# SCIENTIFIC INTEGRITY

BIPARTISAN POLICY CENTER

*"The use of science in regulatory policy is another area in which government needs to get beyond the stale debates and false dichotomies of the past. The question is not whether scientific results should be used in developing regulatory policy, but how they should be used."*

**Bipartisan Policy Center**

## Introduction

How to obtain, and then apply, the best available science to regulatory policy can be controversial. Commentators have differing views as to what "best available science" actually means.[1] There is general agreement, however, about having in place a rigorous regulatory *process* that encourages open and transparent scientific debate, in which methods are clear and consistent, and assumptions and data widely shared. In this way, the process is likely to produce reasonable and defensible policy results.

John Holdren, President Obama's science advisor, wrote, "Successful application of science in public policy depends on the integrity of the scientific process both to ensure the validity of the information itself and to engender public trust in government."[2] Yet exactly how that process should be defined and structured remains an ongoing debate. That debate involves a host of questions: how should particular studies be chosen and then considered? To what degree should the studies' underlying data and assumptions be open to scrutiny and widely shared? What role should advisory bodies play, and how can conflicts be avoided? What constitutes "junk science" or "politicized science," and how can it be avoided? More broadly, what role should science play in influencing policy?

Despite some nuanced, and even profound, disagreement about the answers to these questions, there is nevertheless some general agreement on the basics. For instance, observers generally agree on preventing scientific bias from distorting policy. Bias—described variously as "junk science," "paid-

[1] "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," A Report from the Research Integrity Roundtable, *The Keystone Center*, September 18, 2012 (http://www.accord3.com/docs/BACKGROUND/Research%20Integrity%20Rountable%20Report.pdf).

[2] John Holdren, Assistant to the President for Science and Technology Policy, "Memorandum for the Heads of Executive Departments and Agencies," December 17, 2010 (https://www.whitehouse.gov/administration/eop/ostp/library/scientificintegrity).

for science," or "advocacy science"—often leads to pre-determined outcomes, which favor or support a particular partisan or ideological viewpoint.[3] Such science is, as former EPA scientist Robert Lackey observed, "a corruption of the practice of good science." He defines bias as "information that is developed, presented or interpreted based on an assumed, usually unstated, preference for a particular policy choice."[4]

As some observers have noted, even well-intentioned civil servants can subconsciously seek out science that confirms their own bias while ignoring scientific evidence that contradicts their beliefs. However, making policy choices on the one hand, and interpreting and understanding science on the other, are two distinct realms and should be clearly presented as such to the public.

As the Bipartisan Policy Center has noted, "some disputes over the 'politicization' of science actually arise over differences about policy choices that science can inform, but not determine." For example, the BPC cited "a clean air rule," in which "the scientific questions might include how many excess deaths or hospital admissions would be expected to result from different atmospheric concentrations of the pollutant." The policy questions would include "how to decide what level of concentration to allow, given the scientific information."[5]

Commentators also generally agree that the scientific process in a regulatory context should ensure transparency and consistency of methods, particularly related to how studies are chosen; how risk assessments are drafted and evaluated; and how the analyses of benefits tied to specific regulations are conducted.

Over the years, however, agencies have struggled to consistently develop and apply these basic elements of the scientific process to policymaking. At times, regulations have resulted in public confusion or have underestimated the costs to the economy. This inconsistency can result in "a deficient regulatory system that either tries to solve problems that do not exist, or fails to prevent harms that could be readily avoided, or worse, both."[6]

For example, the draft evaluation of health effects of formaldehyde, conducted for EPA's Integrated Risk Information System (IRIS), is a case in point. In 2011, the National Research Council (NRC) conducted a thorough review of EPA's assessment and found several shortcomings with its approach, including "problems with clarity and transparency of methods" that persisted for over a decade, and for lacking "sufficient documentation on methods and criteria for identifying evidence from epidemiologic and experimental studies, for critically evaluating individual studies, for assessing the

[3] "Regulatory Science and Policy: A Case Study of the National Ambient Air Quality Standards," by Susan Dudley, George Washington University Regulatory Studies Center, September 9, 2015 (https://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/downloads/SDudley_Regulatory_Science_NAAQS%202015-09-09.pdf)

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

[5] "Improving the Use of Science in Regulatory Policy," Bipartisan Policy Center, August 5, 2009 (http://cdn.bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf).

