments inherent in risk assessment). By framing issues as resolvable by science, current practices both threaten the credibility of the scientific process, and harm resulting regulatory policy. Many of those involved in regulatory decisions have incentives to hide rather than reveal the uncertainty in assessments of risk[14] and to dismiss and denigrate dissenting views.[15] Key policy choices, disguised as science, rest with technical staff; meanwhile, policy makers 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 judgment 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. 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.

The process by which EPA sets National Ambient Air Quality Standards (NAAQS) for "criteria pollutants"[16] under the Clean Air Act illustrates some of the perverse incentives involved in developing regulations, which lead to controversy, lack of transparency, and misdirected resources. 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,[17] but on the other, NAAQS decisions are among the most controversial of EPA policies. Each of the last three presidents has taken the highly unusual step of publicly and personally intervening in EPA's regulatory decisions.[18]

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[14] According to Wagner, "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." Wagner 1995 at 1668.

[15] For example, see posts by the Center for Progressive Reform (http://www.progressivereform.org/13RulesOzone.cfm) and the Center for Regulatory Solutions (http://centerforregulatorysolutions.org/will-epas-ozone-ambitions-reveal-more-collaboration-with-green-groups/)

[16] 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. Available at: http://www.gpo.gov/fdsys/pkg/USCODE-2008-title42/pdf/USCODE-2008-title42-chap85.pdf

[17] Wagner, W. "Science in Regulation: A Study of Agency Decision making Approaches" (referring to the NAAQS development process as "the equivalent of a five-star process for incorporating science into regulatory policy.") 2013: 29. Available at: http://acus.gov/report/science-regulation-final-report

[18] 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

Using NAAQS as a case study, the next section explores the procedures for developing regulations and the institutional incentives that may contribute to the two components of scientization of policy problem identified here: the positive-normative fallacy and hidden policy judgment.

2. PARTICIPANTS IN THE RULEMAKING PROCESS, THEIR MOTIVES & 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 EPA.[19] Regulatory agencies then develop draft proposed regulations consistent with the language in the enabling legislation and according to procedures mandated by both Congress and the President.[20] In particular, the Administrative Procedure Act requires regulatory agencies to notify the public and seek comment on proposed regulations, and to base final regulations on information in the rulemaking record.[21] This notice-and-comment process guarantees interested parties (those affected by potential regulation, non-governmental organizations, and others) an opportunity to present views and information on proposed

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EPA Administrator on "Implementation of Revised Air Quality Standards for Ozone and Particulate Matter," to "ensure that the new standards are implemented in a common sense, cost-effective manner." Available at: http://www.gpo.gov/fdsys/pkg/WCPD-1997-07-21/pdf/WCPD-1997-07-21-Pg1080.pdf) (See Fraas 2011 at 81-85 for an insider's account of the 1997 deliberations.) In 2008, 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 E.O. 12866 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. Available at: http://www.reginfo.gov/public/postreview/Steve_Johnson_Letter_on_NAAQs_final_3-13-08_2.pdf In 2011, the President intervened again. 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 NAAQS" from interagency review. Available at: http://www.whitehouse.gov/the-press-office/2011/09/02/statement-president-ozone-national-ambient-air-quality-standards. This is the only time during President Obama's administration that the White House has returned a regulation to an agency.

[19] Shoenbrod, David. *Power without Responsibility: How Congress Abuses the People through Delegation*. Yale University Press. 1995.

[20] Dudley, S.E. & Brito, J. *Regulation: A Primer*. Washington, DC: The George Washington University Regulatory Studies Center and Mercatus Center, George Mason University; 2012.

[21] Administrative Procedure Act (5 U.S.C. Subchapter II) Available at: http://www.archives.gov/federal-register/laws/administrative-procedure/

regulations.[22] Additionally, since 1981, presidents have required agencies to conduct regulatory impact analyses of economically significant regulations, and to subject them to interagency review through the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget.[23] Congress has an opportunity to issue a joint resolution to disapprove a final regulation after it is published,[24] and regulations are also subject to judicial review (allowing affected parties to sue to have regulations overturned by the courts).[25] Throughout the rule development process and beyond, 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.

2.1. Authorizing Legislation

The Clean Air Act of 1970 (P.L. 91-604) directed the newly created Environmental Protection Agency to issue NAAQS for each pollutant for which the Health, Education, and Welfare Department 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.[26]

The Act 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,"[27] 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."[28] It further required the Administrator to set "secondary" (welfare-based) standards based on these

[22] Balla, S.J. "Public Commenting on Federal Agency Regulations: Research on Current Practices and Recommendations to the Administrative Conference of the United States." Washington (DC) 2011. Available at: http://www.acus.gov/sites/default/files/documents/Consolidated-Reports-%2B-Memoranda.pdf

[23] See Executive Orders 13563 and 12866 governing regulatory analysis and oversight. Available at: http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo13563_01182011.pdf

[24] The Congressional Review Act of 1996 (5 U.S.C. § 801-808) Available at: http://www.archives.gov/federal-register/laws/congressional-review/.

[25] Dudley, S.E. & Brito, J. 2012.

[26] For a thorough review of the history of NAAQS, see Bachmann, John. "Will the Circle Be Unbroken: A History of the U.S. National Ambient Air Quality Standards." Journal of the Air & Waste Management Association. Volume 57, Issue 6, 2007. He finds, "Even 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." Bachmann, 2007: 655.

[27] The Clean Air Act, 42 U.S.C. § 7408 (b)(1)

[28] The Clean Air Act, §108(a)(2)

criteria at a level "requisite to protect the public welfare from any known or anticipated adverse effects."[29]

Amendments to the Clean Air Act in 1977 (P.L. 95-95) required the Administrator to conduct a "thorough review of the criteria…and promulgate such new standards as may be appropriate," at least every five years.

