

# Science and Regulation: Current Impasse and Future Solutions

We reflect on four articles that examine the Supreme Court's *Daubert v Merrell Dow Pharmaceuticals, Inc* decision and efforts by private interests to derail public health and environmental regulations. The articles' authors make the case that the impact of *Daubert* and related decisions in court settings pale by comparison to the threat that *Daubert*-like thinking poses in the regulatory arena.

A growing number of companies, however, have made substantial changes in practice and in culture by embracing a philosophy where health and environment are priorities. Mechanisms could be established to encourage firms to pledge to use science to meet public health and environmental goals, as well as channel the ingenuity of the private sector towards ecological, economical, and equitable systems of production. (*Am J Public Health*. 2005;95:S8–S12. doi:10.2105/AJPH.2004.059626)

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## FOUR ARTICLES IN THIS

supplement—by Wagner,<sup>1</sup> Neff and Goldman,<sup>2</sup> McGarity,<sup>3</sup> and Michaels and Monforton<sup>4</sup>—focus on the role that the Supreme Court's *Daubert v Merrell Dow Pharmaceuticals, Inc* decision has played in efforts by private interests to derail public health and environmental regulations. *Daubert*, handed down in 1993 and refined with the subsequent *General Electric Co v Joiner* and *Kumho Tire Co v Carmichael* decisions, encourages judges to be “gatekeepers” in determining whether expert scientific testimony can be allowed in tort cases.<sup>5</sup> Taken together, these articles make a strong case that the impact on public health of *Daubert* and related decisions in court settings pale by comparison with the threat that *Daubert*-like thinking and tactics pose in the regulatory arena. With historical reviews, analysis of recent legislative and regulatory decisions, and speculation about future scenarios, the aforementioned articles focus on the exploitation of scientific uncertainty by private interests for the express purpose of delaying regulatory action. Manufacturing uncertainty and promoting inappropriate criteria for assessing the quality of evidence, the authors argue, are central elements of a strategy for opposing regulation, impeding discussion of values and societal priorities, and closing out input from those whose health and quality of life are impacted by regulatory decisions. What these authors have to

say should alarm people and institutions committed to public health. It should also disturb those in the corporate sector who, through their own Environment, Health and Safety experience, have learned that safe workplaces and healthy communities are integral to profitable and sustainable industrial production.

But once alarmed, what to do? Two of the articles offer policy recommendations that could strengthen agency defenses against well-resourced campaigns to dismantle regulatory capacity. If implemented, they may prevent some of the most nefarious efforts to convince policy makers and the public that government action to reduce exposures to hazardous substances is unnecessary and undermines economic progress. These proposals are critical, and we applaud them. We also urge these authors and other leaders not to limit themselves to battles that pit corporate priorities against the public interest, in which science is both a pawn and a weapon. At the conclusion of this commentary, we describe several initiatives involving leadership by particular companies and structures for accountability that we think could be built upon to begin to reverse the destructive relationship between the public, private interests, and science that has so compromised the efficiency and effectiveness of the policymaking process.

The authors of the four articles we discuss here all portray *Daubert*, which has promoted a

reductionist and formulaic approach to assessing the quality of scientific evidence, as part of a broad attack on public health science and scientists that reaches beyond the courts. The authors argue that efforts to expose so-called “junk science” and promote instead an idealized “sound science” (common rhetoric used by defendants filing *Daubert* motions to exclude evidence brought by plaintiffs) are pretenses for campaigns to prevent, rescind, delay, or do an end-run around regulatory action. “*Daubert*-like” thinking, in which science is presumed to comply or not with a set of prescribed standards for quality research, has permeated science policy debates beyond the courts and is a powerful tool in efforts to discredit the basis of proposals to restrict emissions, exposures, or other activities that pose a threat to public health or environmental quality.

Wendy Wagner<sup>1</sup> focuses on parallels between *Daubert* and two recent “good science” laws (the Data Access Amendment and the Data Quality Act), which she says “expand the avenues for interest groups to challenge agency regulations . . . and provide strong incentives for these groups to mischaracterize fundamental policy conflicts as instead disagreements over ‘good science.’” Neff and Goldman’s article<sup>2</sup> opens with the following:

There is broad agreement that regulatory decisions about the environment, safety, and health should be based on evidence.

But pressures for . . . 'sound science' 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.

With the application of *Daubert*-like criteria in judicial review, McGarity<sup>3</sup> anticipates a suite of actions by regulatees to generate criticism of the science that can be brought "to the attention of credulous judges. . . . The bottom line will be fewer rules to get in the way of regulatees and fewer protections for the beneficiaries of the congressionally mandated programs."

Michaels and Monforton<sup>4</sup> and Neff and Goldman<sup>2</sup> examine the history of debate over regulation of several highly hazardous substances. They document a host of disingenuous tactics used by proponents of "sound science" to "raise the issue of scientific uncertainty no matter how powerful or conclusive the evidence," and a suite of case examples in which industry-funded organizations challenged robust evidence demonstrating links between exposures and human disease. The articles provide compelling details on the extremes to which antiregulatory interests have gone to undermine credible science and attack credible scientists. How much might have been accomplished—by industry, citizen groups, and government—with the resources that have been expended in marshalling and responding to these attacks? How much human disease might have been prevented?

A second theme common to the four policy papers in this supplement is the role of *Daubert*, related Court decisions, and the "good science" laws in institution-

alizing one of the most successful of the antiregulatory tactics, that is, forcing scrutiny of individual studies against unrealistic or inappropriate standards early on in the debate, thereby truncating the body of evidence that can be reviewed in its totality. In the court setting, the impacts of judges' decisions to exclude credible scientific evidence can magnify as courts look to past cases for precedent. Noting that the US Chamber of Commerce advocates "the adoption of an Executive Order requiring all federal agencies to apply the *Daubert* standards in the administrative rulemaking process," Michaels and Monforton state that "the legal, economic, and political obstacles faced by regulators who currently use a weight-of-the-evidence approach will increase dramatically when *Daubert*-like criteria are applied to each piece of scientific evidence used to support a regulation."<sup>4</sup>

A related theme is inappropriate expectations for the role of science and scientists in legal and regulatory decisionmaking. Taken to their extreme, interpretations of *Daubert* suggest that the quality of scientific evidence can be measured against a gold standard, articulated, Neff and Goldman point out, as "criteria for soundness," and that that standard is static across disciplines and contexts. For some judges and other decision-makers, the logical extension of a *Daubert* approach to science appears to be that studies not meeting a certain level of proof either disprove a causal relationship or are irrelevant, and that conclusions drawn on the basis of a body of evidence that includes anything but studies meeting the gold standard are unscientific. With a *Daubert* worldview, the distinc-

tion between legitimate and illegitimate science is clear, and the context for the science does not affect the standard of proof. Moreover, as Neff and Goldman suggest, scientists who equivocate with words like "might," "may," "possibly," or "potentially" impugn the quality of the research they refer to. Under *Daubert*-like thinking, decisions to regulate in the face of uncertainty cannot be justified. Of course, this approach constrains both the body of evidence and the scientists who can contribute to science policy decisionmaking. It is inconsistent with the practices of many in the scientific community, and it fails to factor in the context for a given decision, which will affect the degree of proof considered necessary and appropriate. (Elsewhere in this series, Sheldon Krinsky<sup>6</sup> describes the variations among scientific norms across disciplines. In her article in this supplement, Sheila Jasanoff<sup>7</sup> notes that science in the context of legal and regulatory decisionmaking is distinct from science in other contexts; she argues that the legal system's goal to mete out justice, for example, appropriately requires a different level of proof than does the goal of seeking truth through scientific inquiry.)

Moreover, *Daubert*-like thinking about science and scientists undercuts the role of societal values in decisionmaking in both the legal and regulatory contexts. Neff and Goldman assert that "sound science pressures . . . result in elevating the role of technical information in decisionmaking above other societal values." They note that reliance on technical information preceded *Daubert*, as a result of "the rise of risk assessment" and the increasing involvement of the

courts responding to legal challenges to regulatory action. In reviewing "requests for correction" of specific information made thus far under the Data Quality Act, Wagner finds that the vast majority actually veiled challenges to agency policies. Lobbies for private interests appear to understand that a discussion of values would rapidly erode their footing, so they hide behind disputes over sound science.

The impact of undercutting the role of values in decisionmaking may be substantial. Jasanoff<sup>7</sup> speculates that failure to take into account factors such as "costs and repercussions of wrongly deciding liability; the relative economic or social power of plaintiffs/defendants; distributive impacts of injury; responsibility for failure to produce relevant knowledge in time, etc. . . . may impede the fair distribution of the costs of uncertainty between the producers and the unwitting consumers of risk." Neff and Goldman contend that the elevation of technical information and the demoting of values-based discussion noted above have led to increased public exclusion and distrust.

The authors of all four articles reflect on the decreasing role of the public in influencing policy decisions related to occupational and environmental hazards. The power of grassroots groups peaked in the 1970s and 1980s, resulting in the establishment of the Environmental Protection Agency and the passage of most major environmental laws. Since then, professional interest groups have taken over on both sides of the debate. Although grassroots groups remain strong at the local and state levels, many environmental organizations working on federal policy have responded to

the increasing complexity of policy debates on these topics by hiring technically and scientifically trained staff who operate, as Wagner details, in relative isolation from the constituencies they represent. The disparity in resources and capacity of interest groups on either side of the debate about regulation is enormous—regulated industries employ thousands of analysts and lobbyists to track and intervene on every proposed regulation or other policy decision, whereas public interest and labor organizations, though often remarkably effective given their resources, pick their battles.

These authors argue that organizations working on behalf of private interests are devoting enormous resources to deconstructing and undermining the best evidence that exists on links between environmental and occupational exposures and human health, resulting in substantial and needless mortality and morbidity. In the meantime, the “science wars” they describe result in vast expenditures by the agencies to justify regulatory proposals, which are magnified when companies challenge agencies’ science in court. We concur with these authors that the primacy of a *Daubert*-like approach to scientific evidence, along with an increasing number of successful efforts to enshrine it in public policy, will further hamstring agencies from preventative decisionmaking consistent with a public health approach. Debate over the quality of science needed in public decisionmaking is not illegitimate. In its current iteration, however, it is misleading and unproductive.

Motivated by a range of factors—potential liability, media attention, new science, and de-

sire to “do the right thing”—some companies are bucking the trends described in these articles. A number of them have taken on two of the themes we identify in particular—the exclusion of the public from debates about links between environment and health, and the avoidance of discussion of societal values, making substantial changes in practice and in culture in the context of a commitment to sustainable development. Participants in processes like the Rio Earth Summit (1992) and its successor in Johannesburg (2002) have discussed and embraced long-term societal goals and engaged with nongovernmental organizations in doing so. Several have made commitments to specific public interest organizations regarding transparency and public involvement on regional and local levels. Retailers in the UK, for example, have responded to a safer chemicals campaign by Friends of the Earth by producing strategies, timelines, and progress reports on phasing out certain bioaccumulative chemicals. Recently, Royal Dutch Shell has engaged community-based organizations and international environmental groups in a process of reducing and monitoring emissions from refineries into neighboring communities.

Individual companies and local communities have also undertaken to develop “good neighbor agreements” that commit companies to a range of practices, and they often include provisions for communities to hire their own industrial hygienists to inspect potentially hazardous plants and make safety recommendations.<sup>8</sup> In one such instance, an industrial hygienist doing an inspection on behalf of a Massachusetts community

organization found numerous safety hazards and potential explosion risks in a factory, which were corrected voluntarily.

The behavior documented in the articles in this supplement seems to be inconsistent with the spirit of these initiatives. Indeed, many of the same companies that have participated in international conferences about sustainability and initiated projects to address public concerns nonetheless have been avid participants in campaigns to discredit both research and experts who conclude that environmental exposures are linked with health problems.

We are aware of companies that appear to be exploring new, more productive approaches to the development and use of scientific information. Several of these cases involve decisionmaking about whether or not to reduce use of a hazardous substance when relevant science is still uncertain. Samsung Electronic’s position paper on the “use and phase out of certain substances when appropriate” states that “in some special cases, we may even consider strong evidence that cannot strictly be scientifically proven, such as suspected links between chemical causes and environmental or health effects, as enough basis for decision making.”<sup>9</sup> Samsung has committed to phasing out all packaging applications of polyvinyl chloride (PVC), the mass production and disposal of which, it says, can have some “very adverse environmental effects,” and to “researching other short lifespan uses of PVC in order to find alternatives.” Samsung has also committed to including “ALL uses of PVC within the phase-out plan, which we will produce by the end of 2005.”

Fujitsu, a maker of computers, has committed to reducing emissions of chemicals that are on a Japanese Ministry of the Environment list of “endocrine disruptors,”<sup>10</sup> despite substantial uncertainty about the implications for human health of a chemical’s ability to disrupt the endocrine system.<sup>11</sup> In the past 2 years, Fujitsu has reduced its emissions of Bisphenol A by approximately 90%.<sup>12</sup>

Samsung and Fujitsu’s initiatives may derive in part from anticipation that regulation is just around the corner. Whatever their motivations, their actions in the face of scientific uncertainty are a far cry from those of companies described by the authors of the four aforementioned articles, which use uncertainty—both real and manufactured—to justify opposition to rule-making. Such decisions to reduce or eliminate use of or exposure to chemicals on the basis of strong suggestive evidence of harmful effects—even when that evidence could be challenged as incomplete or too weak to prove a causal relationship—have been characterized as “precautionary.”<sup>13</sup>

There are several opportunities for promoting on a wider scale this kind of action by companies that manufacture or use hazardous substances. In the context of sustainable development, voluntary frameworks for characterizing commitments made by companies and benchmarking progress include pledges and principles such as those generated by the Coalition on Environmentally Responsible Economies (CERES)<sup>14</sup> and structures for public reporting, such as the Global Reporting Initiative.<sup>15</sup> Similarly, companies can define best practices concerning research

on worker protection<sup>16</sup> and report progress in implementing an approach to chemical exposures consistent with the precautionary principle.<sup>17</sup>

None of these schemes directly address the issues of corporate use and misuse of science, but they could. One or more Coalition on Environmentally Responsible Economies principles could address the design, funding, and dissemination of research in the private sector. Under the Global Reporting Initiative, relevant information to report could include, for example, resources committed to pursuing cleaner production, policies and actions when the evidence on risk is uncertain, adverse effects' information and decisions made as a result. Global Reporting Initiative processes for deciding on reporting elements are well developed and would need to run their course, but they should include scholars with perspective on the inherent challenges and opportunities of conducting "clean science" with corporate funding, as well as scientists with direct experience in the use and misuse of science in public policy decisionmaking.

Ironically, the same people who label as "junk" the science used by plaintiffs to support toxic tort litigation or proposed regulations also criticize these voluntary mechanisms that encourage corporate responsibility. Steve Milloy, sponsor of the Web site junkscience.com, has established a new site, called Corporate Responsibility Watch, which states the following:

Businesses are increasingly under attack by the anti-business movement, i.e. social activists operating under the banners of Corporate Social Responsibility (CSR) and Socially Responsible Investing. These activists threaten

businesses, investor interests, jobs and the free enterprise system . . . distract[ing] corporate managements from their traditional responsibility of operating businesses in the long-term best interests of investors. CSR can harm a company's ability to conduct business based on sound economics, sound science, and traditional business goals and practices.<sup>18</sup>

Milloy gives a bad name to corporate leaders who see their pursuit of environmental, health, and social goals as integral to the economic success of their company. In addition to leading by example, as Samsung and Fujitsu have done, we encourage companies to take a stand against the kinds of tactics detailed in the four articles and employed by Milloy and his compatriots. Specifically, we urge them to condemn practices like ignoring the weight of the evidence where it is strong and instead critiquing and discrediting individual studies, one by one, or pursuing specious research questions and re-analyzing existing data in order to discredit science showing associations between exposures and effects. We urge them to pull their support for or publicly cancel membership in consortia that use junk-science rhetoric as a pretext for opposing regulatory action.

Ultimately, we believe a fundamental shift in corporate culture and practice is needed towards the proactive pursuit of design and production solutions that do not introduce hazardous materials into the air, water, and soil. McDonough and others describe a Next Industrial Revolution that measures progress by how many buildings have no smokestacks or dangerous effluents, interprets prosperity as accruing natural capital in productive ways, and defines productivity as rates of

people who are gainfully and meaningfully employed.<sup>19</sup> Firms in a widening array of sectors are applying these concepts to their operations, in most cases transforming both the goals of the company or a product line within it and the practices in place to achieve those goals.<sup>20</sup> These practices and vision take the public health paradigm discussed by Michaels and Monforton to another level; enhancement of health and environment are elevated as priority goals for the economic engines of our society. In this future, the feuds between those calling for and those opposing regulation lose their fuel. The Next Industrial Revolution, McDonough et al. contend, would "not require regulations whose purpose is to stop us from killing ourselves too quickly."

A shift in orientation of this magnitude would likely transform the relationship between industry, government, and the public, as well as change the nature of the debate about the quality of scientific evidence. Without entrenched and eternal battles between pro- and anti-regulatory forces, political pressure on science and scientists would diminish.

If such a shift is occurring, then it is happening slowly; the political forces necessary to bring about such a major transition have not yet coalesced. In the near term, strong regulations remain essential. In addition, implementing recommendations made by the authors of the articles in this supplement, along with our suggestions about the use of global mechanisms for promoting corporate accountability, would help curtail some of the most egregious tactics to discredit public health science. These include Wendy Wagner's

recommendations specific to the "good science laws," that is, developing a formal decisionmaking step to distinguish between challenges that are against the quality of the evidence versus against a policy position, charging challengers for the costs agencies incur in responding to them (if the challenge is ultimately denied) and encouraging scientific organizations to establish a balanced committee of scientists to investigate complaints against researchers and to defend innocent researchers. Michaels and Monforton's recommendations include that federal agencies adopt requirements for "research integrity" comparable to those used by biomedical journals in which parties that submit data from research they have sponsored must disclose if the investigators had the contractual right to publish their findings without the consent or influence of the sponsor. They suggest that the findings of post hoc analyses (and re-analyses) be labeled accordingly and be accorded less weight and significance than those of original research. In the judicial arena, McGarity urges that the courts "forcefully reject this invitation to play an overtly political role in transforming protective health, safety and environmental regulation to fit the regulated industries' views on the proper role for federal regulation in society."

More difficult but critical will be policy changes to align incentives and disincentives with the kind of vision McDonough and others espouse. It has been argued, for example, that the current regulatory framework creates incentives for manufacturing uncertainty by giving the government the burden of proving that a chemical is unsafe

before it can be regulated. This contrasts with a framework that requires a manufacturer to demonstrate that a substance or product is safe before it can be marketed (as is the case with pharmaceuticals).

Scientists have a role to play here, too; it is worth examining, as Kriebel et al. have suggested, whether the tools we use to draw conclusions about scientific evidence are appropriate for prevention-oriented public policy.<sup>21</sup> In addition to continuing to expose disingenuous attacks on science and regulation, we urge scientists—who have engaged in unprecedented numbers in recent debates about the use and misuse of science in public policy—to help channel the ingenuity of the private sector towards ecological, economic, and equitable systems of production. ■

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Polly J. Hoppin and Richard Clapp shared responsibility for researching and writing this commentary.

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is a network of investment funds and environmental and public interest organizations, is one such initiative. Over 70 companies have endorsed principles developed by CERES, including commitments to “reduce and make continual progress toward eliminating the release of any substance that may cause environmental damage to the air, water, or the earth or its inhabitants,” to “strive to minimize the environmental, health and safety risks to our employees and the communities in which we operate through safe technologies, facilities and operating procedures, and by being prepared for emergencies,” and to “inform in a timely manner everyone who may be affected by conditions caused by our company that might endanger health, safety or the environment. We will regularly seek advice and counsel through dialogue with persons in communities near our facilities. We will not take any action against employees for reporting dangerous incidents or conditions to management or to appropriate authorities.” Pressure from shareholder resolutions and initiatives by corporate leaders have resulted in significant commitments from corporations, particularly in the area of climate change. In April 2004, for example, ChevronTexaco became the first oil company to disclose its entire greenhouse gas footprint, including the emissions associated with the use of its end product (e.g., emissions from cars that consume its gasoline). The company has taken the fundamental step of assuming a cost for carbon (of \$5–\$20/ton) whenever it considers a new capital investment, and it is considering a major investment in renewable energy.

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