[6] Ibid at 1, p. 3.

weight of evidence, and for selecting studies for derivation of the [reference concentrations] and unit risk estimates."[7]

Formaldehyde is used in a wide variety of applications, including building materials that are essential for modern, affordable home construction.[8] By the same token, the chemical, at certain high doses, can irritate eyes, noses, and throats.[9] EPA is responsible for devising the appropriate responses to adequately protect the public. However, if EPA adopts risk management programs for chemicals or other substances that are not grounded in the best available science that weighs the benefits against the costs and available alternatives, consumers could face higher costs without experiencing any corresponding public health benefits.[10]

The Food and Drug Administration (FDA) provides an example of the importance of maintaining scientific integrity even in the face of pressure from an alarmed public whose fears are not backed by the science. In November of 2015 the FDA resolved an issue regarding the genetically modified AquAdvantage Salmon.[11] The fish's modification allows it to grow more rapidly so that it can be ready for markets in less time.[12] Five years previously, the FDA had "accepted a risk assessment's conclusion that the modified fish was safe to eat and posed no threat to the environment."[13] Nevertheless, the FDA decided to reopen its investigation on its own accord after members of the public disputed the agency's scientific findings.[14]

After reviewing data from the company that produced the fish and from other scientists, the FDA concluded that the "salmon met the criteria for approval established by law: namely, safety and effectiveness."[15] The agency determined the salmon were safe for humans to consume and would not have a significant effect on the environment, as many opponents had incorrectly feared.[16] The FDA's actions in this example serve as further proof that rational and well-executed scientific research is critical to the formation of beneficial public policies.

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[7] National Research Council, "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," 2011 (http://www.ncbi.nlm.nih.gov/books/NBK208222/)

[8] "Our Breath Causes Cancer?" The American Chemistry Council (https://formaldehyde.americanchemistry.com/ProductsTechnology/Formaldehyde/New-Graphic-Illustrates-Problems-with-EPAs-Formaldehyde-Risk-Assessment.pdf).

[9] Agency for Toxic Substances and Disease Registry (http://www.atsdr.cdc.gov/mmg/mmg.asp?id=216&tid=39).

[10] EPA responded to the NRC report and eventually instituted broader reforms recommended by the NRC to the IRIS program. But if EPA had already had a sound scientific process in place, these problems, and their associated costs to society, could have been avoided years ago.

[11] FDA, "AquAdvantage Salmon Fact Sheet (https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm473238.htm)

[12] Progressive Policy Institute, "Federal Agencies Should Investigate on Reasonable Fears, But Regulate on Science", by Phil Goldberg, March 8, 2016 (http://www.progressivepolicy.org/issues/energy-environment/federal-agencies-should-investigate-on-reasonable-fears-but-regulate-on-science/)

[13] Ibid

[14] Ibid

[15] FDA, "FDA Has Determined That the AquAdvantage Salmon is as Safe to Eat as Non-GE Salmon" (https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm472487.htm#1)

[16] Ibid

## I. Scientific Integrity

If a federal agency lacks a robust process to consider, evaluate, and apply science, it will inevitably produce regulatory outcomes that put the economy and public health at risk. Citizens can also lose faith in regulators' ability to protect them. According to a report by the Food and Drug Administration, "[e]stablishing and maintaining integrity of the scientific process and of scientific data is crucial to the agency's ability to arrive at sound decisions and to maintain public trust."[17] Similarly, President Obama stated in 2009 that, "[t]he public must be able to trust the science and scientific process informing public policy decisions."[18]

To gain the public's trust, the regulatory process must adhere to a high standard of scientific integrity. In order to have integrity, policymakers must ensure their scientific processes are transparent. Policymakers should always ask of the science that supports their rulemakings, "[h]ow easily can a reasonably informed, interested citizen find the analysis, understand it, and verify its underlying assumptions and data?"[19] That basic question leads to what should be an essential principle of any regulatory process: when federal regulators develop and use certain scientific research in rulemakings, that research—including its underlying data and assumptions—should be made publicly available.

Executive orders and administrative guidance from the previous White House reflected this basic principle.[20] Recognizing this, President Obama stated his support for the notion of releasing taxpayer-funded research to the public:

> If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. [21]

Similarly, Obama's science advisor reiterated this commitment in a 2013 memorandum:

> The Administration is committed to ensuring that, to the greatest extent and with the fewest constraints possible and consistent with law and the objectives set out below, the direct results of federally funded scientific research are made available to and useful for the public, industry, and the scientific community." [22]

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[17] Food and Drug Administration, "Plan to Increase Access to Results of FDA-Funded Scientific Research," February 2015 (https://www.fda.gov/downloads/scienceresearch/aboutscienceresearchatfda/ucm435418.pdf)

[18] President Obama, "Memorandum for the Heads of Executive Departments and Agencies," March 9, 2009 (https://www.whitehouse.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09).