The Supreme Court has confirmed EPA's interpretation that, when it sets primary standards, the statutory language precludes consideration of the costs of achieving the standard.[30] Thus the Clean Air Act itself, at least in this reading, succumbs to the positive-normative fallacy by framing the Administrator's decision as resolvable by considering science alone, despite statutory language such as "requisite to protect public health," and "adequate margin of safety," which are clearly normative.[31]

The statutory framing makes it difficult to follow the BPC's 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."[32]

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

[29] The Clean Air Act, 42 U.S.C. § 7408 (b)(2)

[30] *Whitman v. American Trucking Associations, Inc.*, 531 U.S. 457 (2001) 99-1426.175 F.3d 1027 and 195 F.3d 4, affirmed in part, reversed in part, and remanded.

[31] An amicus brief in this case, signed by a bipartisan group of 42 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." Arrow, K.J. et. Al. National Ambient Air Quality Standards (NAAQS) Brief. Washington (DC): Joint Center, AEI-Brookings Joint Center for Regulatory Studies; 2000 July. Available at: http://www.brookings.edu/~/media/research/files/reports/2000/7/naaqs%20litan/07_naaqs_litan.pdf A former EPA science advisor observed regarding 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?" (Dr. Joe Mauderly Comments on the NAAQS Review Process March 3, 2006. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf)

[32] Bipartisan Policy Center; 2009:4.

> 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."[33]

While the Act left the decision for setting NAAQS to "the judgment of the [EPA] Administrator," the 1977 amendments required 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 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…" (109(d)(2) By inviting the scientific advisors to make normative recommendations regarding what level is appropriate, this language further blurs the distinctions between scientific expertise and policy judgment.[34]

2.2. EPA

EPA follows a multi-step process when reviewing and setting NAAQS, as shown in Figure 2.[35] It begins by developing an Integrated Review Plan that identifies the science and policy issues that will be reviewed during the 5-year assessment. Next, 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. 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 interprets various studies and data to generate a single concentration-response model to predict health effects at different levels of exposure. EPA's presentation of the available studies and data necessarily involves judgment 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. In recent reviews (*e.g.*, ozone, PM) concentration-response models assume that adverse health effects occur in a linear manner, at exposures down to zero.[36]

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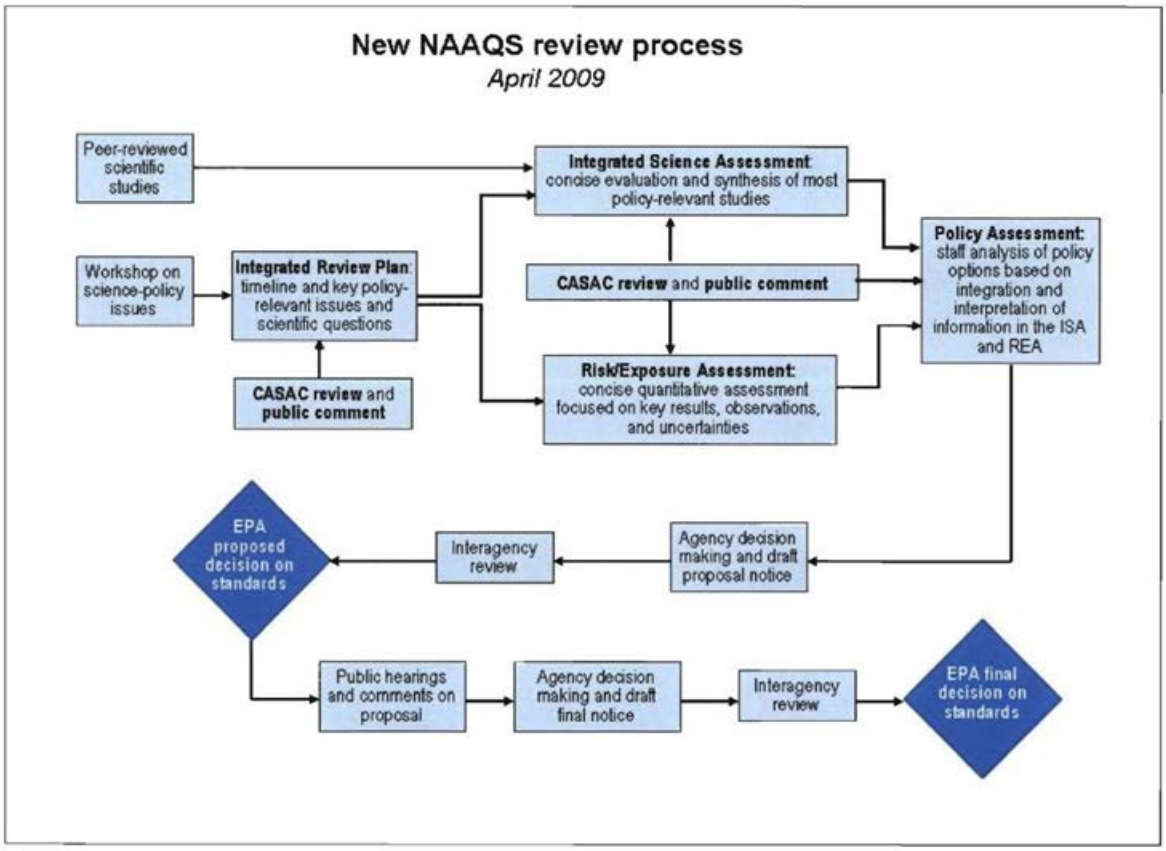
[33] Schoenbrod, D. "Politics and the Principle that Elected Legislators Should Make the Laws." *Harvard J. Law Public Policy* 2003, 26: 270, citing Clean Air Act Amendments of 1977: Hearings Before the Subcomm. on Envtl.Pollution of the Senate Comm. on Env't and Public Works, 95th Cong. 8 (1977).

[34] 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." Bipartisan Policy Center; 2009:17.

[35] Craig, E. (EPA Acting Administrator for Air and Radiation). Letter to: Kadeli, L. (Acting Assistant Administrator for Research and Development). 2009 May 21. Process for Reviewing National Ambient Air Quality Standards. Available at: http://www.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf

[36] See final regulations governing $PM_{2.5}$ (Available at: http://www.gpo.gov/fdsys/pkg/FR-2013-01-15/pdf/2012-30946.pdf); Nitrogen dioxide (Available at: http://www.gpo.gov/fdsys/pkg/FR-2010-02-09/html/2010-1990.htm); and Ozone (Available at: http://www.gpo.gov/fdsys/pkg/FR-2008-03-27/html/E8-5645.htm)

Figure 2.



