Recent Developments that Threaten the Freedom and Integrity of Academic Research
Center for Progressive Regulation

Censorship of Science: The Competitive Enterprise Institute Suit and Other Data Quality Act Petitions

- The Data Quality Act allows interested parties to petition agencies to "correct" information they "disseminate;" yet rather than seek correction, most petitioners seek the redaction of information from agency websites and publicly available databases.
- In February, the Competitive Enterprise Institute's (CEI) petitioned several agencies to "cease dissemination of the National Assessment on Climate Change."[1] The agencies denied the petition and denied the subsequent appeal. CEI has filed the first case seeking judicial review of a denied Data Quality Act petition. CEI requests the court to rule that the two climate change models and the National Assessment are not reliable and to order the removal of the models and the National Assessment from government websites and publicly available databases.[2]
- The National Academy of Sciences has characterized the two climate change models under attack as "well-regarded."[3] The two models have also been peer-reviewed by over 300 scientific and technical experts, subjected to a 60-day public comment period, and assembled under the supervision of a panel of experts convened by the President's Committee of Advisors on Science and Technology.
- The CEI action is only one of several recent efforts to censor information available to the public. For example, the Center for Regulatory Effectiveness (CRE), an industry funded nonprofit, filed a petition to forbid EPA from disseminating research by Professor Hayes, University of California at Berkley, on the endocrine effects of atrazine on frogs.[4]

Threats to Universities: The Center for Regulatory Effectiveness Letters

- There is growing concern that those who are adversely affected by regulation might move "upstream" with Data Quality challenges, threatening not only researchers, but their academic departments and universities with stigmatizing DQA complaints and then using 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 the universities that they have become aware of academic research that is afflicted with "significant omissions, inaccuracies, and manifest biases" and that the universities should update their policies to comply with federal data quality standards.[5]
- A CRE source suggested that Data Quality Act challenges against research will ultimately be communicated to the federal funding source in an effort to cut off funding.[6]
- Since there are no sanctions for filing frivolous Data Quality petitions, some groups could use this law to bully and harass researchers by publicizing the fact that the reliability of their research is under attack.

Politicized Peer Review: OMB Peer Review Guidelines and EPA's Assessment Factors

- Over the past two decades, there has been concern that peer review conducted by the Executive Branch runs the risk of being corrupted by politics.[7]
- OMB has recently proposed peer review guidelines required 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.[8]

- 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 1995[9]), the conflict guidelines proposed by OMB depart from those adopted by scientific journals insofar as they identify reviewers as presumptively biased if they have expressed specific views on the issue or worked with the agency in the past. By contrast, reviewers who work with regulated parties are perceived as potentially conflicted only if they have a "financial interest in the matter at issue," which could be read to require stock options or some other direct financial stake. Moreover, OMB provides no specifications for how these financial conflicts are to be disclosed.[10]
- Beyond establishing peer preview panels, EPA officials and staff also expect to preside independently over the quality of third-party research using their own "assessment factors" for scientific quality.[11] 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.[12] Under the guidelines, there appears to be no means for adversely affected scientists to appeal EPA determinations that challenge 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. The internal process for EPA's review of the quality of third-party research is similarly opaque.

A Double Standard for Privately Sponsored Research

- Most private research is exempted from the Data Quality Act.[13] OMB, for example, has exempted industry-sponsored research when corporations claim that it is propriety information. As a result, neither agencies nor independent observers, can subject the research to the same level of scrutiny that corporations seek for information that is produced by universities or nonprofit organizations. Academic research funded by the federal government is the prime target of the Act, despite general evidence that shows that sponsored research is afflicted with considerably more bias and inaccuracies.[14]
- Private research will rarely be subject to the peer review processes established by OMB because it is usually produced only when mandated in narrow regulatory circumstances and hence rarely considered "significant regulatory information."[15]
- There is no federal oversight of the quality or objectivity of privately conducted science, in stark contrast to scientific misconduct, objectivity, and ethics requirements for federally funded research.

Continuing Concerns about Adverse Effects of the Data Quality Act

- The Data Quality Act is not a legitimate law.
  The Data Quality Act was passed as a rider to an appropriations bill, without legislative history, debate, or even congressional awareness.[16] It was drafted by a consultant to industry, Jim Tozzi.[17]
- Harassment/critique of researchers remains a continuing concern.
  Prominent scientists have expressed concern that a related rider, the Data Access Act, could be used to harass scientists whose discoveries are unpopular with industry.[18] The broadscale attacks on Dr. Hayes' research on atrazine, mentioned earlier, may bear out these concerns under the Data Quality Act as well.[19]
- Blurring of science and policy in the name of science occurs in many DQA petitions.
  Many of the petitions target agency policy decisions, but attack them as erroneous technical judgments.[20] Not only does this make the policy debates less transparent, but the challenger avoids the operative statutory mandate -- often a protective mandate -- by arguing simply that the agency used wrong science.

Endnotes

---

[1] *See, e.g.*, Competitive Enterprise Institute, Petitions to Cease Dissemination of the National Assessment on Climate Change (Feb. 20, 2003), *all available at* http://www.epa.gov/oeiinter/qualityguidelines/af_req_correction_sub.htm.

[2] *See, e.g.*, Andrew C. Revkin, *Suit Challenges Climate Change Report by U.S.*, NEW YORK TIMES, Aug. 7, 2003.

[3] National Academy of Sciences, National Research Council, *Climate Change Science: An Analysis of Some Key Questions* (2001), available at http://books.nap.edu/html/climatechange.

[4] Kansas Corn Growers Association, the Triazine Network, and the Center for Regulatory Effectiveness, Request for Correction of Information Contained in the Atrazine Environmental Risk Assessment, Docket No. OPP – 34237A (November 25, 2002). Specifically, this group of industrial actors argues:

> As soon as possible, EPA should correct its *Environmental Risk Assessment* at pages 11, 90-94, to state that there is no reliable evidence that atrazine causes "endocrine effects" in the environment [and thus exclude the Hayes study from regulatory consideration]. EPA's corrected *Environmental Risk Assessment* should state that there can be no reliable, accurate or useful information regarding atrazine's endocrine effects until and unless there are test methods for those effects that have been properly validated.

Kansas Corn Growers' Petition, at 9, *available at* http://www.thecre.com/pdf/petition/atrazine2B.pdf.

[5] Letter from Jim Tozzi, Center for Regulatory Effectiveness, to American Association of University Professors (identical letter sent to universities), August 6, 2003, at 3.

[6] *Industry Data Quality Warning to Universities Draws Sharp Response*, INSIDEEPA, August 22, 2003. That article reports:

> A CRE source says the letter is meant to give universities a chance to be proactive about data quality requirements. "If they get on top now, it could save them a lot of problems in the future," the source says. "If they don't . . . we will be more direct in our concerns." The source says the next step would be to inform a federal agency that material a university submitted cannot be disseminated. "If the agency agrees, then the question is, why give money to universities if they can't do anything with their research funds? If we really start to invoke this, millions of federal government research dollars couldn't be used. . . We've been nice up to now. Rounds two and three, we'll be more direct."

[7] Sheldon Krimsky, Science in the Private Interest, chpt. 6 (2003).

[8] OMB, Peer Review and Information Quality, § 2.

[9] H.R. 9 (1995).

[10] Under OMB Guidelines, a reviewer is suspected of having a conflict of interest if he/she: "(i) has any financial interests in the matter at issue; (ii) has, in recent years, advocated a position on the *specific* matter at issue; (iii) is currently receiving or seeking substantial funding from the agency through a contract or research grant (either directly or indirectly through another entity, such as a university); or (iv) has conducted multiple peer reviews for the same agency in recent years, or has conducted a peer review for the same agency on the same *specific* matter in recent years."[10] The panels may "often" be charged with issuing reports as a group, rather than individually, thus lessening individual responsibilities in providing rigorous reviews. OMB, Peer Review and Information quality, §2.

[11] EPA, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, 68 Fed. Reg. 39086 (2003). The guidelines are published electronically (and not in the Federal Register) at http://www.epa.gov/oei/qualityguidelines/af-- home.htm, http://www.epa.gov/osp/spc/2polprog.htm.

[12] According to EPA, "[t]his Assessment Factors document is intended to inform information-generating scientists about quality issues that should appropriately be taken into consideration at the time information is generated. It is also an additional resource for Agency staff as they evaluate the quality and relevance of information, regardless of source." *Id.* at 1.

[13] In the Data Quality Act guidelines, the OMB exempts from the reach of the Data Quality Act all information claimed as trade secret protected, an exemption that effectively excludes a great deal of industry-produced health and safety information. *See* U.S. OMB, Guidelines for Ensuring and Maximizing

the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8452, 8460 §V.3.b.ii.B.i. (2002); *supra* Part III.B.1 (discussing how large this category of CBI information is). Research prepared by regulated actors and submitted as "public filings" (which arguably could include data required by the Toxic Research Inventory under EPCRA or routine monitoring data) or used in "adjudications" (which could include information required in applications for licenses and permits under the environmental laws) are also exempt from the Act under OMB's Guidelines. *Id*. §V.8. Depending on how EPA interprets these terms, OMB's exceptions may exempt from the Data Quality Act a rather large category of industry-prepared information.

[14] Sheldon Krimsky, Science in the Private Interest, chpt. 9 (2003).

[15] Much private research submitted for health and safety research claims confidential business information privilege and remains classified until a party requests that information under FOIA (and might remain classified if the agency decides classification is appropriate). More than 90% of the applications submitted to EPA to market new toxic substances contain information claimed as confidential by industry. Federal studies have found that many of these claims are not justified, however. GAO, Toxic substances control act: legislative changes could make the act more effective. Report No: GAO/RCED-94-103, at 0:4.3 (1994); EPA Office of Pollution Prevention and Toxics. Final Action Plan: TSCA Confidential Business Information Reform (June 20, 1994); Sheila A. Ferguson et al. Influence of CBI Requirements on TSCA Implementation. Hampshire Research Associates, Inc. (March 1992).

[16] *See, e.g*., NAS, DATA QUALITY TRANSCRIPT, Day 1, at 32 (April 21, 2002) (available at http://www7.nationalacademies.org/stl/4-21-02_Transcript.doc) (Alan Morrison stating that the Data Quality Act "came up as part of a very large appropriations act that most people didn't even know contained this particular piece of legislation in it").

[17] *See, e.g*., James T. O'Reilly, *The 411 on 515: How OIRA's Expanded Information Roles in 20 02 Will Impact Rule-making and Agency Publicity Actions,* 54 ADMIN. L. REV. 835, 840 n.20 (2002) ("Discussion at the American Bar Association Fall Administrative Law Conference dinner . . . honoring past directors of the OIRA, suggested that Jim Tozzi, former OIRA director, had been the principal drafter of the 515 language").

[18] *See, e.g.,* NATIONAL RESEARCH COUNCIL, ACCESS TO RESEARCH DATA IN THE 21ST CENTURY: AN ONGOING DIALOGUE AMONG INTERESTED PARTIES: REPORT OF A WORKSHOP 2 (2002) (reporting that scientists oppose the Data Access Amendment "on the grounds that it would invite intellectual property searches by industry and scientific competitors, jeopardize the privacy of research subjects, decrease the willingness of research subjects to participate in studies, expose researches to deliberate harassment, and increase costs and paperwork"); *id*. at 14 (reporting on the views of invited speaker, Bruce Alberts, on the Data Access Amendments from the perspective of a bench scientist: Dr. Alberts expressed concern that "there is a danger that the [Data Access] [A]mendment could be used to harass scientists whose work is found objectionable by anyone, for any reason");

[19] In the Data Quality Act petition filed to exclude Hayes' atrazine studies from EPA's atrazine risk assessment, industry petitioners complained that "Dr. Hayes has killed and continues to kill thousands of frogs in unvalidated tests that have no proven value." Kansas Corn Growers petition, *supra* note 131, at p.8. Hayes' scientific credibility is similarly chided in a number of related critiques. See, e.g., Avery, A. Frog Sex-Change Claims Flawed, Center for Global Food Issues, October 30, 2002, Center for Global Food Issues *available at* http://www.cgfi.org/materials/articles/2002/oct_30_02.htm (last visited March 18, 2003); Triazine Network, The Significance of the Hayes et al. (2001) Milloy, S. Freaky-Frog Fraud, Fox News Channel, Nov. 8, 2002, *available at* http://www.foxnews.com/story/0,2933,69497,00.html (last visited March 18, 2003); Milloy, S. Frog Study Leaps to Conclusions, Fox News Channel, April 19, 2002, *available at* http://www.foxnews.com/story/0,2933,50669,00.html (last visited March 18, 2003).

[20] *See, e.g*., Kansas Corn Growers Association, the Triazine Network, and the Center for Regulatory Effectiveness, Request for Correction of Information Contained in the Atrazine Environmental Risk Assessment. Docket No. OPP–34237A. (Nov. 25, 2002); Chemical Products Division, Request for Correction of the IRIS Barium substance file (Oct. 29, 2002); Letter from Paul Gilman, Assistant Administrator, EPA to Jerry Cook, Chemical Products Division (Jan. 30, 2003); Competitive Enterprise Institute, Petitions to Cease Dissemination of the National Assessment on Climate Change (Feb. 20, 2003), *all available at* http://www.epa.gov/oeiinter/qualityguidelines/af_req_correction_sub.htm.