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Importing *Daubert* to Administrative Agencies Through the Information Quality Act

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IMPORTING *DAUBERT* TO ADMINISTRATIVE AGENCIES THROUGH THE INFORMATION QUALITY ACT

*Wendy E. Wagner**

INTRODUCTION

Exasperated at the inability of the common law to adequately protect the public health and environment from toxic hazards, Congress passed a series of vigorous environmental laws in the 1970s to regulate activities involving dangerous products and wastes.[1] The common law had proven woefully ineffective to redress these harms since it required proof of harm and convincing evidence of causation before granting recovery. Stringent common law causation requirements thus effectively exculpated most defendants who produced or disposed of toxics due to substantial scientific unknowns regarding the long-term effects of their

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[1] *See, e.g.*, ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY 72 (3d ed. 2000) (arguing that the "inadequacies of the common law" help explain the "rapid growth of regulatory legislation"); SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH 15 (2003).

> When Congress adopted risk regulation, it rejected the common law paradigm in favor of a regulatory system which would reduce technological risks before they caused significant harm to individuals and the environment. Congress accomplished this goal by designing statutory triggers that permit the government to act on the basis of anticipated harm.

Id.

activities.[2] Congress appreciated these inherent limitations in the common law and developed a broad regulatory system that regulates potential hazards without requiring definitive evidence of harm as a prerequisite for regulatory control.[3]

Because the evidentiary demands of the common law and regulation are so different, regulators and the courts historically have had little in common when it comes to assessing scientific evidence. The fact that courts developed a new, vigorous test called "*Daubert*"[4] to scrutinize scientific evidence in order to determine whether it is "reliable" before proceeding to trial was essentially irrelevant to regulators' assessments of risks.[5] Regulators generally err on the side of protecting the public health and environment when crafting protective regulatory standards and do not require vigorous gate-keeping of scientific evidence in order to avoid juror confusion or the excessive transaction costs associated with trials.[6]

With the passage of the Information (or Data) Quality Act (IQA) in 2001,[7] however, the foundations of these heretofore separate institutional worlds are beginning to collide. The IQA imposes an evidentiary screening process on regulatory agencies

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[2] *See generally* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 790-96 (1997) (summarizing common law standards).

[3] *See, e.g.*, SHAPIRO & GLICKSMAN, *supra* note 1, at ch. 3; *see also* Wendy E. Wagner, *The 'Bad Science' Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation*, 66 LAW & CONTEMP. PROBS. 63, 85-87 (2003) (listing the environmental statutes that require only limited evidence of harm as a precondition to regulation).

[4] *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993).

[5] Not surprisingly, a review of the entire *Federal Register* reveals that the *Daubert* case was referenced only four times by a federal agency and never in a way that was intended to alter or supplement the agency's independent assessment of technical information. Search on Westlaw for term "Daubert" in *Federal Register* database, November 5, 2003, with date restriction "aft 1/1993" (the date *Daubert* was published).

[6] *See infra* Part I.A (discussing EPA's congressional directive to err on the side of protection in their regulations).

[7] Treasury and General Government Appropriations Act for Fiscal Year 2001 § 515, Pub. L. No. 106-554, 144 Stat. 2763 (2001).

that looks very much like the courts' *Daubert* test since it equips regulatory participants with the opportunity to file complaints for "correction" of information disseminated by agencies that they believe is unreliable.[8] Just as *Daubert* motions seek to exclude scientific testimony that cannot be validated, IQA complaints generally seek to exclude "unreliable" research from public dissemination or agency use.[9] The IQA thus provides a rather dramatic signal of growing institutional overlap in the processes governing the use of scientific information for regulation and common law adjudication.[10]

In this commentary, I discuss this new convergence heralded by the *Daubert*-like test imposed on administrative agencies, particularly the Environmental Protection Agency, and consider its significance. While some celebrate an added check on regulatory decision-making as a positive development,[11] this essay approaches the IQA more skeptically given its thin justification and suspicious, industry-based origins.[12] Part I provides background on the agencies' use of scientific information and the changes to these practices introduced by the IQA. Part II explores whether some of the most problematic features of *Daubert* are likely to be replicated, and even amplified, in the administrative agencies as they implement the IQA. Part III closes with two reforms to the IQA and *Daubert* that promise to reduce at least some of their worst adverse effects, while maximizing the benefits of imposing an added screening test to sort the "good" science from the "bad."

I. BACKGROUND ON THE INFORMATION QUALITY ACT

Agencies have considerable capacity to consider a range of scientific research that has bearing on public health and environmental protection. Most importantly, the agencies'

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[8] *Id.*

[9] *See infra* notes 31-33 and accompanying text (discussing IQA petitions).

[10] *See, e.g.*, *infra* Part II.A.4.

[11] *See, e.g.*, Frederick R. Anderson, *Data Quality Act*, NAT'L L.J., Oct. 14, 2002, at B9.

[12] *See* Part I.B.

authorizing statutes generally direct them to bypass heavy burdens of proof in promulgating regulations, thus allowing them to consider all available science. By contrast, common law judges must ensure the reliability of proffered scientific evidence early in the litigation in order to preserve precious judicial and litigant resources.[13] Also in contrast to the courts, agencies are staffed with hundreds of experts and can press still more into the service of overseeing the quality of scientific evidence used for regulation. Courts do not have such expert support and instead are hamstrung by limited resources and prohibitions against *ex parte* contact that constrain their ability to access expertise outside of the litigation.[14] This background section considers the agencies' use and oversight of scientific evidence relative to the common law courts both before and after passage of the IQA.

A. Checks on the Quality of Science Used for Regulation

Agencies like the Environmental Protection Agency (EPA) have developed multiple oversight processes to ensure that they find and use the best available science in their regulation, especially when public health is in jeopardy from the failure to regulate proactively.[15] The process for incorporating science into regulation is messy; politics and economic interests often drive and sometimes affect the resolution of the decision-making exercise.[16] But in contrast to courts, there are numerous internal and external checks to ensure that an agency uses science wisely in its decision-

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[13] *See* sources cited *supra* note 3.

[14] *See, e.g.,* Jack B. Weinstein & Catherine Wimberly, *Secrecy in Law and Science*, 23 CARDOZO L. REV. 1, 27-29 (2001) (discussing limitations on the ability of judges to do independent research on scientific issues raised in a case).

[15] *See, e.g.*, Wagner, *supra* note 3, at 65, 81-86 (describing the checks and balances that apply to EPA science).

[16] *See, e.g.*, Nicholas A. Ashford et al., *A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking*, 7 HARV. ENVTL. L. REV. 297, 342 (1983) ("EPA's formaldehyde deliberations powerfully illustrate the ease with which matters of policy may be confused with matters of science . . . [EPA's] analysis purports to justify, in the name of science, a risk assessment policy far less protective of human health than the agency's prior policy.").

making. For example, to ensure their scientific assessments are competent, agencies often empanel experts to oversee their use of science in regulatory decisions[17] and routinely employ various forms of internal and external peer review.[18] In cases when science has direct regulatory consequences, agencies also risk an appeal to the court of appeals by those concerned with the factual veracity of their rulemakings.[19] Controversial technical decisions made by agencies are scrutinized informally by Congress (usually in the course of oversight hearings), and in exceptional cases, the public. Because of its vulnerability to multiple reprimands from the courts, Congress, the White House, and the public at large, agencies have many reasons to get the science right the first time, particularly when their science-based decisions have direct and significant consequences for public health and the economy.