As statistician Louis Anthony Cox observed in a recent public comment on EPA's proposed ozone NAAQS,

> EPA's quantitative risk estimate (QRA) provides no legitimate reason to believe that the proposed action is "requisite to protect public health" or that reducing the ozone standard further will cause any public health benefits. The QRA's model-based projections to the contrary are known to rely on mistaken assumptions (for the MSS model) and mistaken interpretations of curve-fitting (for the epidemiological risk assessment in Section 7). Past data on human health before and after reductions in ozone do not reveal any such causal impacts. Given EPA's information and the unquantified model uncertainty that remains, there is no sound technical basis for asserting with confidence, based on the models and analyses in EPA's ozone risk assessment, that an ozone standard of 65 ppb would be any more protective than 70 ppb, or that 80 ppb is less protective than 60 ppb. To the contrary, available data suggest that further reductions in ozone levels will

> make no difference to public health, just as recent past reductions in ozone have had no detectable causal impact on improving public health.[37]

Further, the risk assessment policy judgments that are embedded in these models are not transparent. The findings of the ISA and REA will depend heavily on how the staff decides to answer such questions as what effects are considered "adverse," the 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, EPA considers reversible, asymptomatic cellular changes and transient symptomatic effects (such as coughs) to be "adverse," even when those effects may be similar to risk levels people accept in their daily decisions, like driving, eating, playing, and working.[38]

A recent report from the Institute of Medicine observed:

> 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.[39]

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."[40] EPA assumes a causal relationship based on epidemiological evidence of an association between PM concentrations and mortality, however, as all students are taught, correlation does not imply

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[37] Cox, LA Jr. "Public Interest Comment on the Environmental Protection Agency's Proposed Rule: National Ambient Air Quality Standards for Ozone." The George Washington University Regulatory Studies Center. March 17, 2015. http://regulatorystudies.columbian.gwu.edu/public-comment-national-ambient-air-quality-standards-ozone

[38] See, for example, discussion of health effects in National Ambient Air Quality Standards for Ozone; Proposed Rule. December 17, 2014. (79 FR 75263) "Cox 2015"

[39] Board on Population Health and Public Health Practice; Institute of Medicine. *Environmental Decisions in the Face of Uncertainty*, Committee on Decision Making Under Uncertainty, 2013. Available at: http://www.nap.edu/catalog.php?record_id=12568

[40] Office of Information and Regulatory Affairs. 2*012 Report to Congress On the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*. Washington (DC): Office of Management and Budget, Executive Office of the President; 2013:19. Available at: http://www.whitehouse.gov/sites/default/files/omb/inforeg/2012_cb/2012_cost_benefit_report.pdf

causation (*cum hoc non propter hoc),* and EPA cannot identify a biological mechanism to explain the observed correlation. As Dominici, Greenstone & Sunstein 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."[41] Further, statistical experts raise questions as to whether the correlation EPA claims is real, and present analysis that suggests EPA's estimates of $PM_{2.5}$ mortalities are a product of model and data choices, rather than a real measured correlation.[42]

Another key assumption on which EPA's estimates of adverse effects hinge is that the concentration-response function for fine particles is 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.[43] However, EPA assumes a linear concentration-response impact function that extends to concentrations below background levels.

Based on its assumptions of a causal, linear, no-threshold relationship between $PM_{2.5}$ exposure and premature mortality, 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), the effects of reducing $PM_{2.5}$ would be significantly less than EPA's assessments estimate, including zero.

Yet, these uncertainties are not presented in the ranges of risks reported. Cox's review of EPA's ozone NAAQS proposed in December 2014 finds:

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[41] Dominici, Francesca, Greenstone, Michael, &Sunstein, Cass R. "Particulate Matter Matters." *Science* Vol 344. April 18, 2014.

[42] See, e.g., Cox L.A. "Reassessing the human health benefits from cleaner air." 2012 May;32(5):816-29. Risk Analysis 2012, and Krstić, G. "A reanalysis of fine particulate matter air pollution versus life expectancy in the United States," J Air Waste Manag Assoc. 2013 Feb;63(2):133-5. Cox's statistical analysis suggests with a greater than 95% probability that no association exists, and that instead, EPA's results are a product of its choice of models and selected data, rather than a real measured correlation. Krstić's 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."

[43] See, for example Texas Commission on Environmental Quality, "$PM_{2.5}$ Standards may be set Lower than Scientifically Justifiable," noting 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." Available at: http://www.tceq.texas.gov/assets/public/comm_exec/pubs/pd/020/2013/Outlook-Mar-2013-x.pdf

> 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.[44]

One former EPA science advisor called for "a more explicit characterization of uncertainty in estimates of causality and exposure-response relationships … for both primary and secondary standards," noting:

> 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.[45]

These uncertainties are further hidden from policy makers when, after the ISA and REA are completed, EPA staff prepares a Policy Assessment (formerly called the Staff Paper) that "bridges the gap" between the ISA and REA, and develops a set of policy options to present to the Administrator. The Policy Assessment "presents staff conclusions regarding the adequacy of the current suite of standards as well as potential alternative standards for [the Administrator's]

[44] Cox, 2015

[45] Mauderly J. "Comments on the NAAQS Review Process," March 3, 2006. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf

consideration."[46] This presentation of staff's judgment (informed by CASAC) regarding what is "requisite to protect public health" further blurs the lines between science and policy judgments.[47] 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." Uncertainty at lower levels of exposure is discussed vaguely to justify setting levels greater than zero.[48] As a result, the policy options presented constrain the ultimate decision of the Administrator, who is the accountable decision maker under the CLEAN AIR ACT.

