

Protecting Special Interests in the Name of “Good Science”

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WITHOUT FANFARE OR DEBATE, A MEMBER OF Congress places a rider on the omnibus appropriations bill enacted at the end of the Clinton Administration in late 2000.¹ A new 2-sentence law, now known as the Data Quality Act (DQA),² directs the administration’s Office of Management and Budget (OMB) to provide a potent mechanism for interested parties to change the way government agencies review science.³ The full impact of the act is as yet unknown, but it has already resulted in the significant delay of the release and use of valid scientific information. This new tool, to date used primarily by those who have reason to silence or politicize objective scientific research, should be cause for great concern and serious examination.

Focusing on Science as a Strategy to Subvert Policy

Unlike honest differences of scientific opinion, threats to science posed by vested interests—defined as those who for economic, ideological, political, or other reasons are committed to a predetermined outcome whatever the facts—are not new.^{4,5} As is now well understood and acknowledged, the tobacco industry waged war in the mid-20th century on the emerging evidence of its product’s harm. In the modern era, the tobacco industry has led the way in creating a strategy of subverting public policy by exploiting and creating scientific uncertainty rather than engaging head-on the political and economic aspects of regulatory action and policy-making. In a 1969 memo, Brown and Williamson⁶ discussed the strategy of creating scientific uncertainty around tobacco’s ill effects, coining the phrase: “Doubt is our product.” Three decades later, Philip Morris played a significant role in supporting the DQA as part of its strategy to block actions on environmental tobacco smoke.⁷

Tobacco and other industry interests—whether coal and oil industry interests opposed to climate change policy or asbestos industry interests fighting asbestos regulation—have learned that both the public and decision makers have a far greater appetite to forestall action based on a seeming scientific debate rather than acknowledge that the

science is well settled in the view of the scientific mainstream. In the last decade, these efforts framed this discussion by invoking the need to bolster “good science” to fight against “junk science”—the latter referring to the mainstream consensus with which they disagree.⁸ By so doing, legitimate domain for debate is shifted away from the political arena and attention is focused on the science rather than the political side of the crude but useful formula: science + politics = policy.

Creating uncertainty by undermining science and scientific processes is not new. Reflections during my tenure as director of the National Institute for Occupational Safety and Health (1994-2000) drew attention to the pattern of these efforts and a call for a more informed awareness and thoughtful response rather than the issue-by-issue, substance-by-substance reaction that was then and still remains so common.⁹ It is useful to recap the tactics identified as background for understanding why the situation has worsened both qualitatively and quantitatively.

Examples of tactics that might be grouped in the category of financial influence include influencing or delaying unwanted research results (eg, through legal arrangements that pressure individual investigators to withhold research findings); buying new studies with the goal of manipulating data to achieve predetermined results (eg, conducting a parallel study designed to favor a certain outcome); buying favorable opinions (eg, direct payment to experts for editorials, opinion articles, and reviews); and trying to reduce budgets of those agencies that helped create the science base from which guidelines and regulatory action would follow (eg, in the mid-1990s, eliminating the Office of Technology Assessment and attempting to do the same for the National Institute for Occupational Safety and Health and the Agency for Health Care and Policy Research [now the Agency for Healthcare Research and Quality]).

Another major tactic is to create delay in releasing or acting on scientific evidence. Examples include initiating litigation and finding mechanisms for adding new layers of “peer review” (eg, industry achieving through congress-

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sional appropriations riders in the late 1990s repeated reviews of the same body of ergonomic literature that had already documented strong evidence of links between workplace exposure and musculoskeletal disorders).⁹ Yet another major tactic is to target (if not harass) individual investigators (eg, making allegations of scientific misconduct) and institutions such as federal agencies.

