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Regulatory Parallels to *Daubert*: Stakeholder Influence, "Sound Science," and the Delayed Adoption of Health-Protective Standards

Roni A. Neff, ScM and Lynn R. Goldman, MD, MPH

Roni A. Neff is with the Department of Health Policy and Management and Lynn R. Goldman is with the Department of Environmental Health Sciences at the Johns Hopkins Bloomberg School of Public Health, Baltimore, Md.

Correspondence: Request for reprints should be sent to Lynn R. Goldman, MD, MPH, Department of Environmental Health Sciences, Johns Hopkins Bloomberg School of Public Health, 615 N. Wolfe St., Room E6636, Baltimore, MD 21205 (e-mail: lgoldman@jhsph.edu).

ABSTRACT

There is broad agreement that regulatory decisions should be based on evidence. But interested parties have used the "sound science" mantle to demand extended research, analysis, and review of evidence for the sole purpose of delaying health-protective regulation. This historical review shows how the forces behind the "sound science" reasoning leading to the *Daubert v Merrell Dow Pharmaceuticals, Inc* decision on science in the courtroom have operated in parallel in environmental regulation.

Like *Daubert*, certain "sound science" regulatory tools can be used to improve decision quality. However, these tools can also challenge the federal government's ability to safeguard the public's health and well-being. Most recently, political tampering with science provides the foundation for some policymakers to disregard science completely in the environmental regulatory process.

INTRODUCTION

There is broad agreement that regulatory decisions about the environment, safety, and health should be based on evidence. But pressures for ever-increasing documentation, review, and "sound science" have been used to create unreasonable standards of evidence, interfering with the government's task of protecting the public. "Sound science" pressures and the availability of analytic tools have created an environment in which interested parties can demand more and more data and repeated scientific review for the sole purpose of delaying the adoption of health-protective standards.

Advocates use the terms "sound science" and "junk science" and often specific criteria for soundness to divide and characterize evidence or simply to label and exclude unwanted evidence. "Sound science" has come to describe not only the evidence itself but also the approach of basing policy only on very stringent evidence. "Sound science" pressures in regulation are based on the implication that regulators are not using "sound" enough science. However, Wagner¹ cites multiple reviews of agency science indicating a lack of evidence for a

problem and little literature in the other direction. Furthermore, she notes many existing checks on agencies to assure proper use of science.

The "sound science" movement reached one of several peaks in the early 1990s, as demonstrated by the *Daubert v Merrell Dow Pharmaceuticals, Inc*² decision affecting the legal arena and the ascent of the antiregulatory 104th Congress. (We use the term, "sound science" only to refer to the "sound science" ideology, rather than as an endorsement of the quality of evidence.) Today, the Bush Administration and Congress are again aggressively promoting policies and taking actions that use a "sound science" approach with the effect of supporting industry's agenda. Like *Daubert*, many of these policy tools were little recognized initially and may seem benign. We argue that whereas a reliance on evidence is important, "sound science" efforts have raised the bar for assurance so high as to challenge the government's ability to protect the public. Moreover, by politicizing the approach to science, antiregulatory advocates have increasingly succeeded in persuading the government to disregard scientific evidence altogether in crafting regulatory standards.

This historical review complements the series on the influence of the *Daubert* Supreme Court decision in the legal arena by examining the parallel pressures on science in environmental regulatory decisionmaking. We begin with an example and background; then we review the history of how pressures for more data and review have increasingly been fixed into policy tools and used to delay regulatory outcomes from the 1970s to today.

DIOXIN AS A CASE STUDY

The dioxin risk assessment is instructive as a relatively flagrant example of stakeholders using "sound science" to promote delay. The Environmental Protection Agency (EPA) began its initial risk assessment in the 1970s, finding in 1984 that dioxin was the most potent synthetic carcinogen yet identified.³ Industry disagreed and sought reassessment, arguing particularly that carcinogenic effects might not occur at exposures below a certain threshold.⁴ EPA dropped its first draft reassessment in 1988 and began its current reassessment process in 1991,³ prompted in part by an inaccurate report of findings from the industry-sponsored "Banbury Conference" of dioxin experts.⁵⁻⁷ Participants protested afterwards that they had not known that the chlorine industry was funding the event, and disagreed with the industry press release stating they had reached consensus that dioxin was less harmful than previously thought. Nonetheless, that statement was widely quoted, including (perhaps unknowingly) by EPA administrator William Reilly, who initiated the 1991 dioxin reassessment.⁷