For example, the Policy Assessment 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 $\mu g/m^3$.[49]

EPA staff prepares yet another document, 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."[50] This document is not depicted on the decision diagram, and 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." The results of the RIA feature prominently in EPA press releases, however. For the recent (December 2012) $PM_{2.5}$ NAAQS, EPA announced that meeting the Administrator's selected

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[46] United States Environmental Protection Agency, Office of Air and Radiation. Policy Assessment for the Review of Particulate Matter National Ambient Air Quality Standards, Second External Review Draft. Washington (DC): United States Environmental Protection Agency; 2010 June. Available at: http://www.epa.gov/ttnnaaqs/standards/pm/data/20100630seconddraftpmpa.pdf

[47] 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." Committee on Research Priorities for Airborne Particulate Matter, National Research Council. Research Priorities for Airborne Particulate Matter. Washington (DC): National Academic Press; 1998.

[48] For example, the December 2014 ozone proposal argues 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." 79 FR 65236

[49] Office of Air and Planning. Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards. United Stated Environmental Protection Agency; 2011. Available at:http://www.epa.gov/ttnnaaqs/standards/pm/data/20110419pmpafinal.pdf

[50] Executive Order 12866, Section 1(a). 1993

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 tightening—going from a standard of 12 $\mu g/m^3$ to 11 $\mu g/m^3$—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 $\mu g/m^3$ to 11 $\mu g/m^3$ are greater than those associated with a reduction from 13 $\mu g/m^3$ to 12 $\mu g/m^3$, it is curious that the Policy Assessment did not recommend, or at least examine, standards below 11 $\mu g/m^3$. Neither the Policy Assessment nor RIA explains this, nor the Administrator's decision to set a standard of 12 $\mu g/m^3$, which these documents suggest leave 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.

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.[51]

The statutory language forces EPA staff to present vague justifications that are careful not to express considerations 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

[51] Bachmann, 2007: 687

in a charade in which EPA sets standards at non-zero levels and justifies the decision based solely on arguments that are characterized as strictly scientific.

2.3. CASAC

CASAC is a seven-member committee the Clean Air Act established "to provide advice and recommendations to EPA."[52] Members generally serve for two consecutive three-year terms, and meet 12 to 15 times a year. Their expertise is often supplemented by panels of 20 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"[53] or "to answer questions that go beyond matters of scientific judgment."[54] 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." The Act does not require CASAC's *approval* of the Administrator's policy choice however, 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,

[52] See EPA Science Advisory Board. United States Environmental Protection Agency Charter. Environmental Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/currentcharter?OpenDocument

[53] Bipartisan Policy Center; 2009: 5.

[54] The Keystone Center. Research Integrity Roundtable. *Improving the Use of Science in Regulatory Decision Making: Dealing with Conflict of Interest and Bias in Scientific Advisory Panels, and Improving Systematic Scientific Reviews.* Washington (DC): The Keystone Center; 2012: 8. Available at: https://www.keystone.org/images/keystone-center/spp documents/Health/Research%20Integrity%20Rountable%20Report.pdf

> CASAC has in past years removed itself from the process, leaving the formal proposal and final choice of standards to the Administrator.[55]

This CASAC role 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.[56]

Recent Committees, however have been very vocal in recommending specific regulatory options, and criticizing administrators who deviate from their recommendations. 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) ...."[57]

In 2008, CASAC's ozone review panel stated in a letter to 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.[58] (emphasis in original)

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[55] McCarthy, James. E. "Air Quality Standards and Sound Science: What Role for CASAC?" CRS Report RL33807, January 19, 2007:2. Available at: http://www.policyarchive.org/handle/10207/bitstreams/3076.pdf

[56] Weinberg, Alvin M. 1972,.

[57] Letter of Rogene Henderson et al. (of the Clean Air Scientific Advisory Committee) Letter to: to Hon. Stephen L. Johnson EPA Administrator) regarding the PM NAAQS, Sep 2006. Available at: http://www.epa.gov/sab/pdf/casac-ltr-06-003.pdf. Italics in original.

[58] Letter of Rogene Henderson et al. of the Clean Air Scientific Advisory Committee to Hon. Stephen L. Johnson, EPA Administrator, April 7, 2008, Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/4AF876432433128885257425 0069E494/$File/EPA-CASAC-08-009-unsigned.pdf

The CRS report observes that CASAC's recent advocacy deviates from its past practice, when it refrained from objecting to policy decisions that differed from its recommendations. It points to two examples where 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.[59] 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,"[60] and recommendation "that the primary standard for PM_{10} should be revised downwards."[61]

The more activist stance of recent committees may cross 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, 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. [62]

Former chairman, Bernard D. Goldstein, M.D., 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

[59] McCarthy, James. E. 2007:9.

[60] Dr. Jonathan M. Samet et al. letter of the Clean Air Scientific Advisory Committee to Hon. Lisa Jackson, EPA Administrator. May 17, 2010. EPA-CASAC-10-011

[61] Dr. Jonathan M. Samet et al. letter of the Clean Air Scientific Advisory Committee to Hon. Lisa Jackson, EPA Administrator. September 10, 2010. EPA-CASAC-10-015

[62] Cowling, Ellis. "Comments on the NAAQS Review Process," March 3, 2006. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf

> apparent, and this difference should be made clear in the charge questions given to CASAC.[63]

Dr. George T. Wolff made a similar point, observing:

> 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.[64]

Former CASAC chairman, Dr. Joe Mauderly, 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."[65]

This blurring of the lines between science and policy is illustrated in CASAC 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."[66] They presented various non-science arguments in support of their preferred, more stringent, policy

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[63] Goldstein, Bernard, M.D. "Comments on the NAAQS Review Process." March 3, 2006. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf

[64] Wolff, George T. "Comments on the NAAQS Review Process," March 3, 2006. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf

[65] Mauderly, J. "Comments on the NAAQS Review Process." March 3, 2006. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf

[66] US EPA CASAC Lead Review Panel Public Advisory Meeting 2/7/07 CCR # 14610-13 page 15

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..."[67]

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.[68]

Transcripts of CASAC's 2007 meetings on the lead NAAQS decisions, for example, reveal that its members have few real disagreements with each other or with EPA staff, so the committee lacked the value of independent analysis and challenge that is so essential to the scientific method. The discussions exhibit the "asymmetrical trust" symptomatic of insular group dynamics that perpetuates an "us vs. them" mindset.[69] 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.[70] 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 must have a conflict of interest.[71]

Former CASAC chair George Wolff raised concerns that EPA's selection of panel members has exacerbated 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

[67] US EPA CASAC Lead Review Panel Public Advisory Meeting 2/7/07 CCR # 14610-13 pages 15-16

[68] Sunstein, Cass. Going to Extremes: How Like Minds Unite and Divide. New York: Oxford University; 2009:86.

