

Guest Perspective

Data Quality Or Scientific Censorship?

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Over the past few years a number of regulatory efforts, most notably the Data Quality Act (DQA), have been adopted with the stated purpose of improving the quality of agency science. Despite reservations from the scientific community regarding these developments, and despite the absence of a documented problem with the quality of academic and government research used in regulation, these “sound science” reforms are multiplying and dividing, creating offspring that look quite different from what the reformers originally promised.

In this commentary, we argue that rather than being used to improve the quality of regulatory science, the “sound science” reforms are being used in an attempt to censor government or other public research that threatens powerful economic interests. This commentary begins with an analysis of the most far-reaching example of this campaign -- the effort by the Competitive Enterprise Institute (CEI) to “cease dissemination of the National Assessment on Climate Change.” We then place CEI's suit in the larger context of the Data Quality Act and review the Act's track record during its first, formative year. We conclude with brief accounts of other recent developments that similarly threaten to censor or politicize the review of scientific research.

The CEI Lawsuit

CEI's Data Quality Act suit began as a series of lengthy, but run-of-the mill Data Quality Act petitions. In March 2003, CEI petitioned several agencies to withdraw two climate change models used in the National Assessment because CEI maintained they were not reliable and had not been adequately peer reviewed. Although we leave CEI's substantive complaints to the many scientists familiar with these models, it is worth noting that the National Academy of Sciences identifies the two models that CEI seeks to censor as “well regarded” in its recent report. See National Academy of Sciences, National Research Council, *Climate Change Science: An Analysis of Some Key Questions* 18-22 (2001). It is also worth noting that both models have been extensively peer reviewed. Perhaps because of these and other features of the models, the agencies ultimately denied the CEI petitions and administrative appeals.

In August 2003, apparently frustrated by its failure to convince the Bush Administration to censor the climate change models, CEI petitioned a district court judge to rule that the two climate change models and the National Assessment were not reliable and to order their removal from government websites and publicly available databases. The suit presents an interesting new twist to “sound science” by insinuating that federal judges, rather than the scientific community or expert agencies, should be the final authority in determining whether two internationally used climate change models are “scientifically reliable.” We doubt the judiciary will welcome this new role as arbiter of the scientific quality of disseminated information, even if judges conclude that they have the scientific competence to decide these disputes.

Regardless of the merits, the court's jurisdiction over CEI's case is doubtful. First, the Data Quality Act does not provide a means of seeking judicial review, and the Administrative Procedure Act (APA) prohibits courts from hearing challenges to agency decisions when Congress has indicated there is to be no judicial review. Congress's failure to define any of the key terms in the Data Quality Act is a strong indication that Congress did not intend for there to be judicial review of an agency's rejection of a Data Quality complaint. The requirements that are explicit in the rider further support this interpretation. Specifically, the DQA requires the White House Office of Management & Budget (OMB) to draft government-wide guidelines that are then used to prepare agency-specific DQA guidelines. It also

requires agencies to “report periodically to the Director” concerning “the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency” and concerning “how such complaints were handled by the agency.” In other words, Congress envisioned that OMB would establish standards for agency guidelines and intended OMB to police agency adherence to those guidelines through the report-back provision. A court could use the definitions established by OMB to effectuate judicial review, but to do so would ignore that Congress failed entirely to define these terms, a strong signal that it did not contemplate that the rider would create a private right of action. Moreover, the fact that Congress assigned OMB the responsibility for monitoring agency compliance with the legislation supports the conclusion that no judicial review was intended.