The first draft of the reassessment required 12 years of effort and was complicated by unusually extensive review mechanisms.^{8,9} Ironically, each time the agency revisited the data, they found additional evidence of toxicity.¹⁰ The EPA published its first draft reassessment in 1994.¹⁰ The *National Journal* reported that that year the Chlorine Chemistry Council increased its budget six times from the prior year to \$12 million and multiplied its staff by 12. Among the group's projects were a scientific review panel to respond to the EPA's draft dioxin reassessment and a national public relations campaign in which sympathetic local scientists spoke to the press and community leaders about dioxin.¹¹ EPA completed the next draft reassessment in 2000. Industry again criticized the adequacy of the scientific basis, claimed that uncertainties were not fully articulated, and urged that the Scientific Advisory Board have the chance to review the full "3000-plus page" report rather than just the earlier sections it had identified as problematic.¹² A Chlorine Chemistry Council representative stated to an EPA panel that "We hope the recommendations of this Peer Review Panel will include having EPA redo the cancer risk assessment using all the data, [and] properly consider a non-linear approach."¹³ Discussing industry's comments, the *New York Times* described the "primary goal" of "some industry officials" as "simply to keep the study of dioxin . . . going for as long as possible."⁴

In 2003, the EPA sent a new draft reassessment to a specially convened Interagency Working Group for review. The group could not agree on a conclusion by a Congressionally imposed deadline, and in October 2003 the draft was sent to a National Academy of Sciences panel for additional review, where it remains at press time.¹⁴

Throughout the process, scientists with industry funding have questioned the "soundness" and adequacy of the available science, emphasized risk-minimizing interpretations, and suggested time-consuming revisions including ongoing updating of the literature reviews. These scientists did not always disclose their affiliations; the Center for Health and Environmental Justice documented that 6 of 19 members of the EPA's review panel for the dioxin report had received undisclosed financial support from 91 "dioxin-polluting companies."^{4,15}

Whereas more research can always be done and more studies incorporated into decision-making, the net result of these "sound science" pressures has been almost 20 years of waiting for regulation (to be based on the final risk assessment) for a substance still classified as the most potent synthetic carcinogen.^{16,17} Furthermore, the dioxin reassessment has cost millions of dollars⁷ and years of staff time that could have been invested in other hazards. Although dioxin is a flagrant example, it shows how real scientific disagreements can be turned into a context for prolonged inaction. As this article will show, this process is pervasive throughout the regulatory enterprise. Whereas most of the imposed delays may be small, their summed impact is significant. In addition to the negative public health and environmental effects and unfair benefits to some industries, "sound science" pressures also result in elevating the role of technical information in decisionmaking above other social values, leading to public exclusion and distrust. And of course, beyond delay, these pressures can change regulatory outcomes, commonly in the direction of reduced protections.

Foundation for Science in Regulation

The regulatory state is built on the idea of government's role in protecting the public from hazards. Generally the federal government creates regulations with a "precaution-ary approach"—that is, based on scientific knowledge but with a significant safety buffer to help assure protection.¹⁸⁻²⁰ At the same time, government has an obligation to scrutinize regulations to evaluate their likely public benefit, either associated with direct impact or the averted potential for harm, as well as their potential burdens. Science typically provides at least part of the underlying data base for such assurance, and risk analysis methods such as risk assessment, cost-benefit analysis, and peer review provide the tools for interpreting the science in policy context. The scientific process of risk analysis and characterization is intended to be conducted without regard for political concerns. Afterwards, the more political risk management can follow, taking into account issues like equity, feasibility, and political will.

The *Daubert* decision affecting the legal torts arena requires evaluating each piece of evidence separately, using stringent criteria, before determining whether it may be used in decisionmaking. As will be discussed, the Data Access and Data Quality Acts affecting regulation parallel this approach, and there are pressures for more and stronger *Daubert*-like regulatory policy tools. For now, such tools remain the exception. As Krimsky (in this series) and others have described, regulatory decisionmaking tends to be based on a "weight of evidence" approach that uses all of the relevant evidence but weighs studies based on quality in order to determine the most strongly supported conclusions.²¹ In the regulatory arena, one use of "sound science" has been to challenge key studies individually until the "weight of evidence" appears inadequate.²²

Agencies undertake scientific review and analysis of regulatory information for a variety of reasons. Many reviews are legally mandated under the Administrative Procedures Act (1946), presidential Executive Orders, Congressionally passed requirements, or specific statutes.²³⁻³¹ Agencies may opt to exceed these requirements to assure that decisions are scientifically appropriate, support the public interest, are fair, and give opportunities for stakeholder participation, as well as to protect themselves in the event of challenge. It should be noted that parties often need considerable financial and scientific resources to take advantage of the available procedural options, including challenging procedures, participating in peer reviews, submitting public comments, and filing lawsuits. Compared with industry, the public health and environmental communities cannot hire commensurate

numbers of scientists; in practice, they participate only in the largest and most visible efforts. For example, the nonprofit group OMB Watch reported that 72% of information quality challenges under the Data Quality Act (discussed below) were brought by industry.³² There is no question that "getting the science right" is a value shared by all parties, but, at the same time, it is important to identify where this process adds value and where it simply provides opportunities for more delay.