[69] Sunstein, 2009.

[70] US EPA PUBLIC MEETING 12/12/07 CCR# 15740-1 Page 145

[71] US EPA PUBLIC MEETING 12/12/07 CCR# 15740-1 Page 33. 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."

> 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.[72]

Former CASAC chair Roger McClellan 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 "in some cases, the individuals have already offered opinions as to how the science should be used to set NAAQS, a more stringent standard based on their science."[73] According to a Congressional investigation, 16 of the 20 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 14 of the 20 members had been principal or co-investigators for EPA grants totaling more than $120 million.[74]

The blurring 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 didn't rely on current data and modeling techniques. When EPA staff pointed out that this simplified method would more likely lead policy makers to a level preferred by CASAC than the more sophisticated method, CASAC members dropped their objections.[75]

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."[76]

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[72] Wolff, 2006.

[73] Committee on Science, Space, and Technology hearing, "Quality Science for Quality Air," 112th Cong., 1st sess, October 4, 2011. http://www.gpo.gov/fdsys/pkg/CHRG-112hhrg70587/html/CHRG-112hhrg70587.htm

[74] Lamar Smith, Chairman Committee on Science, Space, and Technology letter to EPA Administrator letter to Gina McCarthy. March 19, 2014. http://science.house.gov/sites/republicans.science.house.gov/files/documents/03-19-2014%20Smith%20to%20Administrator%20McCarthy.pdf

[75] US EPA PUBLIC MEETING 12/12/07 CCR# 15740-1 Page 67

[76] CASAC letter to EPA Administrator Johnson, September 29, 2006. EPA-CASAC-LTR-06-003

This assertion that uncertainty demands a "prudent" policy decision stands in contrast to the statement of former chairman, Bernard Goldstein, who told 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.[77]

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. This may be due, in part, to the individuals EPA staff select to serve on the committee and panels,[78] and the charge EPA gives them.[79] 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 noted, "some disputes over the 'politicization' of science actually arise over differences about policy choices that science can inform, but not determine."[80] In other words, they may reflect scientization of policy rather than politicization of science.

2.4. 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."[81] 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."[82] Though EPA staff prepares a

[77] Goldstein, 2006.
[78] Wolff, 2006.
[79] As former CASAC chair Bernard D. Goldstein, M.D. observed, 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." Comments on the NAAQS Review Process March 3, 2006.
[80] Bipartisan Policy Center; 2009.
[81] 42 USC § 7409(b)(1)
[82] 42 USC § 7409(b)(2)

regulatory impact analysis, including an assessment of the likely costs and benefits of achieving different standards, the Administrator does not consider it, and staff does not present it to her.[83]

In choosing the level of the standard, the Administrator faces pressure from EPA staff and CASAC members, as well as outside groups, including state and local governments (which are ultimately responsible for establishing the implementation plans that will enable their areas to attain the standard), potentially regulated parties, non-governmental organizations (NGOs), and Congress. In addition, 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 influence the Administrator's determination.

The Administrator deviates from the recommendations of the Policy Assessment and CASAC at her peril.[84] If she makes a decision outside of the box 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 attorneys at the Justice Department's Environment and Natural Resources Division to make sure that the Administrator loses the lawsuit).[85] Public disagreements also put policy officials at a public relations disadvantage, when exercising policy judgment is characterized as going against science.[86] 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 Policy Assessment.[87]

Not only does the current practice discourage policy makers from setting standards higher than those recommended by staff, but lower 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.[88] Available data and modeling made it difficult for the Administrator to conclude that a

[83] 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."

[84] CASAC letter to EPA Administrator Johnson, September 29, 2006. EPA-CASAC-LTR-06-003

[85] Bell, Larry. "EPA's Secret And Costly 'Sue And Settle' Collusion With Environmental Organizations." Forbes. February 17, 2013. http://www.forbes.com/sites/larrybell/2013/02/17/epas-secret-and-costly-sue-and-settle-collusion-with-environmental-organizations/

[86] See, for example, Union of Concerned Scientists blog, "EPA Air Pollution Decision Threatens Public Health: Science Disregarded, Misrepresented on Particulate Matter Standard." http://www.ucsusa.org/scientific_integrity/abuses_of_science/epa-air-pollution-decision.html

[87] See for example: http://switchboard.nrdc.org/blogs/jwalke/the_president_sabotages_clean.html

[88] Author's personal experience in NAAQS discussions as administrator of OIRA.

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. 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 for policy officials to defer to the options recommended by staff and CASAC.[89]

In 2008, during the interagency review of EPA's ozone NAAQS, disagreement over the form of the secondary "welfare" standard was so contentious that President Bush ultimately had to step in to resolve it.[90] 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.[91] Out of respect for his concern, correspondence between the OIRA Administrator and Deputy Administrator of EPA explaining their respective positions was shared publicly on the agencies' websites,[92] 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.[93]

2.5. States

States have a great interest in the level of the NAAQS. Under the Act, 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.[94] If a state fails to develop a plan that meets with EPA's approval, the agency may impose an even more draconian (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 done so yet. By imposing the obligation of NAAQS attainment on the states, 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

[89] Mauderly, 2006, noting "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.'"

[90] In the rarely-used section 7 of E.O. 12866, "conflicts 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."

[91] Author's personal experience as OIRA Administrator.

[92] See memo from Susan Dudley to Steve Johnson on OIRA's RegInfo site: http://www.reginfo.gov/public/postreview/Steve_Johnson_Letter_on_NAAQs_final_3-13-08_2.pdf.