[19] "Regulatory Analysis and Regulatory Reform: An Update," by Jerry Ellig and Sherzod Abdukadirov, Mercatus Center, January 2015 (http://mercatus.org/sites/default/files/Ellig-Reg-Reform-MOP-012715.pdf).

[20] See, for example, Executive Order 13563, and OMB Circular A-110.

[21] Ibid. at 8.

Yet the federal government has often ignored these commitments and its own administrative guidance. This relates in part to how the government stores and presents scientific information. As one regulator said recently, "[a] lot of the critical information that the government creates and makes available, like cancer risk or proximity to traffic, are stored in huge datasets that are hard to access and even harder to interpret."[23] In another respect, agencies have sometimes refused to make public the data they use.

Consider the National Ambient Air Quality Standards, updated every five years by EPA under the Clean Air Act (CAA). For more than 30 years, EPA has relied on two long-term cohort studies as the basis for setting standards for particulate matter (PM) and ozone.[24] The aim of these studies was to determine whether there is a statistical association between mortality and exposure to fine PM. For years, researchers and congressional investigators have requested access to the underlying data from these studies, to test whether their conclusions are accurate and reproducible. [19]

These two studies are important for many reasons. According to a report by the White House Office of Information and Regulatory Affairs (OIRA), nearly all of EPA's health benefit claims from its air quality regulations—which account for 60 to 81 percent of the estimated health benefits claimed by the entire federal government—are based on the datasets from these two studies. More specifically, EPA says the CAA will generate $2 trillion in benefits through 2020, and that those benefits exceed costs by a ratio of 30-to-1—notably, the data from these two studies are "the origin of 85 percent of these benefits."[25]

EPA's air quality standards are among the most expensive rulemakings in U.S. history, with the most recent ozone revision in 2015, according to EPA estimates, costing $1.4 billion annually to implement (industry estimates put the cost even higher). Thus it's important to know whether the science behind them—that is, the health impacts of air pollution, and the benefits of EPA's rulemakings—is accurate, objective, and reliable. Yet EPA has not made the underlying datasets from the two studies in question available for public review and analysis, despite requests to do so.[26]

Another issue involved in ensuring the integrity of science used to support regulation is to prevent conflicts of interest on federal science advisory panels. Advisory panels play an important role in helping policymakers understand fundamental scientific issues and how they relate to particular questions of policy.27 The Government Accountability Office found in 2004 that nearly 1,000 advisory committees provide insight, counsel, and advice to federal agencies on a variety of topics.28 In a 2012 report, the Keystone Center stressed the importance of maintaining the integrity of advisory panels:

[22] John Holdren, Director, White House Office of Science and Technology Policy, Memorandum for Heads of Executive Departments and Agencies: "Increasing Access to the Results of Federally Funded Scientific Research," February 22, 2013 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf)

[23] EPA blog, "Environmental Justice in Action," June 28, 2016 (https://blog.epa.gov/blog/2016/06/ej-check-out-ejscreen-2016/).

[24] Cancer Prevention Study, Harvard Six Cities Study

[25] Letter from Sen. David Vitter (R-LA), Ranking Member, Senate Environment and Public Works Committee; Rep. Lamar Smith (R-TX), Chairman, House Science, Space, and Technology Committee to EPA Administrator Gina McCarthy, March 4, 2013.

[26] Ibid.

Agencies ranging from the Food and Drug Administration to the Environmental Protection Agency need the best and latest research findings that may be available to help establish policy. That task frequently entails evaluating scientific information that is incomplete, emergent, contested, inconsistent, or uncertain. When federal agencies use panels to help them review science, they need to utilize policies and procedures that eliminate or minimize conflicts of interest, and take into account biases to ensure that advisory panels can be balanced and fair-minded.[29]

Over the years, legitimate questions have been raised about whether certain individuals are serving as truly independent advisors. That's due to the fact that, in some cases, certain individuals have received funding from those agencies or from the industries those agencies are charged with regulating. These situations could represent a conflict of interest, with the individual either accepting grants to conduct research on topics for which the individual is then asked to provide advice to the agency in a regulatory proceeding; or accepting industry funding that could bias the individual in favor of the regulated industry. While employment by regulated industries should not preclude an individual from participating on advisory panels, especially given their first-hand experience with the subject matter, safeguards are necessary to ensure they are not merely doing the bidding of their former employers.