In the next sections, we examine the history of these pressures for scientific review in the regulatory arena before, during, and after the "*Daubert*" era of 1993–1994. The history demonstrates the growing strength of the "sound science" movement and shows how advocates have effectively put into place and used policy tools and persuasion to promote extended scientific review and delayed decisionmaking on the basis of "sound science."

Before the *Daubert* Era

The EPA was established in 1970, and through the early 1970s public concern and outrage about industry activities held sway. Accordingly, Congress established most early environmental statutes to be health- or environment-based, meaning the EPA was to implement them based only on assessment of what was necessary to protect health or the environment, without regard for factors such as cost or feasibility. Particularly for carcinogens, which are seen to pose health risk with any exposure, health-based regulations minimize the need for in-depth evaluation of the specific risk level. There is less detail to be argued and less justification for extended scientific review compared with other types of regulation: simply documenting hazard and potential exposure is enough to support regulation.

By the mid-1970s, the balance was shifting. In the Toxic Substance Control Act (TSCA, 1976), Congress established a standard of "unreasonable risk" that has been interpreted by the courts to require the EPA to balance potential hazards against costs in determining which substances would be regulated. Because in practice this balancing needed data for justification and because of the TSCA's tremendous potential scope, it significantly expanded the role and volume of science analysis and review in regulation.

Building through the late 1970s and early 1980s, two important trends impelled agencies to demand ever more scientific support and input in rulemaking: agencies' use of risk assessment and court decisions. Risk assessment involves using data to characterize the hazard of a substance, establish a dose-response relationship, assess exposure, and determine the overall risk with a margin of safety. Since 1983 it has become a routine analytic procedure in many agencies.³³ By providing a common language and tool, the method represented a significant step forward. However, it also contributed further to moving environmental regulation away from a precautionary stance in which standards would be based on whether substances posed any hazard at all and towards a stance of regulating to a specific level of hazard.³⁴ Once that change occurred, industry critics could focus on challenging the details of risk assessments, thus increasing agencies' need for lengthy and detailed analytic procedures, documentation, and scientific review. Furthermore, the technicalities of risk assessment caused debates about regulation to move further into the realm where only experts could effectively participate. The growing use of other analytic tools like cost-benefit analysis have had similar impacts. We emphasize that, although these are not "antiregulatory" tools, one of their net effects has been a social change that benefits those opposed to new regulations both by slowing the process of regulation and also by providing opportunities for sophisticated analytical attacks on the process.

The second trend was ubiquitous court challenges to regulatory decisions. Although such scrutiny is a sign of an effectively functioning democracy, it also stimulated the EPA and other agencies increasingly to exceed requirements for scientific and stakeholder review and comment. For example, in preparing its asbestos ban under the TSCA, the EPA went beyond requirements to amass a 45,000 page record with 10 major regulatory analysis documents including an extensive economic analysis, 22 days of public hearings, thousands of pages of testimony, and 13,000 pages of comments.³⁵ Industry stakeholders challenged the rule, and a controversial 1991 Circuit Court case overturned it, mainly on the grounds that the EPA had not adequately stated the risks and benefits of alternative technologies and had not taken the "least burdensome" approach to addressing the

problem.³⁶ That decision raised the bar for an even higher standard of documentation for rule-setting and had a chilling effect on future rulemaking efforts to control the risks of chemicals under the TSCA, thus delaying and preventing protective rules on many other substances in addition to asbestos.

By the early 1980s, industry had come to successfully characterize itself as an underdog, arguing that without some mandated balance, overvigilant regulators would target any risk, no matter the size or cost to control it. The Reagan administration came to power and many saw it as having, in the words of one observer, "a mandate to do something longterm, permanent and sensible about rationalizing the regulatory process."³⁷ Among President Reagan's early actions were establishing a Task Force on Regulatory Relief and postponing new regulations.³⁸ The antiregulatory backlash gained significant power, with Reagan and (later) Congress issuing multiple antiregulatory policies, cutting agency staff, and otherwise hampering agencies' ability to act. Reagan's policies led to more dependence on data and review and more delays. A key policy was Executive Order 12291 "in order to reduce the burdens of existing and future regulations," which required agencies to submit increased documentation with their regulations (Regulatory Impact Analyses), and required that regulations be submitted to the OMB for review and oversight.²⁵ By the time of a 1986 lawsuit, the Environmental Defense Fund reported that OMB review added an average of 91 days to the EPA's promulgation of regulations and had caused the EPA to exceed legal or judicial deadlines in 86 of 169 relevant regulations.^{39,40} In some cases, regulations would disappear into the OMB for review and never be heard from again. (No explanation for these delays was required until the Clinton era.²⁶)

In the background, the movement for "sound science" continued to build through the late 1980s and early 1990s. Part of its later swell in power came from the retelling of certain stories seen as justifying the need for advocate efforts.

One example is the 1989 controversy over the pesticide, Alar (daminozide). In 1989, 22 years after carcinogenicity was first documented, the manufacturer provided new data to the EPA showing increased rodent tumors after exposure.^{41,42} The EPA began work to cancel Alar's registration but, in the process, extended its tolerance. Frustrated, the Natural Resources Defense Council (NRDC) published a report with a risk assessment indicating that childhood exposure to apples could eventually cause cancer in thousands of current preschoolers.⁴²⁻⁴⁴ The EPA staff calculated a risk about 10 times lower, although still significant.⁴² After a 60 *Minutes* exposé, there was great public concern and a major impact on the apple market. The manufacturer voluntarily withdrew daminozide from the market that fall.^{35,41,45}

Among the most vocal critics of the so-called "Alar scare" was the American Council on Science and Health, which received \$25,000 from Alar's manufacturer, among other industry grants.⁴⁶ The American Council on Science and Health has since produced at least five reports claiming to debunk the scare and paid Walter Cronkite \$25,000 to narrate a television documentary that he later stated "was meant to be propaganda."⁴⁶⁻⁵¹

There remains disagreement as to whether the course of events regarding Alar was appropriate.^{51,52} Critics have convinced the media and public that the Alar story reflects an environmental group using "unsound" science to frighten the public and force the company to overreact by withdrawing its product.^{50,53} Yet, daminozide continues to be listed as a "probable human carcinogen" by the EPA and the International Agency for Research on Cancer (the latter for the breakdown product, unsymmetrical dimethylhydrazine) and as a carcinogen by the State of California.⁵⁴ In response to a libel suit against the NRDC, a federal court held that NRDC's 1989 report was "not a polemical tract preying on raw emotions and irrational fears."⁵⁵ Furthermore, there is no evidence that either NRDC's or EPA's risk estimates were based on implausible or rarely used assumptions that would have been grounds for rejection in scientific review and plenty to support the notion that prompted regulatory action by EPA could have prevented the publicity about Alar's risk and, thus, averted this "food scare."^{42,43,52}

A second major event in the growing strength of the "sound science" movement was the lead industry's attack on scientist Herbert Needleman of the University of Pittsburgh. Needleman had published research (now

replicated many times) showing that low-level lead exposure is harmful to the brains of developing children.⁵⁶ These findings were critical to the EPA decision to stay the course on the phase-out of lead from gasoline, as well as to the Centers for Disease Control and Prevention's decision in 1985 to lower the threshold for "elevated blood lead levels" from 30 to 25 µg/dL.)⁵⁷ The change had enormous regulatory implications: the EPA had been required to develop additional restrictions on lead in drinking water, lead emissions from smelters, and lead in Superfund cleanups. The conflict surfaced in the context of litigation regarding a major lead smelter. The plaintiff's experts, Drs Clare Ernhart and Sandra Scarr, filed requests to view Dr Needleman's original data. Eventually, they accused him of fraud and filed a complaint with the NIH Office of Research Integrity. In the effort to discredit him professionally, industry's attacks often became personal. The University of Pittsburgh later conducted public hearings to address the allegations of fraud, and Dr Needleman in essence was acquitted⁵⁸; however, Ernhart and Scarr continued the attack.⁵⁹ The net effect of this controversy was to postpone or dilute efforts to clean Superfund sites that were contaminated with lead (and for whom Drs Scarr and Ernhart served as expert witnesses).⁶⁰

It is clear that the offensive on environmental science was hitting its targets by 1991. That year, then-EPA Administrator William K. Reilly chartered an expert panel to investigate the EPA's effectiveness in "obtaining and using sound science for credible decisions."⁶¹ The report, published in 1992, failed to identify scientific irregularities at the EPA but did recommend that the EPA consider scientific advice earlier and more frequently. It was the first to recommend that the EPA strengthen its peer review processes for "scientific and technical efforts to obtain data used for guidance and decisions." Implementing these recommendations could undoubtedly improve EPA science and credibility but not without increasing the time invested per regulatory decision.

Several popular and influential books contributed to the "sound science" movement's theory and strength at this time. Peter Huber's 1991 *Galileo's Revenge*⁶² was an engaging and derisive examination of the use of so-called "junk science" in tort cases. Whereas the book contributed to the growing sense among conservatives that advocates were misusing science to create policy, in fact it reserved relatively kind words for regulators, stating, "Almost always [scientific and engineering investigations] trigger appropriate reaction by the EPA, [other regulators], or the industry itself years before trial lawyers achieve anything at all."⁶² The second key book was *Breaking the Vicious Circle: Toward Effective Risk Regulation*,⁶³ authored by Justice Stephen Breyer before he was appointed to the Supreme Court. Breyer emphasized that scientific uncertainty provides openings for political influence into decisionmaking. (He highlighted the influence of environmental advocacy groups promoting regulation of small risks, although he did acknowledge industry influence as well. He suggested creating an agency and skilled cadre aimed at "rationalizing" regulation.

In sum, by the early 1990s, a combination of process requirements in regulation, industry advocacy, the evolving evidence base, developing policy analysis tools, intellectual trends, and other factors led to increasing questioning of regulatory science and calls for "sound science." Industry stakeholders did not drive all of these changes, but they used them effectively to promote their agenda, with particularly powerful effects by the mid-1990s.

***Daubert* and the 104th Congress**

In a brief 2-year period from 1993 to 1995, the *Daubert* decision was written, the 104th Congress was elected and sought to enforce the Contract with America, and multiple other policies were proposed and some enacted to promote the "sound science" ideology and create high standards for regulation.

The Supreme Court passed down the *Daubert* decision on June 28, 1993. There can be little doubt that members of the court were aware of the "sound science" movement operating outside their doors and, furthermore, that movement members were well aware of the court decision. Indeed, the US Chamber of Commerce,⁶⁴ the Washington Legal Foundation,⁶⁵ and the National Association of Manufacturers/Business Roundtable/Chemical Manufacturers' Association,⁶⁶ themselves submitted *amicus curiae* (friend of the court) briefs in the case. And,

the judge reviewing the case in the US Court of Appeals for the Ninth Circuit quoted from *Galileo's Revenge*.^{62,67,68} Leading scientific societies and biomedical journals also submitted *amicus curiae* briefs on behalf of the manufacturer, with emphasis on the importance of peer review to determine legitimacy.^{69,70} Whereas in later years, such organizations and journals have taken different stances on related issues, for example,^{71,72} their support at the time may have reinforced the idea that essentially political arguments in "sound science" terms could garner the endorsement of these most respected groups.

In the *Daubert* deliberations, there was some discussion of the relevance to regulatory policy. On the public health side, a group of scientists⁷³ emphasized that *Daubert*-like criteria are not required for regulatory decisionmaking and, thus, that sound decisions can be made without them. However, the National Association of Manufacturers and others argued that a distinction be made between administrative and legal action: "Administrative action is prophylactic and not retrospective; its purpose is to warn of possible health effects and not to judge whether a given agent in fact caused a specified ailment. Administrative action in the health sciences is undertaken by trained professionals pursuant to a statutory mandate, not by jurists and jurors. And administrative agencies, unlike federal courts, are not bound by the Federal Rules of Evidence."⁶⁶ As the discussion below suggests, the apparent importance of this distinction to such advocates has since declined if not evaporated.

About a year after *Daubert* was written, 316 Republican candidates for the House of Representatives signed the "Contract with America," indicating their conservative legislative agenda for their first 100 days in office if elected. A key aspect was the Job Creation and Wage Enhancement Act, later introduced as HR 9.⁷⁴ The Act focused on reducing regulatory burden to industry, including promoting scientific review in regulation (it only addressed its namesake jobs and wages through the implied mechanism that regulatory relief would enable employers to improve them). Not surprisingly, business interests were significantly behind this movement. The full Contract with America was written with strong input from the industry-funded conservative Heritage Foundation,⁷⁵ and Representative Tom DeLay (R-TX) arranged for antiregulatory industry funders to provide more than \$2 million in financial support to conservative candidates in the 1994 election.⁷⁶ Republicans interpreted their sweeping victory that November as a mandate to enact the Contract with America principles. HR 9 did not ultimately pass as such; however, advocates have since succeeded in incorporating many of its elements into policy.⁷⁷

Congressional Action Post-*Daubert*

In the years since *Daubert*, antiregulatory forces have continued to enact new "sound science," regulatory review, and other policies that create barriers to regulatory action. Table 1* shows the history of Congressional directions in environmental statutes regarding how regulators were to use scientific information. Until 1990, when Congress incorporated such language, it sought to assure that agencies would comprehensively assess available information—most strikingly in the TSCA, where the EPA was directed to consider "any study of any effect." At other times, Congress was silent or directed EPA to assess "available" or "readily available" information. All of that changed in the post-*Daubert* era.

TABLE 1— Environmental Legislation Over Time: Provisions Relevant to the Use of Science in Risk Assessment and Decision Making

Year	Statute	Language on Scientific Information to be Used in Applying Statute
1969	The National Environmental Policy Act §4344 (2)	". . . Timely and authoritative information concerning the conditions and trends in the quality of the environment both current and prospective"
1970	Clean Water Act	(No language regarding selection of science for regulatory analyses)
1976	Toxic Substances Control Act (TSCA)§ 2 (6) (definitions)	"The term 'health and safety study' means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter."
1978	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) §136w (d)(1) Science Advisory Panel	Various requirements to consult with EPA's FIFRA Science Advisory Board including any actions to suspend the registration of a pesticide but also "comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency"
1980	Comprehensive Environmental Response, Compensation, and Liability Act §121	(No language regarding selection of science for regulatory analyses)
1980	Resource Conservation and Recovery Act	(No language regarding selection of science for regulatory analyses)
1986	The Emergency Planning & Community Right-To-Know Act § 11023 (d)(2)(a) (addition of new chemicals for reporting of TRI emissions) Clean Air Act	"Sufficient evidence"
1990	§103 (d) (2) (C) (i) (assessment of hazardous air pollutants under §112) ^a	"available toxicological and epidemiological information for the pollutant to ascertain the levels of human exposure which pose a significant threat to human health and the associated acute, subacute, and chronic adverse health effects"
1990	§111 (b)(1)(B) (performance for new stationary sources) Federal Food, Drug and Cosmetic	"Readily available information on the efficacy of such a standard"

Act §346a Tolerances and Exemptions for Pesticide Chemical Residues

1996	§346a (b)(2)(A)(ii) (determination of safety) ^b	"all anticipated dietary exposures and all other exposures for which there is reliable information"
1996	§346a (b)(2)(C)(i) (exposure of infants and children) ^a Safe Drinking Water Act	"available information"
1996	§300G-1 (b)(1)(B)(ii)(II) (Standards: regulation of unregulated contaminants) ^b	"Such findings shall be based on the best available public health information, including the occurrence data base established under section 300j-4(g) of this title."
1996	(b)(3)(A) (Standards: use of science in decisionmaking)	"In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use <ul style="list-style-type: none"> i. the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and ii. data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."

In 1996, the 104th Congress enacted two environmental statutes: the Safe Drinking Water Act and the Food Quality Protection Act, hailed as major environmental achievements. Both contained provisions related to "sound science." The Food Quality Protection Act instructs the EPA to use "reliable information" in making decisions, a somewhat more stringent criterion than in the past. The Safe Drinking Water Act went much further, emphasizing use of peer-reviewed research (performed with "sound and objective scientific practices") and accepted or best available methods of data collection. Furthermore, for each risk included in estimating a drinking water contaminant's public health effect, it is necessary to specify populations, risk estimates, upper and lower bounds, and uncertainties. These guidelines were relatively little-noticed until OMB relied on their Congressional imprimatur to promote them as a national standard several years later, stating: "Congress, for health decisions under the Safe Drinking Water Act, has already adopted a basic standard of quality for the use of science in agency decisionmaking."⁷⁸

Congress passed two other policies of particular note in the post-*Daubert* era. The 1999 Shelby Data Access Amendment was a single sentence tacked on to an unrelated appropriations bill, stating that data generated in federally funded published studies should be obtainable under the Freedom of Information Act.⁷⁹ Senator Shelby authored the amendment after failing to gain access to particulate matter data used in a 1997 regulation affecting companies including a prominent power company in his home state (suggesting his concern was political, not scientific).⁸⁰⁻⁸² There was contentious debate surrounding OMB's interpretive rule on the Data Access Act.⁸³ Scientific organizations argued that opponents of regulation could use it to challenge legitimate studies used in decisionmaking by harassing researchers, submitting Freedom of Information Act requests, reanalyzing slowly, and even reanalyzing data purposely to produce favorable results. In addition, the policy makes no requirements for sharing *industry*-funded data used in regulation, although much of that data does not even get the public exposure or peer review that would be involved in publication.^{80,84-86} No studies evaluating the Data Access Act's outcomes were identified in research for this paper.

The second "sleeper" was the 2001 Data Quality Act, which ostensibly aimed to assure accuracy of government-disseminated information.⁸⁷ It too was passed as a rider on an unrelated appropriations bill with little advance awareness.^{88,89} Evidence suggests that it was sponsored at the behest of lobbyist Jim Tozzi of the industry-supported Center for Regulatory Effectiveness.⁸⁸ The Data Quality Act required each federal agency to develop information quality guidelines to assure "the quality, utility, objectivity, and integrity of information (including statistical information) disseminated by the Federal government."⁸⁷

Industry, conservative groups, and OMB have interpreted the Act to mean it applies not just to disseminated information but also to information used in rulemaking. Most agencies seem to have incorporated OMB's boilerplate text on this into their own guidelines.^{90,91} Furthermore, the US Chamber of Commerce stated that the act is "the most significant change to the federal rulemaking process since the Administrative Procedures Act was enacted more than 50 years ago."⁹² However, following a data quality challenge related to dioxin in biosolids,⁹³ the Center for Progressive Regulation wrote to EPA and OMB requesting that they formally clarify that, in fact, a literal reading of the data quality guidelines suggests they do not refer to data used in rulemaking.⁹⁴ At press time, the issue has not been resolved.

What has been the Act's impact? In a report to Congress, OMB reported that most "nonfrivolous" data quality requests failed to gain approval, most commonly because it was found possible for a "reasonable scientist" to concur with the agency.⁹⁵ The report thus notified would-be request filers that: "Such correction requests might have been better focused if they had addressed the inadequate treatment of uncertainty rather than the accuracy of information." OMB also reported that "neither OMB nor our engaged stakeholders has noticed or commented on any slowdown of the regulatory process." "Watchdog group" OMB Watch strongly critiqued OMB's report, claiming that OMB reported only 35 of 98 data quality requests, that the agency omitted the fact that 72% of requests were submitted by industry, and perhaps most importantly, that the reported lack of delay in regulation was not based on any data collection. OMB Watch noted that OMB in fact stated that request fulfillment was taking longer than predicted and cited an EPA official's corroborating statement to suggest that the Act is indeed slowing regulation.³²

Promoters of data quality and data access have not stopped at the federal level. The conservative American Legislative Exchange Council promotes model legislation on both topics for state legislatures.⁹⁶

"Smart Regulation" at the Office of Information and Regulatory Affairs

Outside of Congress, "sound science" proponents have found eager allies in the current Bush administration. The front line office for regulatory review is the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), currently directed by John Graham, PhD, a former Harvard academic and longtime recipient of industry funding. He has sought to expand the office's role, including participating in "upfront" review while regulations are being developed, on the theory that waiting longer makes it harder to request significant changes. OIRA has adopted as official US government policy, the doctrine of so-called "smarter regulation," focused in three categories: "more openness in deliberation, better regulatory analysis, and higher quality technical information for use by regulators."⁹¹ Under the latter two "sound science" goals, the office has heavily promoted tools for review and interpretation of scientific data, including risk assessment, cost benefit analysis, and peer review in regulatory analysis. It has stated that it will exercise oversight over the methods themselves and might challenge the process or thoroughness of their use. It has set out new (draft) guidelines on peer review for all agencies.^{97,98}

It is expected and appropriate that OIRA will meet with industry through stakeholder participation channels and that industry will try to promote its agenda. To what extent has industry *driven* OMB's decisions and activities? We refer to multiple reports documenting Bush Administration regulatory activities in which science has been overshadowed by stakeholder needs.⁹⁹⁻¹⁰¹ For example, OMB Watch and the Center for American Progress' (2004) *Special Interest Takeover* provided nine examples of OIRA intervention to weaken proposed standards.¹⁰¹ In each, industry groups were reported to have pressured OIRA, including meeting with the agency

on record. In two cases, the report identified industry documents with identical language to that proposed by OIRA. Five of OIRA's interventions resulted in the agency weakening proposed standards, one in weakening existing standards, two in doing nothing, and one in a request for additional study.

For example, in the case of regulations for runoff from factory-type animal farms, Dr Graham and other OIRA staff met with affected industry groups almost a year before the office's formal review of the regulations. A month later, OIRA told the EPA to review a recommendation from the industry-funded Mercatus Center advising weakening the standards. The EPA dropped some important protections from the Clinton-era draft and submitted its proposed regulation to OIRA for review. While the proposal was under review, OIRA met again with industry groups. When OMB finally completed its revisions, the proposed rule was significantly weakened in several key areas, including following the advice provided by the American Farm Bureau in a letter to OIRA.^{90,101}

Another example is manganese regulation in soil and drinking water. Manganese, emitted by industry, is associated with central nervous system, respiratory system, and sexuality effects at high exposures.¹⁰² After a 1998 consent decree with Environmental Defense, the EPA had proposed a rule including manganese on a list of "hazardous wastes." The rule would have required treating wastes with manganese to safe levels before surface disposal or underground injection. However, following steel industry advocacy, OIRA removed manganese from the list. The EPA said it would instead perform additional study, although according to the report, such study has not occurred in the subsequent 3 years.¹⁰¹

What is the effect of all these "sound science" efforts at OMB? OMB Watch has documented in some detail the regulatory slowing under the current Bush administration. In the first 2 years, for example, the EPA only proposed 9 economically significant rules, compared with 28 and 12 in the Clinton and first Bush administrations, respectively. Of the new proposed rules, 5 reduce existing environmental protections, and OIRA weakened 3 from earlier drafts. EPA finalized only 2 "economically significant" rules in those 2 years, compared with 23 in the first 2 years of the Clinton Administration and 14 in the first 2 years of the first Bush administration. Both of the finalized rules were court ordered and both were weakened from the initial proposals following industry efforts.¹⁰³ In a September 2003 speech, Dr Graham stated that "the preliminary evidence suggests we [OMB] are making a difference."⁹¹ He reported that the estimated average annualized impact of major regulations passed in the George W. Bush administration was less than \$1 billion compared with \$8.5 billion under the first Bush administration and \$5.7 billion under Clinton.