[93] Environmental Protection Agency. "National Ambient Air Quality Standards for Ozone." 73 FR 16497. http://www.gpo.gov/fdsys/pkg/FR-2008-03-27/pdf/E8-5645.pdf

[94] Greenstone, M., List J.A., Syverson, C. "The Effects of Environmental Regulation on the Competitiveness of U.S. Manufacturing." MIT Center for Energy and Environmental Policy Research working paper. CEEPR WP 2012-013; 2012.

use controls and other regulatory options that are not available to 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 in 2008 or the even tighter (0.060 to 0.070 ppm standards) being considered[95] at the time of this writing in 2015.[96]

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 that supported tightening the ozone NAAQS last 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 non-attainment states file comments on proposed standards, but several recently threatened to sue EPA for failure to issue more stringent standards.[97] In contrast, of the six states that filed comments that opposed 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 et al 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].[98]

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

[95] Environmental Protection Agency. "National Ambient Air Quality Standards for Ozone." Proposed Rule. 79 FR 75233

[96] Environmental Protection Agency. http://www.epa.gov/groundlevelozone/designations/2008standards/final/finalmap.htm

[97] http://www.epa.gov/ttn/naaqs/standards/ozone/data/ENV_DEFENSE-650358-v1-Ozone_NAAQS_decision.pdf

[98] Greenstone & Syverson, 2012.

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 yet more stringent ozone standards in 2008, accusing EPA of considering factors other than public health in setting the NAAQS.[99]

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 – 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. EPA's oversight of NAAQS attainment acts in much the same way that economic regulation affects an otherwise competitive industry.[100] 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.[101]

2.6. Courts

As noted earlier, the United States Supreme Court confirmed EPA's statutory interpretation that it cannot consider costs when setting the NAAQS.[102] 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, *see Lead Industries Ass'n v. EPA*, 647 F.2d at 1156 n.51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety."[103]

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.[104] States

[99] http://online.wsj.com/article/SB121115921730002453.html

[100] See discussion regarding "presumption against economic regulation" in OMB Circular A-4, "Regulatory Analysis." Available at: http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf

[101] This behavior is consistent with economic theory regarding regulation, particularly the colorfully named "bootlegger and Baptist" theory. Smith, Adam, Yandle, Bruce. *Bootleggers and Baptists: How Economic Forces and Moral Persuasion Interact to Shape Regulatory Politics.* Cato Institute. 2014.

[102] *Whitman* v. *American Trucking Associations*, 531 U.S. 457, 465–472, 475–76 (2001)

[103] National Ambient Air Quality Standards for Particulate Matter; Final Rule. January 15, 2013. Available at: http://www.gpo.gov/fdsys/pkg/FR-2013-01-15/pdf/2012-30946.pdf

[104] See, for example, OPENING BRIEF OF STATE PETITIONERS in STATE OF MISSISSIPPI, et al v. EPA. USCA Case #08-1204 Document #1369352 Filed: 04/17/2012, arguing that EPA's 2008 ozone NAAQS be remanded "on grounds that the primary NAAQS does not protect public health with an adequate margin of safety

supporting less stringent standards sue 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 U.S. Chamber of Commerce, the Utility Air Regulatory Group, and the National Association of Home Builders).[105] 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."[106]

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.[107] 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.[108] EPA often submits draft regulations to OIRA for interagency review just days before such deadlines.[109]

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 she makes a policy decision that conflicts with the policy preferences of EPA

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and the secondary NAAQS does not protect public welfare, as required under the Act"; and PROOF BRIEF FOR ENVIRONMENTAL PETITIONERS in STATE OF MISSISSIPPI, et al v. EPA. USCA Case #08-1204 Document #1369354 Filed: 04/17/2012.

[105] See, for example, JOINT OPENING BRIEF OF PETITIONER STATE OF MISSISSIPPI AND INDUSTRY PETITIONERS in STATE OF MISSISSIPPI, et al v. EPA. USCA Case #08-1204 Document #1369355 Filed: 04/17/2012.

[106] Bachmann 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.'" Bachmann 2007: 687.

[107] For example, EPA faces a judicial deadline to issue final ozone NAAQS by October 15, 2015. http://www.epa.gov/ttn/naaqs/standards/ozone/data/201404ozonenaaqsorder.pdf

[108] Fraas, Arthur. "Observations on OIRA's Policies and Procedures." *Administrative Law Review* Vol. 63, Special Edition: OIRA Thirtieth Anniversary Conference (2011), p. 86.

[109] Since the mid-1990s, the average interagency review time for NAAQS rules subject to deadlines was less than 20 days, compared to an average review time of more than 70 days for all EPA rules over the same period. Statistics can be derived from data available at www.RegInfo.gov.

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 she may have about the merits of the options placed before her, the safest thing for the Administrator to do is simply acquiesce in the recommendations of her staff. The deference that courts properly owe to the political branches is captured, instead, by an unelected bureaucracy and outside science advisors.

2.7. Summary

The NAAQS process exemplifies the incentives at work that compel every party to the regulation to engage in the science charade. First, Congress directs EPA to set the standards to achieve noble goals, but restricts the agency from considering key factors, falling prey to the positive-normative fallacy by asserting instead the pretense that science alone is sufficient to develop policy. 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 tight deadlines for issuing revised standards. Executive branch career and policy officials respond by 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 questions opponents' credibility and motives, rather than a constructive discussion regarding appropriate assumptions and data. The real reasons for selecting a particular standard may not even be discussed.

Furthermore, EPA is setting standards for fine particulate matter and ozone that are unattainable for the foreseeable future for many parts of the country.[110] Perhaps most important, the actual public health and welfare benefits of these standards, particularly when one considers the opportunities forgone, are in considerable doubt.[111]

[110] EPA lists areas in nonattainment with each of the NAAQS on its website: Available at: http://www.epa.gov/airquality/greenbook/hnc.html

[111] Cox, Louis Anthony. "Reassessing the human health benefits from cleaner air." Risk Analysis 2012 May; 32(5):816-29.

3. CONCLUSIONS AND RECOMMENDATIONS

Despite the National Academy of Science's guidance over 30 years ago, controversy remains surrounding regulatory actions aimed at reducing risk, leading to accusations of "politicized science," "advocacy science," or "junk science." The analysis here suggests that "scientized policy" is a more accurate name for the problem, and that it stems from what the Academy in 1983 identified as "a blurring of the distinction between risk assessment policy and risk management policy."[112]

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 the politicization of science *and* the scientization of policy. When people condemn the "politicization" of science,[113] the problem may really be that we ask too much of science in addressing policy problems. Many statutes, including the Clean Air Act, succumb to the positive-normative fallacy and do not permit transparent consideration of relevant policy factors when developing regulations. As the BPC 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."[114] This would not only help address the positive-normative 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."[115]

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

3.1. Positive-Normative 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 positive-normative fallacy and resist delegating decisions to agencies on the pretense that "science" alone can make the normative

[112] National Academic Press, "Red Book." 1983.
[113] Mooney, C. The Republican War on Science. New York: Basic Books; 2006.
[114] Bipartisan Policy Center, 2009:4.
[115] Bipartisan Policy Center, 2009:5.

determination of what policy should be. 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 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, policy makers 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.[116]

Codifying executive requirements for regulatory impact analysis, including benefit-cost analysis, could provide a "supermandate" that would require agencies explicitly to present uncertainties and tradeoffs and to justify decisions in a transparent manner.[117]

2. Legislators and policymakers must clarify the appropriate role for scientific advisors.

The engagement of scientific advisory panels can provide a 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 not ask them to recommend specific regulatory policies. When asked to advise on policy choices, as the case with CASAC, it is difficult for members not to embed their policy views in their scientific recommendations.[118]

As a former EPA scientist observed:

[116] Dudley & Gray, 2012.

[117] Dudley, Susan E. "Improving Regulatory Accountability: Lessons from the Past and Prospects for the Future." Case Western Reserve Law Review. Vol 65. No. 1 (Summer 2015)

[118] "The choices that must be made on defining or clarifying policy relevant to meeting the legislative mandates must be made by the Administrator and/or by Congress through revisions to established Acts, and CASAC's role must be limited to highlighting the issues at the science-policy interface and the scientific knowledge that informs these issues." Hopke, Philip K. "Comments on the NAAQS Review Process." 2006. Available at: A-17. http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf

> 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.[119]

Cox observes:

> Experts, like other people, typically have high confidence in their own judgments, even when these lack objective validity.[120] 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.[121]

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.[122] As both the BPC and Keystone 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.'" [123]

3.2. Hidden Policy Judgments

3. The executive branch must recognize that risk assessment necessarily involves assumptions and judgments as well as pure scientific inputs, and 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 recommendation continues the theme of expert reports issued over the last three decades, including recent recommendations from the Institute of Medicine and BPC. One way to make the

[119] Lackey, 2013.

[120] Kahneman D. *Thinking Fast and Slow*. 2011. Farrar, Straus, and Giroux. New York, New York. (as cited in Cox 2014)

[121] Cox 2014.

[122] Several former CASAC officials encouraged EPA to be clearer in its charge questions to distinguish between science and policy. Environmental Protection Agency Clean Air Scientific Advisory Committee (CASAC). CASAC Input on EPA's revised NAAQS Review Process; 2006 March. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/NewNAAQSProcess?OpenDocument

[123] The Keystone Center, 2012: 8. (Internal citation to BPC at 5.)

risk assessment policy choices more transparent would be for agency scientists to calculate and present multiple risk estimates based on a variety of scientifically plausible data sets, endpoints, models, *etc.*[124] This would be in stark contrast to the current practice in which 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."[125]

Once a range of plausible risk outcomes is identified based on different scientifically plausible inputs, agencies could transparently identify which set of inputs, model, and outcome comported with its preferred risk assessment policy choice. Policy officials would choose specific numerical values from a range of scientifically plausible risk estimates and publically 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 not only encourage more openness and constructive discussion about science and policy, but would likely engender greater acceptance of the ultimate policy decision reached.[126]

4. The executive branch should increase the robustness of regulatory science by institutionalizing reforms that encourage greater feedback and challenge.

Greater transparency in the models, assumptions, and risk assessment policy choices could encourage more open, constructive debate on those choices. 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.[127] Institutional reforms that engage competing views could go a long way to improve the clarity of the risk assessment process and the decisions that depend on scientific input.

[124] Dudley & Gray 2012
[125] Lackey, 2013.
[126] Dudley & Gray, 2012.
[127] Sunstein, 2009.

President Obama has built on his predecessors' efforts to provide for interagency review of different aspects of regulatory decisions, including the underlying science. He has 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."[128]

Successful reforms might involve pre-rulemaking disclosure of risk assessment information, to engage broad public comment on the proper choice of studies, models, assumptions, etc. long before any policy decisions are framed, and "positions" established. Advanced notices of proposed rulemaking could be used effectively to gather such input.[129]

5. Scientific advisory panels should be required to represent a diversity of perspectives, disciplines, expertise, and experience.

The 2012 Keystone Group report offers a series of recommendations on "the composition of committees that are empaneled to review the science behind a regulatory decision."[130] Acknowledging the importance of choosing panelists that "have the knowledge, training, and experience needed to address the charge to the panel,"[131] 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."[132]

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 rep-resents the mainstream."[133]

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[128] Obama, Barrack. Executive Order 13563. "Improving Regulation and Regulatory Review." 76 FR 3822 January 18, 2011.

[129] Balla, Steven J. and Dudley, Susan E. "Stakeholder Participation and Regulatory Policymaking in the United States." A report prepared for the *Organisation for Economic Co-operation and Development*. 2014. http://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/downloads/Balla-Dudley-US-Stakeholder-Reg-Process-11-2014.pdf

[130] Keystone, 2012:4.

[131] Keystone, 2012:14

[132] Keystone, 2012:15

[133] Keystone, 2012: (quoting BPC at 24)

Former CASAC Chair George Wolff's observations, quoted above, that the lack of balance among the individuals EPA empaneled to review the PM standards published in 2006 "predetermined the outcome of the review" [134] illustrates the effects on policy of not engaging a range of perspectives.