These multiple checks and balances substantially improve the scientific grounding of resulting regulatory products. At least in the case of EPA, various expert advisory panels, including the National Academy of Science (NAS), and prominent academics conclude that EPA does a satisfactory-to-good job identifying reliable science and using it in regulation.[20] Although there

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[17] Science advisory boards are mandatory for EPA's promulgation of air quality standards and for regulatory action on pesticides. *See* 42 U.S.C. § 7409(d)(2)(B)-(C) (2000); 7 U.S.C. § 136w(d)-(e) (2000); *see also* 42 U.S.C. § 4365(c)(1) (2000) (establishing a science advisory board to review scientific and technical information relevant to any proposed action under EPA's authority if EPA is forwarding the proposal to any other federal agency for formal review).

[18] *See, e.g.*, ENVTL. PROT. AGENCY, PEER REVIEW HANDBOOK (2d ed. 2000), *available at* http://www.epa.gov/osp/spc/prhandbk.pdf.

[19] *See* 5 U.S.C. § 706(2)(B) (1996).

[20] *See, e.g.*, *Strengthening Science at the U.S. Environmental Protection Agency—National Research Council (NRC) Findings: Hearing Before the House Subcomm. on Energy and Env't*, 106th Cong. 106-97 (2000); COMM. ON RESEARCH & PEER REVIEW IN EPA, NAT'L ACAD. OF SCI., STRENGTHENING SCIENCE AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY: RESEARCH MANAGEMENT AND PEER REVIEW PRACTICES (2000); TED GREENWOOD, KNOWLEDGE AND DISCRETION IN GOVERNMENT REGULATION (1984); MARK R. POWELL, SCIENCE AT EPA: INFORMATION IN THE REGULATORY PROCESS 112-17 (1999); EXPERT PANEL ON THE ROLE OF SCI. AT EPA, U.S. ENVTL. PROT. AGENCY, SAFEGUARDING THE FUTURE: CREDIBLE SCIENCE, CREDIBLE DECISIONS (1992); SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS

remains a cluster of critics who argue that EPA routinely uses "bad science,"[21] a closer examination of these charges reveals that most of the disagreements are in fact over agency policy, rather than scientific quality, and these critics rarely identify problems with EPA's use of science in settings that have direct regulatory consequences.[22] Thus, most of the concrete evidence to date suggests that EPA is relatively adept at finding and using the best science available to formulate protective regulations.

In addition, most environmental laws make it clear that not all science is weighed equally in terms of its implications for regulation. Because Congress demands that EPA err on the side of protection in most statutes, EPA is legally justified, if not compelled, to place lower demands on scientific developments suggesting that regulations might not be protective enough, and a higher bar on developments that suggest more permissive standards are possible without compromising public health. As a result, the scrutiny required of scientific information used for regulation also depends on the statute and regulatory context.

B. The Information Quality Act

Against this backdrop of relatively robust internal and external oversight processes governing EPA's use of science, the IQA imposes an entirely new and additional oversight process. The Act, which was originally passed as an unnoticed rider to an appropriations bill,[23] works by providing interested parties with the

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AS POLICYMAKERS (1990)*'*.

[21] *See, e.g.*, Richard Shelby, *Accountability and Transparency: Public Access to Federally Funded Research Data*, 37 HARV. J. ON LEGIS. 371 (2000); Sen. James Inhofe et al., *Inst. for Policy Innovation, Big Government and Bad Science: Ten Case Studies in Regulatory Abuse* (Bonner R. Cohen, Ph.D. & Thomas A. Giovanetti, eds. Nov. 30, 1999), *available at* http://ipi.org/ipi/IPIPublications.nsf/PublicationLookupFullText/1C84DBE6BCD5AEE98625683A001A354C; *see generally* Junkscience.com, *at* http://www.junkscience.com (last visited Sept. 5, 2003).

[22] *See* Wagner, *supra* note 3, at 78-81.

[23] From the oral history surrounding its passage, it appears that most members of Congress were unaware of the Act's content or existence. *See, e.g.*,

ability to file petitions to "correct" information that an agency has publicized.[24] This correction process must include an appeal process inside the agency.[25] The Act has broad coverage: "Disseminated information"[26] should be corrected if it is found to lack "reliability," "objectivity," "integrity," or "utility"[27] and "information" is interpreted to include essentially anything but opinions from agency staff, thus covering far more than narrow categories of "data" or "science."[28] Moreover, the Act reaches

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NAT'L ACAD. OF SCI., ENSURING THE QUALITY OF DATA DISSEMINATED BY THE FEDERAL GOVERNMENT: WORKSHOP # 1, at 32 (April 21, 2002) [hereinafter NAS, DATA QUALITY TRANSCRIPT, DAY 1], *available at* http://www7.nationalacademies.org/stl/4-21-02_Transcript.doc (comments of 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"). It also appears from the oral history that it was an industrial lobbyist, Jim Tozzi, who leads the Center for Regulatory Effectiveness, and not a congressional staffer that drafted and guided the rider through Congress. *See, e.g.*, James T. O'Reilly, *The 411 on 515: How OIRA's Expanded Information Roles in 2002 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.").

[24] Treasury and General Government Appropriations Act for Fiscal Year 2001 § 515, Pub. L. No. 106-554, 144 Stat. 2763 (2001).

[25] *See* Office of Mgmt. & Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8452, 8459 (Feb. 2, 2002) [hereinafter OMB Data Quality Guidelines].

[26] "Disseminate" means putting out into the public view, although there are a number of exemptions, some of which exempt regulatory information that regulated parties submit. *Id.*

[27] *Id.*

[28] Specifically, "information" means:

> any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions where the agency's presentation makes it clear that what is being offered is

back to information disseminated before passage of the Act, sweeping older agency documents within the scope of potential IQA challenges.[29]

The IQA is quite new—only mid-way through its second year of implementation—thus it is still early to predict how it will be used by regulatory participants. To date there have been only a few IQA challenges, averaging about one per month for the main target of the IQA, the EPA.[30] Nonetheless, most of these petitions are major and take on significant, science-based regulatory developments.[31] For example, in spring 2003, the Competitive Enterprise Institute (CEI) filed a complaint petitioning several agencies to withdraw the climate change models used in the *National Assessment on Climate Change* from agency websites and other public databases, arguing that they were unreliable.[32] CEI's

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someone's opinion rather than fact or the agency's views.

Id. at 8460.

[29] *See, e.g*., Morgan Lewis & Bockius Request for Correction (Aug. 19, 2003) [hereinafter Morgan, Lewis, & Bockius Petition] (seeking correction of information contained in a 1986 EPA publication entitled *Guidance for Preventing Asbestos Disease Among Auto Mechanics* (the "Gold Book")), *available at* http://www.epa.gov/oeiinter/qualityguidelines/afreqcorrectionsub/12467.pdf.

[30] *See* Envtl. Prot. Agency, Requests for Correction Submitted to EPA, *available at* http://www.epa.gov/quality/information guidelines/ipg-list.html (last updated Mar. 17, 2004).