This reality has been flagged as a serious concern by the EPA's Inspector General, who noted in a 2011 report that, "A prospective or active member's research or grant is a potential area of concern if the [Federal Advisory Committee], panel, or subcommittee plans to address work performed under the research grant." He also wrote that, "receipt of such funding could raise concerns of independence depending upon the nature of the research conducted under the grant and the issues addressed by the FAC."[30]

According to the Congressional Research Service, almost 60 percent of the members of EPA's Science Advisory Board and the Clean Air Scientific Advisory Committee (CASAC) have directly received grants from EPA since 2000. These advisors served as principal or co-investigators for EPA grants, totaling roughly $140 million dollars. Congressional investigators found that 22 of the 26 newly appointed members to the CASAC subcommittee on particulate matter "have received more than $330 million in EPA grants." One may argue whether these grants constitute an inherent conflict of interest, but they do, at a minimum, "give the appearance of a lack of impartiality."[31]

[27] Ibid at 4, p.
[28] *Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance*, U.S. Government Accountability Office, April 2004 (www.gao.gov/assets/250/242039.pdf).
[29] Ibid at 1, p. 7.
[30] *EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Panels*, EPA, Office of Inspector General, Report No. 13-P-0387 September 11, 2013 (https://www.epa.gov/office-inspector-general/report-epa-can-better-document-resolution-ethics-and-partiality-concerns).

## II. Conclusion

To avoid these problems in the future, policymakers can take several modest steps to strengthen scientific integrity in the regulatory process. One important and necessary reform, which is already is reflected in administrative guidance issued by OMB, is to make available to the public any scientific research either paid for by federal taxpayers or utilized by federal agencies in their formulation of policy (this includes, but should not be limited to, proposed and final rules as well as guidance documents).

Reform should also take aim at increasing transparency and avoiding bias on science advisory panels, to ensure regulators are getting the best advice and insights about particular scientific issues. For example, EPA's science advisory panels (e.g., CASAC and the SAB) should include more than just scientists from academia: toxicologists and other scientists from state regulatory agencies and industry can provide different, and in many cases real-world, perspectives on key issues. As former CASAC Chairman Roger McClelland has testified, policymakers should "include individuals drawn from a national pool of talent, including those employed in the private sector," to serve on advisory panels.[32]

In addition, policymakers should look to the conflict of interest policies employed by the non-profit "Toxicological Excellence in Risk Assessment (TERA)" as an example of how to achieve balance. TERA's "Conflict of Interest Policy" identifies several situations that would create real or perceived conflicts of interest: "working for an organization that sponsors or contributes to the document to be reviewed, having direct personal financial investments benefiting from the outcome of the review, or authoring or providing significant comments on the document being reviewed." TERA expects bias when a panelist has "previously taken a public position on the subjects to be discussed or is affiliated with an industry, governmental, public interest, or other group with a partiality regarding the subjects to be discussed.[33]

With these reforms in hand, agencies can effectively carry out their missions. As EPA's "Scientific Integrity Policy" states, "The Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which it relies."[34] These and other reforms will enable federal regulators to produce policies that are based on the highest quality science, and ultimately, according to the first principle of sound regulation, pass a rigorous cost-benefit test.

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[31] Letter to EPA Administrator Gina McCarthy, from Sen. James Inhofe (R-OK), February 2, 2016 (http://www.epw.senate.gov/public/index.cfm/2016/2/inhofe-questions-epa-process-for-selecting-air-advisors).
[32] Testimony of Dr. Roger McClelland, Advisor, Toxicology and Human Health Risk Analysis, before the House Science Committee, Subcommittee on Environment, March 20, 2013 (https://www.gpo.gov/fdsys/pkg/CHRG-113hhrg80553/html/CHRG-113hhrg80553.htm).
[33] Testimony of Dr. Michael C. Honeycutt, Chief Toxicologist, Texas Commission on Environmental Quality, before the House Science Committee, Subcommittee on Environment, March 20, 2013 (https://www.gpo.gov/fdsys/pkg/CHRG-113hhrg80553/html/CHRG-113hhrg80553.htm).
[34] United States Environmental Protection Agency, "Scientific Integrity Policy" (https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf).