

# ***Truth and Science Betrayed: The Case Against the Information Quality Act***

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## ***Introduction***

This report takes a critical look at the Data Quality Act – or, as it has been renamed by the Office of Management and Budget (OMB), the Information Quality Act (IQA) – a two-paragraph appropriations rider passed in 2000 that was ostensibly designed to ensure the quality of information disseminated by federal agencies. Disgruntled industries have used the Act as an end run around well-established procedures for promulgating rules to improve air quality, clean up toxic waste sites, and protect children and wildlife from pesticide residues. Indeed, unless these abuses are checked, the IQA may well prove the most destructive half-page of law that most people do not know is on the books.

As the pace and scope of IQA petitions challenging critical environmental, health, and safety information and policies steadily increase, Dr. John Graham, director of OMB's Office of Information and Regulatory Affairs (OIRA), who presides over government-wide IQA implementation, continues to defend the broadest possible interpretation of these provisions. Dr. Graham is a strong proponent of the Act precisely because of its potential to enhance OMB's bureaucratic power and to serve as an effective tool for the Administration's deregulatory agenda.

A serious look at the statute, and the ways it has been used since its enactment, reveals that the IQA provides a redundant, yet resource-intensive, layer of review – one that is heavily tilted toward use (and misuse) by regulated industry. The opportunity costs associated with responding to abusive petitions are unclear. Agencies routinely take months to respond to requests, and they ultimately deny most petitions. In an administration where economic efficiency ranks as a top regulatory priority, the allocation of scarce agency resources to responding to redundant and extra-procedural IQA petitions in the name of good “information” is especially duplicitous. In order to return the resources currently diverted from other, urgent priorities, and for all the reasons discussed in this report, the IQA must be repealed.

We begin by describing the IQA, providing background on its tobacco industry-based origins and the initial rationales

for its enactment. These suspect origins provide Exhibit 1 in the case against the IQA. The report then explains why the IQA was a bad idea at the time of its enactment, because it was a solution in search of a problem, layered on top of time-tested mechanisms already in place for the correction of errors in information. This redundancy provides Exhibit 2 in the case against the IQA.

The report next explores how OMB's implementation of the IQA, as well as its misuse by regulated industries, transform the Act from one that aims to correct factual errors in materials disseminated by the government into an overarching, all-encompassing deregulatory directive that threatens to disrupt longstanding health and safety programs. OMB has interpreted the IQA in ways that do violence to its inauspicious language, finding broad grants of authority to require extensive peer review of regulatory information where none exist. Particularly problematic is OMB's application of the unique standards for risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (SDWA) to all environmental, health, and safety risk information covered by the IQA. OMB's audacious assertion of authority that was not conferred by Congress is Exhibit 3 in the case against the IQA.

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Specific requests filed under the IQA illustrate ways the Act has been misused by industry petitioners to challenge agency policies, decisions, and the treatment of uncertainty in order to circumvent the protective mandates in existing environmental, health, and safety statutes and to limit public access to crucial health and safety information. Although the report does not attempt to provide an analysis of every petition filed, the examples discussed ably exemplify the mischief that the Act has caused. Petitions are routinely filed in attempts to 1.) delay already overdue regulatory actions that have already complied with extensive opportunities for public participation and comment; 2.) exclude or withdraw inconvenient information entirely rather than correct incorrect information; 3.) correct policy decisions on the part of agencies empowered to make such decisions; 4.) bypass existing statutory procedures for regulatory decisionmaking; 5.) prevent agency action in the face of incomplete, rather than poor quality, information; 6.) obtain underlying data without complying with established Freedom of Information Act request procedures; and 7.) sidestep the courts by attempting to discredit information that corporate defendants have either been unable to successfully exclude at trial, or information that they would prefer not to encounter in future litigation. These examples of misuse of the Act constitute Exhibit 4 in the case against the IQA.

Finally, as the report explains, OMB failed to subject the IQA to its own test for regulatory effectiveness. OMB has not even quantified the costs of the policies it has invented to expand its authority over regulatory actions, let alone weigh those costs against the benefits through a quantitative cost-benefit analysis. As this report details, however, implementation of the IQA and its guidelines by federal agencies comes at enormous cost, never analyzed by OMB, and its benefits are questionable at best. Without an understanding of the IQA's costs, it is impossible to know at what expense the IQA comes, and impossible to know whether the diversion of resources from other programs is justified by any corresponding increase in information quality. Failure to pass (or even take) OMB's cost-benefit test provides Exhibit 5 in the indictment of the IQA.

The findings of this report provide a compelling case for repeal of the IQA. The legitimate need for a mechanism to address correction of factual errors was already met by pre-existing agency processes. The IQA, with its vague terms that were never debated in Congress but that have been interpreted expansively by OMB, is neither a necessary nor an appropriate response to a genuine desire to ensure that federal agencies disseminate accurate information. Rather, the perils of the IQA emerge clearly in light of the ways it has been used thus far to challenge the underpinnings of

regulations to protect health, safety, and the environment. The damaging effects of the Act must be made known, and the public interest community must continue to aggressively monitor and critique the most egregious petitions both to encourage agencies to reject these challenges to our environment, health and safety and to continue to build the case against the IQA.

## *The Purpose and Origins of the Information Quality Act*

In late 2000, Congress quietly enacted the IQA as a two-paragraph rider buried in an appropriations bill.<sup>1</sup> The law required OMB to promulgate “policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information . . . disseminated by Federal agencies.”<sup>2</sup> The agencies were in turn required to promulgate their own guidelines and establish procedures under which affected persons could “seek and obtain correction of information . . . that does not comply with the guidelines.”<sup>3</sup> The full text of the Act appears as Appendix A to this Report.

There were no hearings on these provisions and no one referred to them during the debate on the larger bill. The terse statutory language and absence of legislative history support the conclusion that Congress did not intend the IQA to serve as a kind of “uber statute” providing OMB with the overarching authority to deflect agencies from their statutory responsibilities to implement the country's health, safety and environmental laws.

In February 2002, OMB issued guidelines to agencies regarding how to implement the Act.<sup>4</sup> Even though the only explicit congressional directive was a mandate to issue guidelines on agency implementation of data correction procedures, OMB read these ministerial responsibilities extremely broadly, creating out of whole cloth a lengthy set of guidelines defining terms, mandating that agencies adopt or adapt standards for risk information used for purposes of the Safe Drinking Water Act for all health, safety, and environmental information, providing assumptions about peer review, providing criteria for handling information deemed “influential,” and creating an agency appeal procedure that is nowhere mandated in the statute. After seeking public input, agencies adopted their own guidelines to implement the rider.<sup>5</sup>

The IQA was sponsored by Representative Jo Ann Emerson (R-8<sup>th</sup> MO), but was the brainchild of Jim Tozzi, a former OMB-official who parlayed an intimate knowledge of the regulatory process and a willingness to advance the interests of risk-producing corporations in the tobacco,

plastics, and paper industries into a multi-million dollar conglomerate of consulting firms and tax-exempt nonprofit “public interest” groups. Tozzi frequently brags that he was the author of the Act and has also publicly acknowledged broad industry support for its provisions, which industry values as an effective mechanism for slowing or stopping expensive regulation.

Tozzi began his public career as a senior official at OMB, departing government in 1983 to form a consulting company named Multinational Business Services, Inc. (MBS).<sup>6</sup> Over the last two decades, his clients have included a broad spectrum of industries that share a combined interest in reigning in regulatory agencies, including tire and auto manufactures, the lead industry, the plastics industry, the pharmaceutical industry, pollution equipment manufacturers, and, most lucrative of all, the tobacco industry.

In 1985, Tozzi also created a non-profit “think tank” called Federal Focus, Inc.<sup>7</sup> In 1991, he hired former Occupational Safety and Health Administration (OSHA) head Thorne Auchter to head an “affiliate” of Federal Focus, called the Institute for Regulatory Policy (IRP).<sup>8</sup> Its first order of business was to prepare a lengthy report recommending that President George H.W. Bush promulgate an Executive Order specifying requirements for the preparation and peer review of risk assessments prepared by regulatory agencies.<sup>9</sup> After Congress passed the 1995 Paperwork Reduction Act Amendments and the 1996 Congressional Review Act, Tozzi created the Center for Regulatory Effectiveness (CRE) to serve as a “shadow OMB,” using the internet to “monitor and track proposed rules before they are issued, to ensure that Congress has all the necessary and pertinent information to perform an expedited review and to evaluate its potential options, and to establish appropriate forums for meaningful comment by the public and the affected industries.”<sup>10</sup>

Although he represented a wide variety of industries, Tozzi’s most prominent client was the tobacco industry, then engaged in a war of attrition with EPA over the release of a 1990 draft EPA risk assessment concluding that environmental tobacco smoke (ETS) was a known human carcinogen. The companies were motivated not because EPA had the power to regulate tobacco smoke in indoor environments, but because of the potential for this new information to inspire other governmental and private entities to take action banning smoking in public places.<sup>11</sup> Tozzi became the recipient of the first of many \$300,000 “grants-in-aid” from Philip Morris for the purpose of assembling a group of industries that were similarly threatened by regulatory action based on EPA’s risk assessments.<sup>12</sup> A February 3, 1992 memorandum mentions “Tozzi and Auchter’s Institute for Regulatory Policy” in connection with

a project aimed at urging “utility, paper, and diesel industry groups to support a new administration policy on risk assessment which would prevent agency disseminations of health risks which cannot be supported by objective science.”<sup>13</sup> When EPA released its final risk assessment confirming the conclusion in its draft that ETS was a known human carcinogen,<sup>14</sup> Tozzi’s role then changed to helping the tobacco industry implement a strategy for covertly influencing the scientific community’s assessment of ETS risks by attacking EPA and emphasizing other risk-producing activities.<sup>15</sup>

In light of the ETS experience, Tozzi sought other methods for challenging the scientific basis for agency actions outside the formal rulemaking process. The ETS risk assessment that Philip Morris had spent millions of dollars to stymie was not a formal regulation, but it did have a profound impact on the fortunes of the tobacco industry because of the impact that it was having on other entities. The advent of the worldwide web and the growing practice of federal agencies of posting agency reports, risk assessments, and submissions made a vast amount of information available to the public. As a result, the dissemination of information by federal agencies could pose for any industry the same economic threat that EPA’s risk assessment posed for the tobacco industry.

The 1995 Paperwork Reduction Act included language relevant to data quality. One of the purposes of the Act was to “improve the quality and use of Federal information.”<sup>16</sup> The Act required OMB’s OIRA to “develop and oversee the implementation of policies, principles, standards, and guidelines to . . . apply to Federal agency dissemination of public information,” including “statistical information.”<sup>17</sup> Each federal agency had a responsibility for managing information resources in a way that would, among other things, “improve the integrity, quality, and utility of information to all users within and outside the agency.”<sup>18</sup> Agencies were required to “regularly solicit and consider public input on the agency’s information dissemination activities” and “provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products.”<sup>19</sup>

Tozzi apparently interpreted the injunction to “consider public input” as a requirement for agencies to establish procedures for public challenges to the quality of agency-disseminated information.<sup>20</sup> This interpretation of the statute that was exceedingly ambitious given the fact that it was directed exclusively to internal agency procedures and practices, but Tozzi was prepared to promote that interpretation aggressively with OMB. Tozzi’s problem was that the statute did not require OMB or any individual agency

to take any particular implementing action within any given time frame.

In November 1997, CRE prepared a “Draft Outline for Legislation on Integrity and Dissemination of Federal Information” for distribution to CRE members. The document presented in a very concise fashion Tozzi’s vision for what would eventually become the Information Quality Act. In particular, the outline suggested that the “congressional findings” of the proposed legislation would stress the “need for Congress to act” and would conclude that “information by itself can have large impacts without any regulation that is available for administrative or Congressional review.”<sup>21</sup> An additional finding stressing “the importance of presenting information supporting regulations in a complete and consistent manner” suggested that CRE hoped from the outset that the procedural provisions of the Information Quality Act would apply to rulemaking as well as less formal vehicles for information dissemination.<sup>22</sup>