[31] For a summary of IQA petitions filed by industry against both public health and environmental agencies, see Ctr. for Regulatory Effectiveness, Status of Data Quality Act Petitions, *available at* http://www.thecre.com/quality/20030211_cei.html (last visited Feb. 29, 2004).

[32] *See* Competitive Enter. Inst., Petition to Cease Dissemination of the National Assessment on Climate Change (Feb. 20, 2003) [hereinafter CEI Petition], *available at* http://www.cei.org/pdf/3360.pdf (last visited Mar. 1, 2004). The agencies denied the petitions and CEI's internal appeals. CEI then appealed its case to the D.C. District Court where CEI ultimately withdrew its case. *See, e.g.,* Press Release, Competitive Enterprise Institute, CEI Global Warming Suit Draws Ire of Northeast States Attorneys General (Aug. 23, 2003), *available at* http://www.cei.org/gencon/003,03598.cfm. The petition was ultimately withdrawn because CEI believed the Bush administration adequately acknowledged the weaknesses of the models. Press Release, Competitive Enter.

approach—focusing on significant regulatory information and asking for its withdrawal—is repeated in other major IQA petitions filed against EPA, including technical petitions seeking the withdrawal or exclusion of: pathbreaking research on the endocrine disruption properties of Atrazine; brochures warning auto mechanics about risks of exposure to asbestos from brake linings; an EPA technical review of Diisonoyl phthalate (DINP), a toxin used in PVC products; and a letter requesting EPA to ignore public interest group comments on dioxin risks in a biosolids rule and threatening an IQA action if EPA relies on the comments.[33]

All of these IQA petitions bear a striking resemblance to *Daubert* motions. Like *Daubert*, the requested remedy often involves complete exclusion or withdrawal of the challenged information from public databases.[34] Also like *Daubert*, the criteria for "good" versus "bad" science or science-related information is amorphous, but the inability to validate or replicate the study is one of the primary grounds for challenging the information. Finally, those filing the complaints generally do not limit their concerns to scientific quality or reliability, but also contest embedded judgments and policy choices in the agencies' use of scientific research, even though the challenges are framed as if they concerned only technical information.[35]

Inst., White House Acknowledges Climate Report Was not Subjected to Sound Science Law: CEI Drops Lawsuit against Bush Administration (Nov. 6, 2003), *available at* http://cei.org/gencon/003,03740.cfm.

[33] *See, e.g.*, Kans. Corn Growers Ass'n, The Triazine Network, & the Ctr. for Regulatory Effectiveness, Request for Correction of Information Contained in the Atrazine Environmental Risk Assessment, Docket No. OPP – 34237A, at 2 (Nov. 25, 2002) [hereinafter Atrazine Petition], *available at* http://www.thecre.com/pdf/petition-atrazine2B.pdf; Morgan Lewis & Bockius Petition, *supra* note 29; Ctr. for Regulatory Effectiveness, Request to EPA for Correction of "Technical Review of Diisononyl Phthalate," Oct. 16, 2003 [hereinafter CRE Phthalate Petition], *available at* http://www.epa.gov/oei/qualityguidelines/afreqcorrectionsub/13166rfc.pdf; Letter from William G. Kelly, Center for Regulatory Effectiveness (CRE) to EPA Water Docket (Feb. 27, 2003) [hereinafter Kelly letter], *available at* http://www.thecre.com/pdf/20030310_biosolids.pdf.

[34] *See supra* notes 32 & 33.

[35] *See infra* Section II.A.1.

II. IMPORTING MISCHIEF?

On the surface, the similarities between *Daubert* and the IQA would seem a positive development since agencies and courts will adopt similar standards and processes for reviewing and screening science used in legal decision-making. But there are important institutional differences between the agencies and the courts that could lead the IQA to be more damaging and potentially counterproductive as compared with the courts' use of *Daubert*. First, unlike *Daubert*, IQA challenges are not adversarial and do not provide potential opponents with notice or a formal opportunity to contest petitions.[36] Under the IQA, an interested party simply sends a letter to an agency asking for information to be withdrawn, and the complaints are resolved by the agencies without the benefit of broader public input. Second, the decision-maker is a political agency, rather than a "neutral" jurist. The resulting decisions are thus more likely to be affected by politics, even though the decisions might purport to be based on the agency's scientific judgment.[37] Third and compounding the first two problems, agency resolutions of IQA petitions become national proclamations about the quality of the science underlying disseminated information. By contrast, in the courts the resolution of scientific quality is most often resolved at the trial court level and is thus limited in its impact.[38] Fourth, it is not clear what administrative problems the IQA is intended to fix, again a stark contrast with the courts' need for some means of overseeing scientific evidence introduced into the trial process. At least with respect to EPA, for example, there is little evidence of a problem

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[36] At least one interest group has filed a counter-challenge on a Data Quality petition, presumably because the organization learned of the petition before it was decided and had the resources to object. *See* OMB Watch, *Analysis on the Petition against the US Fish and Wildlife Service on Salmon Farming*, VOL. 4 NO. 10 OMB WATCHER, *available at* http://www.ombwatch.org/article/articleview/1521//.

[37] *See, e.g.*, Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995).

[38] *Cf.* General Electric Co. v. Joiner, 522 U.S. 136 (1997).

with the quality of science used in regulation.[39] Current legal protections that govern agency decision-making, most specifically the notice and comment and appeal processes,[40] moreover, make the IQA process largely superfluous and redundant.[41]

Compounding concerns about the capability of the IQA to improve the quality of regulatory science are deficiencies that afflict the IQA's model—*Daubert*—itself. Recent research suggests that *Daubert* is producing some unexpected, but potentially serious adverse side effects, even in its more modest use by the courts. First, since *Daubert* situates the judge as the expert who must determine the reliability and validity of scientific testimony,[42] there is a risk of significant, substantive errors in admissibility rulings. Such substantive errors not only threaten to impair the accuracy of adjudications, but could alienate the scientific community and undercut the legitimacy of the courts.[43] *Daubert* also imposes significant new process costs on both litigants and judges. *Daubert* can thus alter the adversarial playing field simply by virtue of the added time and resources it demands. These problems with *Daubert* appear to be repeated and amplified by the agencies as they implement the IQA.

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[39] *See supra* note 20 and accompanying text.

[40] In addition, at the time the Data Quality Act was passed, EPA had already developed four separate programs dedicated to ensuring the quality of information relevant to regulation, including an electronic error correction system. *See, e.g.*, U.S. Envtl. Prot. Agency, Draft Data Quality Guidelines, 67 Fed. Reg. 21,234 (proposed Apr. 30, 2002) (describing four separate mechanisms in place to ensure the "quality, objectivity, utility and integrity" of information used and produced by EPA).

[41] *See* Sidney A. Shapiro, *OMB's Dubious Peer Review Procedures*, 34 ENVTL. L. REP. 10064, 10065 (2003).

[42] Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993).

[43] *See, e.g.*, THE PROJECT ON SCIENTIFIC KNOWLEDGE AND PUBLIC POLICY (SKAPP), DAUBERT: THE MOST INFLUENTIAL CASE YOU'VE NEVER HEARD OF (2003) [hereinafter SKAPP REPORT] (report by scientists critical of *Daubert*), *available a*t http://www.defendingscience.org/pdf/DaubertReport.pdf.

A. Substantive Errors in Applying a Daubert*-like Test to Sort Reliable Science from Unreliable Science*

1. Blurring the Line between Science and Policy

Under *Daubert,* courts have struggled with expert testimony that is only partly based on testable research, like weight-of-the-evidence judgments on causation that string together a series of disparate studies.[44] The controversy over the *Sandoz* case, where the trial judge excluded the experts' weight-of-the-evidence testimony as inadmissible under *Daubert*, is a recent example of this struggle.[45] In that case, even though the individual studies and reports supported a hypothesis that there was a causal connection between plaintiffs' stroke and defendant's medicine, Parlodel, the district court held that the experts' testimony presenting this causation hypothesis did not pass *Daubert*'s reliability test.[46] As a result, the district court granted summary judgment to defendants since plaintiffs had no remaining scientific evidence in support of causation, and the Eleventh Circuit affirmed.[47] The opinion has been criticized because the judge rejected plaintiffs' causation evidence, even though the circumstantial quality of the evidence arguably presented a weighing decision that the jury is empowered to make. The *Sandoz* decision, it is argued, thus blurs the line between weighing the available evidence, typically a jury decision, and screening out unreliable science, an evidentiary issue for the judge.

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[44] Carl F. Cranor & John A. Eastmond, *Scientific Ignorance and Reliable Patterns of Evidence in Toxic Tort Causation: Is there a Need for Liabilty Reform*?, 64 L. & CONTEMP. PROBS. 5, 26-45 (2001).

[45] Siharath v. Sandoz Pharms. Corp., 131 F. Supp. 2d 1347 (N.D. Ga. 2001), *aff'd sub nom.* Rider v. Sandoz Pharms. Corp., 295 F.3d 1194 (11th Cir. 2002).

[46] *Siharath*, 131 F. Supp. 2d at 1370 (holding that to prevail, plaintiff must provide "at least some support for the causal hypothesis in . . . epidemiological literature, a predictable chemical mechanism, general acceptance in learned treatises, a plausible animal model, and dozens of well-documented case reports").

[47] *Rider*, 295 F. 3d at 1202-03.

These struggles in determining which decisions are best left exclusively to experts and which involve weight-of-the-evidence judgments that should be shared with policymakers or jurors are being repeated, with considerably more confusion, under the IQA. Despite the fact that the Act purports to apply only to the reliability of technical information, and not to agency policy judgments, the petitions filed against EPA repeat this blurring of policy and science under the guise of scientific fact finding. In one of the most significant information quality challenges brought to date, the manufacturer and agricultural users of an herbicide, Atrazine, sought to exclude a recent series of studies done on the hormonal effects of Atrazine from EPA's decision regarding re-registration of the herbicide .[48] The petitioners argue that the science acceptable for regulation must be conducted only under agency-approved protocols and since EPA has not yet promulgated tests for measuring endocrine disruption effects, the studies must be excluded.[49] The industry's argument, however, has nothing to do with technical issues, but instead advances a policy position that new scientific discoveries cannot be considered in regulating pesticides until after the underlying methods have been formally promulgated by EPA.

Other IQA petitions also take issue with EPA's policy judgments rather than with the technical merits of EPA's decisions.[50] In one complaint, industry challenged EPA's barium risk assessment in large part because it disagreed with the agency's conservative assumptions used in preventative regulation.[51] In the

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[48] Atrazine Petition, *supra* note 33.

[49] Atrazine Petition, *supra* note 33. Petitioners argue: "EPA's statements in the atrazine *Environmental Risk Assessment* regarding atrazine's purported endocrine effects violate government-wide data quality standards. These government-wide standards require proper test validation before the tests are considered reliable and reproducible. There are no validated endocrine-effects tests for atrazine."*Id.* at 1.

[50] *See also* Kelly letter, *supra* note 33 (characterizing risk assessment as a science that does not involve policy).

[51] Chem. Products Div., Request for Correction of the IRIS Barium Substance File-Information (Oct. 29, 2002), *available at* http://www.epa.gov/oei/qualityguidelines/afreqcorrectionsub/2293.pdf (last visited Mar. 1, 2004); U.S. Envtl. Prot. Agency, Request for Correction of the IRS Barium and

CEI petitions, the organization argued that the National Oceanic and Atmospheric Administration, and by association the Office of Science and Technology Policy, used flawed models to predict the effects of global warming and that all reports and data relying on those models should be withdrawn. CEI did not, however, acknowledge the basic policy decisions involved in deciding whether to suspend use of the models until a more robust dataset or model is produced, nor did they discuss whether other, more accurate predictive models are currently available.[52]

2. Conflating Responsibility for Producing Research

One of the recurring criticisms of the common law courts' response to toxic tort cases is their failure to take into account a manufacturer's or polluter's social responsibility to produce basic evidence on the safety of their activities. Professor Berger and others have written about the tendency of the common law causation standard to be imposed in ways that increase the plaintiffs' burden of proving harm, despite the fact that the defendant polluters and manufacturers typically enjoy superior expertise and often superior knowledge of product harms.[53] Indeed, by requiring plaintiffs to produce this evidence as a prerequisite to maintaining a viable suit, the common law perversely awards manufacturer ignorance.[54]

Compounds Substance File (Jan. 30, 2003) (letter from Paul Gilman, Ph.D., Assistant Administrator of EPA, to Jerry Cook, Technical Director, Chemical Products Division), *available at* http://www.epa.gov/oei/qualityguidelines/afreqcorrectionsub/2293Response.pdf (last visited Mar. 1, 2004).

[52] CEI Petition, *supra* note 33.

[53] *See, e.g.*, Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117 (1997); *see also* Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 41 (1995); Wagner, *supra* note 2, at 786-89.

[54] There are proposals for reforming the causation standard in keeping with other burden shifting devices, like res ipsa loquitur, that penalize defendants from profiting from ignorance regarding the harms they might be imposing on others. *See, e.g.*, Richard J. Pierce, Jr., *Causation in Government Regulation and Toxic Torts*, 76 WASH. U. L.Q. 1307, 1324-25 (1998).

Rigorous, *Daubert*-like scientific screening devices act indirectly to exacerbate the informational burden on plaintiffs by providing defendants additional opportunities to challenge plaintiffs' evidence.[55] For example, decisions like *Sandoz* permit defendants to challenge the whole of plaintiffs' causation case through a single evidentiary hearing that bases resolution of the case on whether plaintiffs' weight-of-the-evidence testimony can be tested.[56] There are also reports that *Daubert* challenges are so expensive that they can alter the financial calculus of plaintiffs to bring suit.[57]

The IQA exacerbates this problem regarding the lack of manufacturer and polluter responsibility for producing information on their harmful activities, this time in a legal setting where Congress specifically intended to lighten the scientific burden of regulators to respond to health and environmental threats.[58] In most environmental statutes, agencies are directed to pass protective regulations in the face of uncertainty and to err on the side of protecting the public health and the environment.[59] This creates incentives for regulated parties to produce exculpatory information, rather than burdening regulators with heavy information production requirements. The IQA risks counteracting these statutory commands to err on the side of public health by providing regulatory parties with an added mechanism for challenging scientific evidence before regulations take effect.[60] Moreover, since the IQA operates without the requisite notice and comment process required by the Administrative Procedure Act

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[55] *See* Margaret A. Berger, *Upsetting the Balance Between Adverse Interests: The Impact of the Supreme Court's Trilogy on Expert Testimony in Toxic Tort Litigation*, 64 LAW & CONTEMP. PROBS. 289 (2001).