Second, it is not at all clear that CEI has standing to sue. In order to have standing, a litigant must demonstrate that the agency's conduct has caused it an injury, and that it is likely that the injury will be redressed by a favorable decision. CEI is claiming that EPA's failure to censor the climate change models have harmed its members, and that removing the study from public view will remedy this harm. The only harm to the corporations that fund CEI is the possibility that people might act on the basis of the National Assessment on Climate Change in ways that are politically or financially disadvantageous to the corporations. The Supreme Court has long recognized “economic harm” as an injury that satisfied the “injury-in-fact” requirement, but a plaintiff must also establish that its injury is “actual or imminent, not 'conjectural' or 'hypothetical.’” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). CEI or a corporation may seek standing on the grounds that the release of such information is likely to lead to greater regulation, but that claim seems “conjectural or hypothetical,” rather than “actual or imminent” as required by current standing doctrine. As any observer of the regulatory process knows, predicting whether Congress or an agency will act is a difficult feat. Predicting that Congress or an agency will act in a manner that leads to economic injury to a particular company would seem even more daunting. Nevertheless, the Supreme Court has sometimes allowed lawsuits to go forward where the proof of harm was conjectural, despite its apparent prohibition of such suits. In any event, the DQA would only prohibit the dissemination, not the actual use, of these publicly available models by EPA -- so the causal chain from the relief to the result is even more tenuous.

It is also worth noting that there is no legal authority available under the DQA to require CEI to reimburse the agencies' or Department of Justice's costs in responding to their petitions, even if CEI's petition is ultimately found to be frivolous. As a result, taxpayers will shoulder the governments' legal expenses in processing these complaints.

The Data Quality Act

The CEI suit is only one recent development among a growing list of petitions that have been filed since October 2002, when implementation of the DQA first took effect. The act began its public life as an industry-drafted paragraph tucked into an appropriations rider. It was passed without committee hearings, floor debate, or legislative history. Together with the OMB's implementing guidelines, the Act provides interested parties with a formal process for seeking the correction of information that they believe is unreliable, including a formal appeals process when agencies deny requests for correction. There is no limit to the number or size of the petitions, and there are no penalties or other costs levied against entities that file petitions that are without merit.

Under this law, industry has a ready-made vehicle for challenging any and all research, information, and even raw data that suggest their products or activities cause adverse effects. By contrast, most industry research used in regulation is exempted through OMB's exclusions for trade secrets, adjudications (permit or license disputes), and public filings, despite empirical evidence demonstrating that industry-sponsored research is afflicted with more bias and inaccuracies than federally funded research. See Sheldon Krinsky, *Science In The Private Interest: Has The Lure Of Profits Corrupted The Virtue Of Biomedical Research?* Chapter 9 (2003) (describing the “funding effect”).

In keeping with the one-directional focus of its original sponsors, the Act has been used by industry to argue for the suppression and censorship of federally funded research used to support government decision-making. Most DQA petitions filed to date implicitly argue the burden is on the agency to first produce, and then to defend, its documentation of harms to the public or the environment being addressed by the regulation, regardless of the instructions in the authorizing statute. The Act also places no meaningful limits on what constitutes “information”

subject to challenge, and a number of industry petitions exploit this ambiguity by taking issue with the government's risk-averse assumptions in models predicting harmful effects (i.e., health risks from exposure to barium). To the extent that an administration is sympathetic to industry's effort to roll back the protective assumptions in environmental and health regulation, it seems likely that political issues will be decided in a subterranean way, under a charade of "data quality" adjustments.

Another recent Data Quality Act petition exemplifies the counterproductive contributions of the DQA to "sound" regulatory science. In the fall of 2002, the Center for Regulatory Effectiveness (CRE) -- an industry-backed anti-regulatory group -- and the manufacturer and agricultural users of an herbicide, Atrazine, filed a petition seeking to censor a recent series of studies done on the hormonal effects of Atrazine on frogs. These petitioners argued that the science acceptable for regulation must be conducted under a limited number of agency-approved protocols. This means, according to petitioners, that cutting-edge research discovering significant adverse effects on frogs exposed to low levels of the herbicide (the male frogs develop female reproductive organs) must be excluded from the agency's assessment of the herbicide's safety. The petitioners recommended the studies be suppressed until EPA promulgates a single, uniform testing protocol for endocrine effects -- a process that might take decades due to industry opposition.

Recent developments further suggest that those who are adversely affected by regulation will move "upstream" with DQA challenges by threatening not only researchers, but their academic departments and universities with stigmatizing DQA complaints and then use those complaints to argue that federal funding should be curtailed. In August, CRE sent letters to the American Association of University Professors (AAUP) and a number of universities warning them that CRE had become aware of academic research that was afflicted with "significant omissions, inaccuracies, and manifest biases" and suggesting that the universities update their scientific freedom and responsibility policies to comply with federal data quality standards. A CRE source suggested that DQA challenges against research will ultimately be communicated to the federal funding sources in an effort to persuade them to cut off funding.