But "impact" does not equate with damage. A 2003 report from Dr Graham's office reviewed 107 major Federal rulemakings finalized over the past 10 years and found that the estimated total annual quantified *benefits* of these regulations (\$146–\$230 billion) were 3.5–6.4 times the costs (\$36–\$42 billion; calculated).¹⁰⁴ In other words, using OMB's own metrics for benefits and cost, regulations generally have been beneficial to the economy.

These significant OMB activities reflect and contribute to a more general strategy of using "sound science" criteria to delay regulation, which has truly come into its own since the *Daubert* era. The Bush Administration's activities are not consistent with policy statements favoring a more neutral, "smarter," evidence-based decisionmaking approach. In fact, one wonders whether this approach is heading toward an abandonment of science altogether in regulatory decisionmaking. Over the past few years, the Bush Administration has been criticized by the scientific establishment over three main issues, summarized by Donald Kennedy, editor of *Science* magazine, as: "the dismissal and then reconstitution of committees advisory to various scientific bodies that are part of government agencies, such as the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration"; "the questioning of individual appointees to such committees with respect to their personal political loyalty and even their voting record in the last presidential election;" and "changes made in the advice various agencies post on the Web to guide consumers about choices they make in the interests of their own health or safety."¹⁰⁵⁻¹¹⁰ Advocacy organizations and the US House of Representatives staff have

documented how, repeatedly, the Bush Administration has disregarded or even tried to suppress scientific information contrary to decisions they wish to take, on issues ranging from mercury toxicity and emissions to climate change to multiple air pollutants.^{99,100} Years of politicization of the use of science in decisionmaking have enabled these developments by providing policy makers with the excuse that, as stated by Kennedy, "Well, they were doing it too."¹⁰⁵

Conclusions

This article has outlined how pressures for repeated and detailed scientific review and analytic procedures inevitably have led to delays in regulating environmental threats. These pressures in regulation share a similar intellectual history to the *Daubert* decision and have continued to build in its wake. Antiregulatory conservatives and self-interested industry alike have used the ideology of "sound science" to insert ever more hoops for regulators to jump through. In self-protection, agencies themselves have also assumed the yoke of providing these extensive reviews. Meanwhile, industry has sought to influence which science would be considered "sound": at times review committees have been stacked with industry-sympathetic scientists, and industry has supported extensive and often covert public relations campaigns and paid scientists. These stakeholders challenge the "weight of evidence" by attacking one study at a time until the overall scientific grounding for decisions appears weak.²²

The result is that risk assessment and regulatory activities on a small number of issues stretch agency capacity, limiting the ability to address other pressing needs. Furthermore, regulation is often delayed in even those few areas that are addressed, often for decades. And finally, the regulations that survive the process are often weakened and fail to reflect the dictates of the weight of evidence. "Sound science" pressures also remove the decisionmaking process even further from those most affected by it, so that essentially political decisions are recast as technical ones. The more policy decisions rest in the hands of dueling experts, the more members of the public are excluded from the process and the greater the public skepticism and distrust of government.^{34,111}

What's next? Although the current structure provides many pressures for so-called "sound science" criteria to be incorporated into information used in regulation, some advocates have called for the *Daubert* criteria themselves to be made into official regulatory policy. For example, the conservative Annapolis Center recommended that such criteria be adopted, and the US Chamber of Commerce submitted a proposal to the Bush administration to create an Executive Order to that effect.^{67,112} "Regulatory Daubert" proposals suggest that *Daubert* criteria should be required in judicial review of regulatory decisions, not just tort cases.^{1,113}

The *Daubert* principles, as well as the ideas of "sound science" and "smart regulation," on the surface sound innocuous or even beneficial and, thus, generate little public interest and are relatively easy to enact. But the "sound science" movement is about consolidating power, not reason. Public health professionals should recognize these ideologies for what they are and promote policies that lead to science-based precautionary action that works efficiently and effectively to protect the public's health, albeit without posing unnecessary burdens to industry.

It is time to reconsider not only how we incorporate science into regulatory decisionmaking but also whether and when science is considered. Clearly it is time to consider reform in how science is utilized and to question the role of OMB in managing science review processes within the government. The public interest is not well served when such processes, managed by political and economic branches of the White House and not adequately transparent to the public, can be used by industry to forestall protections in the name of "sound science." Certainly, all would agree that the evidence supporting environmental policy-making needs to be subjected to a stringent and thorough evaluation. However, such evaluations should be carried out in a manner that promotes the effectiveness of the government in protecting our health and the health of future generations and is inclusive of all relevant data, even data that do not support the decisions politicians wish to take.

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Footnotes

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