[56] *See supra* notes 45-47 and accompanying text.

[57] *See infra* notes 71-71 and accompanying text.

[58] *See, e.g.*, SHAPIRO & GLICKSMAN, *supra* note 1, at 15.

[59] *Id.*

[60] Two more recent and sophisticated petitions exemplify the considerable extra time and resources that will likely be required of EPA to respond to lengthy tedious requests for information correction. *See* CRE, Phthalate Petition, *supra* note 33; Perchlorate Study Group, Data Quality Act Petition on three EPA Technical Documents on Perchlorate, Dec. 3, 2003, *available at* http://www.epa.gov/oei/qualityguidelines/afreqcorrectionsub.

and potentially with no or limited judicial review, this new process could conceivably be used by agencies themselves to circumvent statutory commands when it is politically attractive to do so. For example, the EPA might agree with the IQA petition on Atrazine and hold that pre-approved protocols are needed before pathbreaking research on new risks of pesticides will be considered in regulating those pesticides, even though this decision constitutes an important policy decision that arguably conflicts with the protective pesticide mandate[61] and should at least undergo notice and comment.

3. Scientific Errors

The most worrisome aspect of *Daubert* is the possibility that judges will make mistakes, particularly in erroneously excluding valuable scientific evidence.[62] Under *Daubert*, a federal judge reaches a formal "legal decision" about the reliability of scientific testimony and its accompanying research. This powerful legal declaration on scientific quality, if erroneous, might not only impair the adjudication of a particular case, but might taint researchers or experts unfairly. Although errors are inevitable, especially on difficult scientific evidence challenges, there is currently little systematic research on the frequency or significance of judicial errors in applying *Daubert*.

It is not clear whether the agencies are more or less susceptible to making errors on the technical merits of scientific evidence. Equipped with an army of scientific staff, the agencies can be expected to fare better than the courts in their technical competence to resolve challenges to the quality of scientific

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[61] *See, e.g.*, Envtl. Defense Fund v. EPA, 548 F.2d 998, 1004 (D.C. Cir. 1976).

[62] *See* David S. Caudill & Lewis H. LaRue, *Why Judges Applying the Daubert Trilogy Need to Know About the Social, Institutional, and Rhetorical—And Not Just the Methodological—Aspects of Science*, 45 B.C. L. REV. 1 (2003) (arguing that judges who are "unduly focused" on scientific methodology in applying *Daubert* "tend to reject reliable—albeit pragmatic—science, welcome unreliable—albeit authoritative—science, and thereby create a body of legal science that is out of sync with mainstream science").

information. On the other hand, there are frailties in the process employed by the IQA that might leave agency staff handicapped in evaluating IQA petitions. The IQA does not provide an adversarial vetting of the petitions, thus an agency decision-maker will be looking at only one side of the issue and must rely on its staff to provide the remaining information needed for a fair evaluation. Being a political body, moreover, it is possible that an appointed official could rule on the quality of scientific research based in large part on political, rather than scientific considerations simply because it is expedient to do so.

4. Forum Shopping

Forum shopping between the courts and agencies for the most amenable ruling on the quality of scientific research seems inevitable once both agencies and courts are shackled by *Daubert*-like complaint processes. Such forum shopping will only further confuse the legal system's collective voice on scientific quality and lead to even more transaction costs in debating esoteric technical public health questions. In the summer of 2003, attorneys defending the asbestos industry in tort litigation engaged in precisely this forum shopping by filing an IQA petition requesting EPA to withdraw a 1986 manual warning auto mechanics about potential exposure to asbestos in brake linings.[63] The pamphlet had been used by plaintiff attorneys to support their causation case, and the defense lawyers had been unsuccessful in excluding the evidence under *Daubert*.[64] In their IQA petition, the defense attorneys argued that EPA's documentation of the causal connection between exposure to asbestos in brake linings and asbestos diseases was incomplete and outdated in the pamphlet.[65] Even though the primary regulatory purpose for the manual was to warn auto mechanics about the risks of encountering asbestos in brake linings, the IQA subjects this type of information to the same

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[63] *See* Morgan, Lewis, & Bockius Petition, *supra* note 29.

[64] *See, e.g.*, Andrew Schneider, *EPA Warning on Asbestos is Under Attack*, ST. LOUIS POST-DISPATCH, Oct. 26, 2003, at A1.

[65] *See* Morgan, Lewis, & Bockius Petition, *supra* note 29, at 4-8.

reliability tests as basic research studies and scientific reports. Now revision of the manual appears to be high on EPA's list of priorities solely because of this forum-shopping by frustrated litigants.[66]

Conversely, in at least one instance a losing IQA petition has been appealed to the court of appeals, even though the IQA itself does not provide a right of judicial review.[67] Although it was unclear how the petitioner could show adverse "direct consequences" to its organization as a result of public dissemination of the climate change models, and the complaint was later withdrawn,[68] it is possible to imagine IQA challenges that will present more compelling judicial appeals in the future.[69] Thus, courts might be petitioned to review agency resolutions of IQA complaints, just as agencies consider administrative information that litigants are unsuccessful in excluding from the courts under *Daubert*.

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[66] *See* EPA Response to Morgan, Lewis, & Bockius Petition, Nov. 24, 2003, *available at* http://www.epa.gov/oeiinter/qualityguidelines/afreqcorrectionsub/12467response-morgan-lewis.pdf.

[67] *See supra* note 19 and accompanying text.

[68] *See, e.g.*, Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA, 313 F.3d 852 (4th Cir. 2002).

[69] *See, e.g.*, NAS, DATA QUALITY TRANSCRIPT, DAY 1, at 22-23, *available at* http://www7.nationalacademies.org/stl/4-21-02_Transcript.doc (comments of John D. Graham) (noting the uncertainty of judicial review and speculating that "it will probably take a few critical court decisions before we know how this law and the associated guidelines will be interpreted by judges"); *id*. at 73-74 (comments of Alan Morrison) (speculating that under the Data Quality Act, courts will not hold "de novo review" of the science even though it is "theoretically possible" that they could); *id*. at 114-17 (comments of Fred Anderson) (speculating that parties will be able to get judicial review of agency information independent from a final rulemaking); *id*. at 143-44 (comments of Dan Cohen) (concluding that an agency's ruling on a correction request is a final agency action subject to judicial review); *id*. at 173-74, 181-83 (comments of Professor Pierce) (expressing initial skepticism about whether courts can review challenges to agency information, and then later conceding that judicial review might be possible under limited circumstances).

B. Process Costs Associated with Implementing a Daubert*-like Test*

1. Exacerbating Imbalances in the Review of Science

Daubert has been criticized for causing greater imbalance in adversarial processes because of the high costs associated with mounting and defending *Daubert* challenges.[70] Litigants endowed with greater resources can gain an advantage by raising highly complex and even unjustified challenges to their less well-financed opponent's scientific evidence in order to drain their time and resources. In civil cases, in fact, the cost of *Daubert* challenges appears to be drying up smaller damage litigation because defending against the inevitable *Daubert* challenges makes smaller litigation unprofitable.[71] By contrast and somewhat perversely, forensic evidence introduced by prosecutors in criminal trials might not undergo rigorous *Daubert* scrutiny because of the prevalence of court appointed counsel and the correspondingly limited resources available for challenging prosecutors' scientific evidence.[72] *Daubert* thus helps the richer litigants gain an edge,

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[70] *See*, *e.g.*, Ellen Relkin, *To Hear or not to Hear: When Are* Daubert *Hearings Appropriate?*, SF78 A.L.I.-A.B.A. 371, 375 (2001) (reporting that *Daubert* hearings can range from a few hours to numerous days and have evolved into virtual mini-trials involving a myriad of experts from both sides that can cost parties "tens to hundreds of thousands of dollars"); *see also* Denise M. Dunleavy, *The Darwin Guide to Survival at a* Daubert *Challenge*, 2Ann. 2001 ATLA-CLE 2775 (2001) (providing lengthy recommendations for anticipating and then preparing for *Daubert* hearings, which resemble mini-trials).

[71] *See, e.g.*, Relkin, *supra* note 70, at 375 (observing that the costs of *Daubert* hearings are being factored into plaintiff attorneys' decisions to reject meritorious cases when the injuries are not catastrophic); *id*. at 381 (reporting that the defendants' costs of a *Daubert* hearing, which the court assigned to the losing plaintiffs, were $87,887.11 (although only $32,853.16 was documented) in one case and $26,921.62 in another).

[72] *See, e.g.*, NAT'L ACADEMY OF SCIENCES, SCIENTIFIC EVIDENCE WORKSHOP 51 (September 7, 2000), *available at* http://www7.nationalacademies.org/stl/Scientific_Evidence_PDF.pdf.

while doing little for indigent parties who might be most disadvantaged by poor quality expert testimony.[73]

The IQA repeats and amplifies these adversarial imbalances. First and similar to *Daubert*, the IQA petition process requires technical sophistication and resources.[74] Those without resources to invest in this exercise may not be able to use the IQA. Rather than presenting an opportunity for broad-based improvements in scientific quality, the IQA may instead provide only a limited opportunity for established, well-financed interest groups to challenge regulatory information when they do not like the underlying policies or direction in which an agency is headed. Exacerbating this imbalance is the fact that IQA petitions are likely to slow down administrative processes simply by virtue of raising additional challenges to agency activities that must be resolved before rulemaking projects can proceed.[75] Thus, at least for EPA, the sophisticated, established interest groups who actually bring IQA petitions will be limited primarily to the industrial sector since regulatory delay generally works at cross purposes with public interest groups' goals of ensuring the expeditious promulgation of protective regulation.[76] In fact, roughly two-thirds of the IQA petitions brought against EPA have been filed by industry.[77]

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[73] *See, e.g.*, SKAPP REPORT, *supra* note 43, at 12-14.

[74] *See supra* note 33.

[75] *See* Wagner, *supra* note 3, at 106.

[76] The only sophisticated, "pro-environment" petition filed against EPA challenged a new exemption for the oil and gas industry from Clean Water Act requirements. Delaying the finalization of this exemption would actually lead to higher environmental protection in the interim, while the petition was being adjudicated and processed.

[77] If one culls out redundant and inapplicable filings, nearly two thirds of IQA petitions filed against EPA have been filed by regulated industries or representatives. *See* Envtl. Prot. Agency, IQA log, *at* http://www.epa.gov/oeiinter/qualityguidelines/af_req_correction_sub.htm (last visited March 17, 2004). Interestingly, by contrast, half the petitions filed against the Department of Interior (DOI) and the Forest Service (FS) are filed by environmental groups, with the other half filed by affected industry/resource users. *See* OMB Watch, Log of IQA Challenges, *at* http://www.ombwatch.org/article/articleview/1417/1/171/. In these cases, delays in timber harvesting or introducing new uses or species is beneficial to environmental interest groups.

Second, and in contrast to *Daubert*, not all science used in regulation is subject to the IQA. Instead, the IQA actually exempts a good portion of privately produced science and focuses predominantly on federally-funded science.[78] Since recent accounts suggest potentially significant problems with the reliability of science sponsored by a regulated party and produced for regulation,[79] the focus on public science in the IQA seems the reverse from what is needed. In fact, a good portion of tort litigation brought against "regulated" products after the regulator approved the products for marketing may be the result of unreliable, privately sponsored research that the regulatory agencies were forced to use to decide whether the products were safe.[80]

Together these imbalances raise doubts about whether the IQA will improve regulatory science in any meaningful way, or instead simply opens a point of attack on a subset of regulatory relevant research where only a few affected parties have the resources or the incentives to file complaints. The one-directional nature of the

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[78] First and most sweeping is OMB's decision to exempt from data quality challenges all information arising in "adjudications," a term that includes information used in permit and licensing decisions. OMB Data Quality Guidelines, *supra* note 25, at 8460, § V.8. Although subtle, this exemption effectively removes from challenge all private information submitted by a regulated party to obtain a license to market a potentially dangerous product, including a pesticide, or to obtain a permit to discharge pollution on land, water, or into the air. OMB's second exemption applies to third party information that agencies receive as "public filings." *Id*. Thus, annual emissions inventories, compliance reports, and other filings required of industry under federal law also appear to be exempt from data quality challenges. Third, OMB exempts all private information classified as trade secret or confidential business information, classifications that can include a considerable amount of private information. *Id*. § V.3.b.ii.B.i.

[79] *See, e.g.*, SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED THE VIRTUE OF BIOMEDICAL RESEARCH? 141-44 (2003); Justin E. Bekelman et. al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 J. AM. MED. ASSOC. 454 (2003).

[80] *See, e.g.*, Thomas O. McGarity, *Beyond* Buckman*: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 WASHBURN L.J. 549, 558-70 (2002).

IQA reforms—directed at public science, while exempting most private research—only serves to reinforce concerns about process imbalances.

2. Potential for Harassment and Abuse of Process

Courts have been the pawn in efforts to disparage and harass researchers through the ability of litigants to challenge scientific evidence, although this is rarely accomplished with *Daubert* challenges alone. A symposium in *Law and Contemporary Problems*, for example, explores how both plaintiff and defense attorneys abuse the third-party subpoena power to intimidate scientists whose research produces damaging findings for their position, even though the researchers are not involved directly in the litigation.[81] The litigants typically accomplish this intimidation by filing overbroad subpoenas to individual scientists seeking the release of laboratory notebooks, data, and ongoing research.[82] When a public university employs the researcher, litigants have also used state public records statutes to file broad document production requests.[83] In some cases, the overbroad requests have also included demands that confidential personal data be disclosed, and in one case the state judge ordered that it be turned over to the opposing party, R.J. Reynolds.[84] Most courts, however, ultimately quash the subpoenas, once challenged, as overbroad; yet advocates seem to understand the gains that can be made simply from the threat of a subpoena or public records action against an unsuspecting scientist.[85] These abuses of process resulted in at

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[81] *See* Symposium, *Court-Ordered Disclosure of Academic Research: A Clash of Values of Science and Law*, 59 LAW & CONTEMP. PROBS. 1 (1996).

[82] *See, e.g.*, Bert Black, *Research and its Revelation: When Should Courts Compel Disclosure?*, 59 LAW & CONTEMP. PROBS. 169, 173 (1996); *see also* Steven Picou, *Compelled Disclosure of Scholarly Research: Some Comments on "High Stakes Litigation"*, 59 LAW & CONTEMP. PROBS. 149, 155 (1996).

[83] *See* Paul M. Fischer, *Science and Subpoenas: When Do the Courts Become Instruments of Manipulation?*, 59 LAW & CONTEMP. PROBS. 159, 159 (1996).

[84] *Id.*

[85] *See, e.g.*, Black, *supra* note 82, at 183.

least one prominent researcher leaving his tenured position in disgust.[86]

The misuse of legal tools to intimidate and discredit researchers can be expected to continue under the IQA. Nobel-prize winning economist, George Ackerloff, observes that one of the best mechanisms for outsiders to assess the reliability of complex information is by the reputation of the person providing it.[87] Disparaging a scientist, even when the disparagement is ultimately false, provides one means for undermining the veracity of complex scientific information. Filing IQA complaints, including complaints directed at a researcher, offer the possibility of not only impairing the researcher's reputation, but promise also to drain the researcher's time and energy if the researcher chooses to become involved in the agency's IQA response. And in contrast to the courts, there are no legal deterrents, such as dismissing frivolous complaints or levying sanctions, to deter these abuses of process. Under the IQA, parties may file as many petitions as they like concerning virtually any information they please.[88] The costs of processing the complaints, even if frivolous, are born by the agency and researchers if they are involved.

Some organizations have already tipped their hand that intimidating and discrediting researchers may be among their plans under the IQA. In a complaint petitioning the exclusion of a study on the herbicide, Atrazine, for example, the industry complained that the researcher "has killed and continues to kill thousands of frogs in unvalidated tests that have no proven value."[89] The same

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[86] *See* Fischer, *supra* note 83.

[87] *See* George Ackerloff, *The Market for 'Lemons': Qualitative Uncertainty and the Market Mechanism*, 84 Q. J. ECON. 488 (1970).

[88] *See, e.g.,* OMB Data Quality Guidelines, *supra* note 25, at 8452. The mandated OMB guidelines interpreting the Data Quality Act provide for its broad application to "the sharing by Federal agencies of, and access to, information disseminated by Federal agencies." *Id*.

[89] Kan. Corn Growers Petition, *supra* note 33, at 8. Hayes' scientific credibility is further questioned in a number of related critiques of his research. *See, e.g*., Alex Avery, *Frog Sex-Change Claims Flawed*, Center for Global Food Issues (October 30, 2002) *at* http://www.cgfi.org/materials/articles/2002/oct_30_02.htm; TRIAZINE NETWORK, THE SIGNIFICANCE OF THE HAYES ET AL. (2001)); Steven Milloy, *Freaky-Frog Fraud*, Fox News Channel, Nov. 8, 2002,

nonprofit then sent letters to the American Association of University Professors (AAUP) and a number of universities warning them to update their scientific freedom and responsibility policies to comply with the IQA,[90] and indicating it plans to move upstream by communicating IQA challenges to the researchers' federal funding sources.[91]

Whether this professional discrediting and intimidation ultimately impairs the researcher's scientific reputation within the scientific community or has other negative spillover effects is unclear, but nevertheless worrisome. While *Daubert* and the IQA are not essential to enable such attacks, they do provide additional public platforms for publicizing complaints against science and scientists.

C. Countervailing Benefits of the IQA?

Set against its considerable process and substantive costs, the potential benefits of the IQA appear both minimal and uncertain.

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available at http://www.foxnews.com/story/0,2933,69497,00.html; Steven Milloy, *Frog Study Leaps to Conclusions*, Fox News Channel, April 19, 2002, *available at* http://www.foxnews.com/story/0,2933,50669,00.html.

[90] Ctr. for Regulatory Effectiveness, Letter from Jim Tozzi, Member, CRE Advisory Board, to Jane Buck, American Association of University Professors, 3 (Aug. 6, 2003), *available at* http://www.thecre.com/pdf/university DQltrBuck.pdf. Identical letters were sent to a number of universities.

[91] *See Industry Data Quality Warning to Universities Draws Sharp Response*, INSIDE EPA, 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."

Id.

As discussed, without evidence of a preexisting problem with the quality of at least EPA's science, it is unclear what facets of regulatory information are actually in need of repair. The fact that the Act was passed as an appropriations rider with no congressional discussion, and was written by an industry consultant who now makes a living filing IQA petitions, presents still more cause for concern.[92]

Nevertheless, in the wake of the passage of the IQA, there is evidence of greater attention by agencies like the EPA to scientific quality. Over the last year and citing to the IQA, EPA and OMB have generated several new initiatives for increased quality control over regulatory science.[93] Several of these initiatives have been criticized as misguided and politically motivated, but at least one initiative—improving the quality of EPA's models—is promising.[94]

The IQA may also cause agencies to think twice before disseminating information, although it is difficult to locate concrete evidence of this effect. Whether this ultimately is a benefit or a cost will depend on the circumstances. If agencies are disseminating bad information that misleads the public or harms regulated parties, creating incentives for greater quality control before disseminating information is precisely what is needed.

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[92] *See supra* note 23.

[93] *See* Office of Mgmt. & Budget, Peer Review and Information Quality, Proposed Bulletin, August 2003, *available at* http://www.whitehouse.gov/omb/inforeg/peer_review_and_info_quality.pdf; Memo from EPA Administrator Whitman (Feb. 7, 2003), *available at* http://www.thecre.com/pdf/whitman_memo.pdf; Envtl. Prot. Agency, 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.

[94] EPA's Assessment Factors were criticized quite heavily at a National Academy of Sciences Workshop, January 21, 2003. *See* Transcript from NAS, Assessment Factors Workshop. OMB's proposed peer review bulletin generated even more criticism. *See, e.g.*, Shapiro, *supra* note 41; Robert Steinbrook, *Peer Review and Federal Regulations,* 350 NEW ENG. J. MED. 103 (2004); Sharon Begley, *White House Seeks Peer Review Standard for Range of Studies*, WALL ST. J., Dec. 5, 2003, at B1.

Conversely, if agencies become inclined to withhold information until the point at which they incorporate it into rulemakings., then the diminished scientific discourse could ultimately impair the quality of regulations and the thoroughness of public discussions in advance of rulemakings.

III. REFORM

The opportunity to look more broadly at implementation of a *Daubert*-like screening test in both the courts and agencies helps to spotlight several significant problems. First, these science-screening tests offer advantages to sophisticated participants to manipulate decision-making, in part by overwhelming their opponents and even the decision-maker through the use of resource-intensive challenges to science. Second, the tests present the risk of significant substantive errors, especially in terms of conflating science and policy disputes.

Both sets of problems could be addressed, at least preliminarily, by relatively simple reforms. With respect to the ability of sophisticated participants to abuse the screening devices to overwhelm opponents and the agencies, one straightforward remedy is to force those parties to pay for the costs of the process, and if they abuse it, to penalize the abuses. IQA petitions currently can be filed at any time, by anyone, and can include as many complaints and challenges as the petitioner desires. There are no meaningful costs or sanctions for filing meritless complaints. In contrast, the benefits of abusing the IQA process can be considerable to the regulated community: IQA challenges may lead to the exclusion or discrediting of pivotal studies that undergird protective regulation, and at the least they can divert an agency's resources and priorities away from developing protective policies.[95] Rule 37 already serves as a mechanism for penalizing frivolous *Daubert* challenges. [96] A similar type of penalty rule could be employed by the agencies in implementing the IQA. For example, if a petitioner does not raise a credible challenge under

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[95] *See* Wagner, *supra* note 3, at 106-08.

[96] *See, e.g.*, FED. R. CIV. P. 37.

the IQA, then the petitioner should be forced to pay not only the agency's processing costs, but a penalty.

Second, with respect to the vague standard for determining scientific reliability, separating problems of research bias from other scientific reliability problems could help to clarify the criteria for screening scientific evidence and counteract the potential for petitioners to challenge policy choices under the guise of science. Currently, both *Daubert* and the IQA have been criticized for conflating problems of bias with problems concerning the reliability of research, and addressing neither (particularly the bias problem) effectively.[97] Moreover, there is evidence that bias is a serious problem in policy-relevant scientific research, especially for research sponsored by manufacturers, waste producers, or regulatory participants or litigants.[98] A number of empirical studies have found that when the research is sponsored, the sponsorship affects the outcome of the research in a way that is more favorable to the sponsor than independent research.[99] There is also evidence that sponsors use contractual provisions to control the design and reporting of research that they sponsor.[100] This means that adverse

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[97] Professor Patterson argues that *Daubert* conflates at least two important science-related problems that can afflict scientific evidence—bias on one hand and whether the testimony is actually scientific on the other. *See* Mark R. Patterson, *Conflicts of Interest in Scientific Expert Testimony*, 40 WM. & MARY L. REV. 1313 (1999). While the *Daubert* test could be read to encompass both concerns, it is applied narrowly in ways that generally consider only whether testimony is based on research that is testable or capable of validation, with almost no attention to the need to identify bias in the underlying research. This is an important oversight in the screening of scientific evidence since cross examination of the witness who relies on the research will not necessarily uncover blatant conflicts and sources of bias that affected the original researcher in conducting the research.

[98] *See* Michael J. Brennan, *Square Pegs and Round Holes: Application of the "Best Scientific Data Available" Standard in the Endangered Species Act*, 16 TUL. ENVTL. L.J. 387, 410 (2003); *see also* Daniel T. Hornstein, *Accounting for Science: The Independence of Public Research in the New Subterranean Administrative Law*, 66 LAW & CONTEMP. PROBS. 227, 243 (2003).

[99] *See supra* note 79 and accompanying text.

[100] *See, e.g.*, Frank Davidoff, *Between the Lines: Navigating the Unchartered Territory of Industry-Sponsored Research*, 21 HEALTH AFFAIRS 235 (2002); Bruce M. Psaty & Drummond Rennie, *Stopping Medical Research*

results might be suppressed or under-reported, while positive results might be presented in ways that overstate the positive findings. Both the IQA and *Daubert*, however, tend to ignore these important sources of bias in scientific research.[101]

One reform to redress this research "bias" problem is to supplement the "reliability" tests of *Daubert* and the IQA with a conflict disclosure requirement. The scientific community uses conflict disclosures to require disclosure not only of the sources of funding, but the types of sponsor influence—like contractual power to suppress adverse results or alter the written report of the findings—that might affect the rigor of the study. When employed by regulators and courts in a legal setting, such expanded conflict disclosures would require scientists who offer testimony or research to disclose all contractual and related constraints that could bias or constrain their work.[102] Similarly, scientists who are employees of sponsors would be required to disclose the extent of sponsor influence over the design, methods, and reporting of their research. When the testimony or evidence is not being offered by

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to Save Money: A Broken Pact with Researchers and Patients, 289 J. AM. MED. ASS'N. 2128 (2003); Drummond Rennie, *Fair Conduct and Fair Reporting of Clinical Trials*, 282 J. AM. MED. ASS'N. 1766 (1999); Drummond Rennie, Veronica Yank, & Linda Emanuel, *When Authorship Fails: A Proposal to Make Contributors Accountable*, 278 J. AM. MED. ASS'N. 579 (1997); *see also* PAUL BRODEUR, OUTRAGEOUS MISCONDUCT: THE ASBESTOS INDUSTRY ON TRIAL (1985); DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY (2001); GARY MARKOWITZ & DAVID ROSNER, DECEIT AND DENIAL: THE DEADLY POLITICS OF INDUSTRIAL POLLUTION (2002); MORTON MINTZ, AT ANY COST: CORPORATE GREED, WOMEN, AND THE DALKON SHIELD (1985).

[101] *See, e.g.*, Frank Davidoff et al., *Sponsorship, Authorship and Accountability,* 345 NEW ENG. J. MED. 825 (2001), *available at* http://content.nejm.org/cgi/reprint/345/11/825.pdf; Jean Hellwege, *Medical Journals Crack Down on Industry Influenced Over Published Studies*, 37 TRIAL 71 (DEC. 2001); Uniform Requirements for Manuscripts Submitted to Biomedical Journals (October 2001) *at* http://www.icmje.org (last visited Mar. 2, 2004).

[102] This proposal was advanced by David Michaels and myself in David Michaels and Wendy E. Wagner, *Science and Government: Disclosure in Regulatory Science*, 302 SCIENCE 2073 (2003).

the original scientist, then those relying on the information would be required to work backwards to learn about potential conflicts and contractual constraints that might compromise the independence of the research.[103] Both in the courts and agencies, these conflict disclosures need not be used to disqualify research or testimony, but they could provide critical information about potential sources of bias that might otherwise be missed.

Adding this supplemental conflict disclosure will diminish the severity of several of the adverse side effects currently experienced under *Daubert* and the IQA. Most significantly, it offers a much more focused method for assessing the objectivity of research and the corresponding expert testimony than the amorphous *Daubert* test.[104] This more focused approach to evaluating research and testimony should also help counteract the ability of well-financed, private parties to use *Daubert* and the IQA exclusively to their advantage. A detailed conflict disclosure policy imposes a speed bump on *all* research. without requiring an outside, sophisticated advocate to intervene. The conflict disclosure requirement could even provide some protection against harassment of independent scientists who are most deserving of protection from the current abuses of process.

CONCLUSION

Daubert has not been without its problems. These problems are instructive as the agencies implement the IQA, a law that imposes a complaint process similar to *Daubert* on information disseminated by federal agencies. This commentary explores some of the adverse side effects that could arise in importing a *Daubert*-like test to the agencies and suggests two straightforward reform proposals that begin to counteract these problems.

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[103] *See id*.

[104] *See also* Patterson, *supra* note 97, at 1366-86.