According to CRE’s plan, oversight of agency compliance would be provided by “administrative review” of complaints with appeals to a “designated agency official.”<sup>23</sup> In addition, the statute would provide for “external independent expert review” by persons possessing the “relevant expertise.”<sup>24</sup> Reviewers would be selected for “representativeness (not balance)” and would be chosen to avoid “conflicts of interest.” An additional layer of review would be provided by OMB or the White House Office of Science and Technology Policy in “especially significant situations.”<sup>25</sup> Judicial review would be available to “require conformance to principles, or withdraw or delete.”<sup>26</sup> The requirements would be applicable to all governmental personnel, contractors and studies funded by the federal government.<sup>27</sup>

One strategy for getting the federal government to put a desired policy into place is to provide a strong signal of a congressional desire to implement a program in an appropriations bill or its attendant legislative history. Tozzi had attempted to persuade congressional allies to include data quality language in the FY 1999 appropriations rider, and he later reported to Philip Morris that language to that effect had been included in the House Report on the bill.<sup>28</sup> The House Report had “urge[d]” OMB by September 30, 1999 to “develop, with public and Federal agency involvement, rules providing policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by non-Federal entities with financial support from the Federal government, in fulfillment of the purposes and provisions of” the 1995 amendments to the Paperwork Reduction Act.<sup>29</sup> The House report language further provided that OMB should require agencies to develop their own rules

governing data quality that, among other things, would “contain administrative mechanisms allowing affected persons to petition for correction of information which does not comply with such rules.”<sup>30</sup> The House report captured the essence of the Information Quality Act that Congress would enact two years later, including especially the emphasis on quality, objectivity, utility and integrity in defining data quality and the petition process. That language, however, did not make it into the text of the FY 1999 appropriations bill or the Conference Committee report. Despite this omission, Tozzi argued that the Conference Committee had “incorporated by reference” the language in the House report.<sup>31</sup> There is no indication whatsoever in the Conference Report that this interpretation was correct, and Tozzi found that his lobbying efforts to get the Clinton Administration to implement these goals was an uphill battle.

In mid-December 1998, Tozzi circulated a “proposed work agenda for 1999” that included three projects for Philip Morris.<sup>32</sup> One was “Data Access/Data Integrity,” which included such tasks as “Development of OMB regulations” and “Development of agency regulations.”<sup>33</sup> Philip Morris agreed to fund part of the data quality initiative,<sup>34</sup> with other companies providing additional contributions. Later that month, Tozzi’s liaison at Philip Morris submitted a contract request form specifying that MBS would “work with federal agencies to encourage implementation of recently enacted data access and data quality provisions” and would be paid \$65,000 per month not to exceed \$780,000 for the year.<sup>35</sup> An agenda for a meeting held on June 30, 1998 in New York on “Data Integrity and Data Sharing” suggests various strategies for reaching industry goals for data access and data quality. Among the suggested “Actions to Provide Greater Authority to OMB” was “Legislative Amendments: Paperwork Reduction Act.”<sup>36</sup>

In mid-1999, Tozzi began to explore opportunities for “scientific cooperation” between Philip Morris and federal agencies on the ETS issue.<sup>37</sup> One possibility mentioned in a lengthy memorandum on that topic was a project to provide assistance to the National Toxicology Program in drafting the Data Quality Guidelines that Tozzi believed were required by the Paperwork Reduction Act.<sup>38</sup> MBS would “offer its assistance to the agency in drafting conforming regulations which will be required once OMB issues its own Data Quality rule,” and special emphasis would be placed on “the petition process for correction of agency information which does not meet the standards laid out in the regulations.”<sup>39</sup> MBS would then sponsor a public workshop on the proposed regulations, and “Philip Morris scientists would be among the invited participants.”<sup>40</sup> Once the procedures were in place, “it would be possible to petition the agency regarding the

quality of the ETS information which it is disseminating.” If the agency denied the petition, “this would serve as the basis for a later legal challenge.”<sup>41</sup>