A composite of many of these approaches is evidenced in the successful turning back in 2001 of a decade-long effort to provide a national workplace ergonomic standard. The initiation of the standard process began in 1990 in the first Bush Administration. Using a number of the aforementioned tactics to question the scientific evidence underlying the proposal, the standard was repeatedly stalled from 1995 until 1999 and finally promulgated late in the Clinton Administration. Ironically, when the new Bush Administration turned back the standard as one of its earliest acts, the main rationale was that it had been “rushed through” at the last minute by its predecessor.⁹

The DQA and the Politicization of Science

What is new in the attacks on science in the last 5 years is the success in securing and using new tools to magnify or even invent scientific uncertainty with the consequence of tilting even further the advantage to vested interests. These successes have been aided and amplified by the extraordinary shift within an executive branch playing an active hand in undermining its own science and scientists.^{8,10,11} The catalog of science “abuses” from the executive branch, as defined by the statement of the Union for Concerned Scientists that has been signed by thousands of scientists, including 48 Nobel laureates, 62 National Medal of Science recipients, and 127 members of the National Academies of Science, includes numerous detailed examples of suppressing and distorting research findings at federal agencies (eg, climate change research and abstinence-only education) and undermining the quality of the scientific review and advisory processes (eg, political litmus tests even for appointments to peer review National Institutes of Health study section review committees).¹⁰ Prior concerns about vested interests undermining science often called for the need for federal agencies to ward against these efforts—but the landscape is transformed when part of the damage appears to be systematically coming from within the executive branch itself.

The DQA is a perfect case in point. Added as a rider at the last moment by Rep Jo Ann Emerson (R-Mo) without prior hearings or debate, it directed the OMB to develop policies and procedures for federal agencies for “ensuring and maximizing the quality, objectivity, utility and integrity of information.”² The act allows individuals or interest groups to request correction of information disseminated by an agency, in essence providing a formal administrative process for challenging the quality of the science and the information an agency uses.

Proponents of the DQA advocate the need for such controls, arguing their usefulness not only in the regulatory process but also in preventing what they consider an effective federal agency tool around the regulatory process, so-called “regulation by information,” often through use of the Internet.¹² The OMB’s Office of Information and Regulatory Affairs published preliminary DQA guidelines in June 2001, drawing the majority of comments from the scientific and academic community that in general wanted to limit the scope of the act. This community raised questions and concerns about the burden of proof of the correction mechanisms, namely how the administrative mechanisms would be put into place to allow affected parties to seek and obtain correction of information disseminated by federal agencies, and about reproducibility of data (raising the specter of avoiding established scientific procedures and creating new high bars for admissibility of scientific findings), costs, and enforcement.¹³

The Association of American Medical Colleges was among the many organizations raising these concerns, stating it was “deeply concerned that the proposed guidelines would impede communication of valid research findings from scientific and health research and, contrary to federal intent, actually diminish the quality, objectivity, utility and integrity of federal information by imposing inappropriate standards and layers of review that supersede time-honored processes for scientific review and validation.”¹⁴ On January 3, 2002, the OMB published its final guidelines, summarizing comments received and providing definitions and mechanisms to ensure that applicable federal agencies implement data quality standards and public correction mechanisms for the information they disseminate.¹⁵

Applications of the DQA

On the face of it, ensuring data quality and objectivity seems reasonable. However, in practice, the law as interpreted by political appointees in an administration open to abetting the goal of thwarting public policy actions aimed at protecting the environment and the public’s health has had significant although still not fully realized negative consequences. It can be argued that the existing regulatory process and oversight of agency performance provide many avenues for comment and redress of incorrect or disputed information.⁹

Although the administration has declined to enumerate the source of challenges under the act,² a *Washington Post* analysis of government records indicated that in the first 20 months since implementation of the act, it has been used predominantly by industry.¹⁶ Among 39 petitions (excluding those correcting minor typographical or factual errors), 32 were filed by regulated industries, business or trade organizations, or their lobbyists.¹⁶ Among the 39, 5 resulted in at least some of the changes requested (all of these filed by industry interests), 5 were denied, 5 were diverted to other forms of redress, and 24 were pending.

A Web-based review demonstrated that, since this mid-2004 investigative analysis, in just 2 federal agencies alone (Health and Human Services [HHS] and the Environmental Protection Agency [EPA]) an additional 28 petitions (11 to HHS and 17 to the EPA) have been submitted, again mostly from industry and many still active (eg, a reading of the docket indicates as active 6 of 11 HHS cases and a number of seemingly final responses from the EPA under appeal.)^{17,18}

Petitions to date have included the American Chemistry Council's challenge to data used by the Consumer Product Safety Commission in its attempt to ban wood treated with heavy metals and arsenic in playground equipment. Sugar interests have challenged the Agriculture Department and the US Food and Drug Administration over dietary recommendations curtailing sugar intake, and the Salt Institute and the US Chamber of Commerce challenged the data on which the National Institutes of Health recommended reduced salt intake.¹⁹ Requests for relatively minor corrections have been numerous, including the US Chamber of Commerce's unsuccessful attempt to alter minutes of a meeting of the Environmental Protection Scientific Advisory Board.²

One of the first challenges was by the Center for Regulatory Effectiveness (a strong proponent of the DQA and often credited with its original authorship)⁸ and the Kansas Corn Growers Association over the quality of the science used by the EPA in its risk assessment of atrazine.²⁰ Atrazine, a widely used herbicide, has been repeatedly demonstrated to be a potent endocrine disruptor, causing among other changes gonadal abnormalities in frogs.^{21,22} For these reasons, atrazine will be phased out of use by 2007 in the European Union. The petition under the act cited a number of aspects of data quality, including reproducibility, relying on its own industry-funded studies (faulted by mainstream scientific opinion and the EPA itself)—studies that had shown results different from those of independent scientists, whose work had appeared in well-respected peer-reviewed journals.

Subsequently, 2 additional petitions have been filed by the same challengers, including questioning the data quality underlying the review by the National Toxicology Program on atrazine's potential carcinogenicity in humans.²³ Atrazine is already classified as an established animal carcinogen and hence a possible human carcinogen by the International Agency for Research on Cancer. To date, despite the mounting scientific evidence, the EPA has yet to restrict atrazine. The National Toxicology Program's review, which serves the role of risk characterization only (ie, a nonregulatory information process, already widely open to review and comment, that describes risk without judgment of cost and benefit of use), is still pending. In sum, for this substance alone, 3 challenges to 2 agencies resulted in significant delay and possible avoidance of regulation, not to mention withholding of important and valid scientific information from the public.

Implications of the DQA

Over the years, vested interests have had many tools—largely derived from economic and, in turn political, clout—to undermine evidence-based public policy. Mechanisms for administrative review of governmental regulatory and other actions, and challenge to underlying scientific assumptions, were quite extensive before the DQA. The act does, however, make it easier for such challenges, and importantly provides a mechanism for challenging data and information far earlier in the continuum of knowledge to action.

One clear intended consequence is to delay the already lengthy regulatory process. It poses the risk as well of inhibiting agencies from acting on emerging science. The DQA is also an unfunded mandate, as agencies with no added resources are required to undertake new rules and procedures and respond to requests for corrective actions, often at significant opportunity not to mention economic costs. At this time, it is still undetermined whether the act allows judicial review, for example, of an agency's response to a data quality challenge.

In a victory for opponents of the DQA, a March 2006 decision by the US Court of Appeals for the Fourth Circuit upheld a lower court's ruling denying judicial reviewability of a data quality decision stemming from a challenge by the Salt Institute and the US Chamber of Commerce to the National Heart, Lung, and Blood Institute. Further judicial tests of the reviewability under DQA are anticipated. If data quality decisions are determined to be subject to judicial review, yet another avenue will be available for using litigation as a major delaying tactic to forestall public policy.

The act also has been used as a subtext for further scientific manipulation within government, for example, the OMB's recent efforts to initiate new peer review guidelines for federal agencies (among other things, it would have precluded those federally funded scientists who are often the most expert but not disallowed those who are solely industry funded).²⁴ Although this venture by the OMB set off a firestorm among the scientific and academic community that resulted in significant revision, it was the DQA that was cited as the inferred basis for the OMB venturing so far afield.²⁵

In summary, although much more needs to be learned about the reach and impact of the DQA, it is already clear that the act provides an additional powerful weapon in the current arsenal by which vested interests foster scientific uncertainty as a socially acceptable means to delay or block actions intended to protect our environment and health. Perhaps more worrisome, and as yet unmeasured, is the degree to which federal agencies, under the burden of the new law and wary of its use, will simply self-censor information that, although of the highest quality, is likely to come under challenge by those who perceive they will suffer from its dissemination. All this was achieved by one member of

Congress tucking in a few lines of text in the midnight hour of a large appropriations bill. For that alone there should be great concern.

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