3.3. Improving 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 a powerful incentive to improve the use of science for predicting the benefits of interventions.

President Obama's executive orders to 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"[135] could facilitate better retrospective analysis. However, these and previous retrospective review guidelines have met with limited success, largely because they did not change underlying incentives.[136] For example, Section 812 of the Clean Air Act Amendments of 1990 requires EPA periodically to assess the benefits and costs of the Act,[137] but 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 outcome 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 offers concrete recommendations for applying statistical tools to test "how changes in inputs (such as exposure)

[134] Wolff, 2006.

[135] Executive Order 12866 (1993) and Executive Order 13563 (2011).

[136] Dudley, Susan E. *Testimony before the Joint Economic Committee: Reducing Unnecessary and Costly Red Tape through Smarter Regulations*, June 26, 2013, http://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/downloads/2013_06_26_Dudley_JEC_statement.pdf

[137] EPA Office of Air and Radiation. The Benefits and Costs of the Clean Air Act from 1990-2012: Summary Report. Environmental Protection Agency; 2011 March. Available at: http://www.epa.gov/oar/sect812/feb11/summaryreport.pdf

propagate through a network of validated causal mechanisms to cause resulting changes in outputs (such as health effects)."[138]

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 new regulation that relies on models. The five-year NAAQS reviews, for example, could be required to apply quasi-experimental (QE) techniques to gather and analyze epidemiology data and health outcome trends in different regions of the country and compare them against predictions.[139]

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 predications. 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.

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.[140] And, mechanisms such as sunset provisions, or offsets (as applied in other countries) could provide incentives for objective evaluation of regulations' effects.[141]

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.

> 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

[138] Cox, 2015.

[139] Cox 2015, and Domenici, Greenstone & Sunstein, 2014

[140] As Greenstone 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." Statement of Michael Greenstone, Milton Friedman Professor of Economics, University of Chicago, Director, Energy Policy Institute at Chicago, before theUnited States Senate Subcommittee on Regulatory Affairs and Federal Management Roundtable on "Examining Practical Solutions to Improve the Federal Regulatory Process." June 4, 2015

[141] Dudley, Susan E. "Can Fiscal Budget Concepts Improve Regulation?" GW Regulatory Studies Center Working Paper. http://regulatorystudies.columbian.gwu.edu/can-fiscal-budget-concepts-improve-regulation (July 2015)

> 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.[142]

Agencies could conduct pilot studies or "deploy different regulations where empirical evaluations of such differences will help resolve disputed issues of regulatory policy."[143]

8. The scientific studies used to support regulation should be subject to peer review and their results 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.[144] 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."[145] These guidelines did not require reproducibility, however, 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."

Yet recent analyses showing that most published studies are not reproducible[146] are leading to calls for a greater focus on more sharing of data and experimental transparency.[147] The journal *Science*, for example, has undertaken "initiatives to increase transparency and promote

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[142] Domenici, Greenstone & Sunstein. 2014:258

[143] John O. McGinnis. *Accelerating Democracy: Transforming Governance through Technology*. Princeton University Press. 2012:311.

[144] U.S. Office of Management and Budget. 2004. *Information Quality Bulletin for Peer Review.* http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf

[145] U.S. Office of Management and Budget. 2002. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies." 67 FR 8452

[146] Open Science Collaboration. (2015). "Estimating the reproducibility of psychological science." *Science.* https://osf.io/ezcuj/wiki/home/

[147] Joel Achenbach, "The new scientific revolution: Reproducibility at last." Washington Post. January 27, 2015.

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."[148]

As the *Science* editorial observes, "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."[149] 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 problems of implementation, while depriving them of the policy discretion that might allow them to solve those problems. The resulting dynamic channels competitive energy into 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 to defer to states 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. Second, it would encourage risk management decisions to be made where they can best reflect the circumstances and preferences of affected citizens. 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.[150] Such an approach would provide the natural experimental framework and data needed for more QE evaluation.

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[148] *Science* 2 January 2015: Vol. 347 no. 6217 p. 7

[149] *Science*, January 2015.

[150] 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 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

10. Agencies should engage in collaborative tools to generate knowledge.

Nobel laureate Fredrich von Hayek 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."[151] 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.[152] 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 not generated interactive, iterative engagement.[153,154]

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, it could provide 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.[155] Larry Sanger, founder of Wikipedia, calls this "distributed knowledge collaboration."[156]

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

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[151] Hayek F.A. 1945. "The use of knowledge in society." *American Economic Review* 35, No. 4: 519-530.

[152] Shirky, Clay. *Here Comes Everybody: The Power of Organizing Without Organizations.* New York: Penguin Press. 2008.

[153] Dudley & Gray, 2012.

[154] Balla & Dudley, 2014.

[155] Dudley & Gray, 2012.

[156] Sanger, Larry "Toward a New Compendium of Knowledge." 2006. http://www.citizendium.org/essay.html

> 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.[157]

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.

4. Conclusions

Institutional arrangements in the regulatory development process tend to aggravate two contributors to the scientization of policy: the "positive-normative fallacy" (not acknowledging that science alone is insufficient to resolve normative policy questions) and "hidden policy judgments" (not acknowledging the policy judgments inherent in risk assessment). By framing issues as resolvable by science, current practices both threaten the credibility of the scientific process, and harm resulting regulatory policy. Many of those involved in regulatory decisions have incentives to hide rather than reveal the uncertainty in assessments of risk and to dismiss and denigrate dissenting views. Key policy choices, disguised as science, rest with technical staff; meanwhile, policy makers charged with making hard policy decisions are able to avoid responsibility by claiming that their hands were tied by the science.

This paper has examined the process by which EPA sets NAAQS under the Clean Air Act to illustrate some of the perverse incentives involved in developing regulations, and offered possible 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 to distinguish between risk assessment and risk management, avoiding the positive-normative fallacy, and making more transparent previously hidden policy judgments. This will improve not only environmental outcomes, but the integrity of environmental science itself.

[157] Shirkey, 2008:122.