Other Developments

Although the petition activity under the Data Quality Act, including the CEI lawsuit, presents the most immediate examples of efforts to censor publicly funded scientific research, there are other developments that reinforce this trajectory of regulated actors' efforts to withdraw unflattering research from public view. They are briefly described below.

Censoring Public Comment

Exercising its rights under the APA and the US Constitution, the Natural Resources Defense Council (NRDC) recently filed public comments on EPA's proposed biosolid's rule. The CRE in spring 2003 submitted a formal "threat of a petition" in an effort to censor NRDC's comments. CRE argued in its letter that "[m]any of NRDC's arguments are based on asserted [sic] need to inject policy bias into the risk assessment, which would be a violation of Data Quality requirements." CRE's view of risk assessment as an unbiased, scientific exercise capable of being validated is not only embarrassingly at odds with long-established principles of risk assessment, but it likely reflects CRE's true hidden agenda, namely to insist on scientific support for all default options in risk assessment, thereby bringing protective regulations to a halt.

OMB Peer Review Guidelines

Over the past two decades, many have expressed concern that peer review conducted by the Executive Branch can be corrupted by politics. Working in what appears to be complete obliviousness to these concerns, OMB recently proposed peer review guidelines that would require such reviews for all "significant" regulatory information. Academic research must be subject to this federally-created peer review requirement if it is used by or disseminated by an agency. Only research that has been published in peer review journals may be exempt from being subject to these

centralized panels.

Aside from the questionable authority to direct all agencies to mandate peer review for significant rulemakings (Congress failed to pass a bill mandating similar peer review requirements in previous years), an added step of requiring peer review for all “significant regulatory information” will delay and potentially obstruct the public's access to this information and could, under the “rubric” of peer review, lead to exclusion of the research from public decision-making and potentially from the public domain. The proposed guidelines are also badly flawed in other ways. First, they adopt a skewed approach to determining conflicts, weighing heavily against consultants retained by federal agencies and in favor of consultants with industry. Second, they require peer review of all significant information instead of limiting this time-consuming process to situations in which it is most likely to improve the information being reviewed, such as complex or novel problems, or where peer review would add authority, such as highly controversial situations. Finally, the proposed guidelines permit agencies to conduct peer review outside of the context of the Federal Advisory Committee Act, thereby avoiding the accountability process Congress established for how the federal government obtains outside advice concerning sensitive and controversial matters.

EPA's Assessment Factors

Beyond establishing these peer review panels, EPA officials and staff expect to preside independently over the quality of third-party research using their own “Assessment Factors” for scientific quality. Despite reservations about the wisdom and need for these “assessment factors” expressed by panelists at a National Academy of Sciences workshop, the EPA promulgated its assessment factors guidelines in July. Under the guidelines, there appears to be no means for adversely affected scientists to appeal EPA determinations that exclude or discredit their research, and it is not even clear that the scientists will or can be involved in EPA's decision-making regarding judgments about the quality of that research. It is too early to tell, but this could provide yet another avenue for EPA to censor science from its deliberations, and these determinations ultimately could be made in ways that are not easily available to attentive members of the public. There is also no assurance that the decisions will be limited to “scientific research” exclusively, as opposed to science-policy matters

And the Beat Goes On.

As Risk Policy Report's coverage reveals, there are continuing developments in this effort to improve the quality of regulatory science through the questionable use of peer review and censorship. The limited space available to us here does not permit discussion of other events, such as the Cannon Caucus, which threatens to impose still more peer review requirements on agencies (see related story, p20); the recent DQA petition filed by a law firm against an 1986 EPA guidance advising auto mechanics regarding asbestos exposure (the firm seeks to censor the guidance so the guidance will also be excluded in tort litigation it is defending); and CRE's petition against the Agriculture Department for relying on a World Health Organization Study in preparing its new dietary guidelines. Nevertheless, these and undoubtedly other developments continue to raise questions about whether the Data Quality Act will ever make any positive contribution to either “good science” or “good government.”

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