Tozzi decided to provide OIRA with a “Model Notice of Proposed Rulemaking on Data Quality” that could serve as a vehicle to jump-start what Tozzi hoped would be a new OMB data quality initiative.<sup>42</sup> Before sending the model data quality rule to OMB, however, Tozzi circulated it to Philip Morris for input by Philip Morris scientists.<sup>43</sup> Tozzi also posted his draft data quality notice of proposed rulemaking on CRE’s website and solicited comments from the general public.<sup>44</sup> Philip Morris was one of several companies that submitted comments to Tozzi’s website.<sup>45</sup>

It soon became clear, however, that the Clinton Administration’s OMB had no interest in Tozzi’s rather officious attempt to prod it into unnecessary action. Undeterred, Tozzi began at the outset of the 2000 election year to press the initiative further, hoping that a new administration would likely be more sympathetic if the Republican Party regained control of the White House. In a letter to Philip Morris, Tozzi laid out a schedule for implementing this strategy.<sup>46</sup> CRE would initiate discussions with industry stakeholders in February and with federal agencies in July. In December, the industry group would initiate discussions with the “Transition Team of the New Administration” in anticipation of presenting new regulations to the new OMB by February, 2001. By July, 2001 OMB would have adopted regulations or CRE would begin “initiation of judicial action.”<sup>47</sup>

Tozzi could, of course, greatly enhance his chances of success, whether or not the Republicans won the election, by persuading a sympathetic congressperson to include in the appropriations bill for FY 2001 language explicitly requiring OMB and the regulatory agencies to promulgate data quality guidelines and providing for a petitions process. Tozzi did exactly that. He persuaded Rep. Jo Ann Emerson (R-Mo.) to insert language almost identical to the language in the House Report for the 1999 appropriations act into the language of the 2001 appropriations bill itself.<sup>48</sup> Sandwiched between a property acquisition appropriation for the Gerald R. Ford Museum and a provision relating to the nonforeign area cost-of-living allowances,<sup>49</sup> the so-called Information Quality Act came into being.

President Clinton signed the appropriations bill on December 21, 2000. Armed with statutory language, rather than a dubious argument based on a House Report, and looking forward to a much more sympathetic hearing from a new Administration, Tozzi proceeded forward on almost precisely the schedule he had recommended to Philip Morris and his other clients at the end of February the preceding year. Tozzi probably did not anticipate, however, the enthusiasm with which the new Administration would embrace his brainchild. As these suspicious origins reveal, the IQA was developed at the behest of industry by an individual who founded an organization that now routinely files petitions under the Act.<sup>50</sup>

Tozzi and his industry clients pushed for data quality legislation because of what they perceived as a worrisome movement towards “regulation by information,” whereby government agencies provide access to information on the activities of regulated entities through the Internet and other media.<sup>51</sup> These concerns are best exemplified by the tobacco industry’s concerns, outlined above, that OSHA, other government entities, and even private entities would take measures to ban smoking in public places as a result of the release of EPA’s risk assessment on second-hand smoke.

According to CRE’s Legislative Working Papers maintained on its website, “[f]ederal information dissemination has the potential to act as a type of indirect regulation by persuading citizens and non-Federal political entities to take political action based on such information.”<sup>52</sup> Tozzi described the dissemination of information through the Internet as a “backdoor Federal Register,” and he proposed the IQA to ensure that risk assessments and other

agency disseminations would not improperly influence the regulatory process.<sup>53</sup>

As detailed above in Tozzi’s legislative outline for what would become the IQA, the Information Quality Act legislation was also viewed as a means to attack new or cutting edge science, assumptions about uncertainty, and policy judgments that are unfavorable to industry.<sup>54</sup> Directives to agencies regarding how to regulate in the face of uncertain or incomplete information are contained in our health, safety, and environmental laws, but direct attempts to weaken these statutes as well as efforts to pass legislation requiring peer review of regulatory information and mandating other procedural requirements for agency decisionmaking have

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failed in recent years.<sup>55</sup> Thus, the IQA was viewed as a necessary vehicle to challenge the preventative assumptions set forth in our environmental, health, and safety laws when attempts to take on those statutes directly or to impose other procedural hurdles have failed.

Finally, the passage of information quality legislation was seen as a means to remedy perceived data quality problems within the federal government, particularly with respect to the science that supports protective regulations.<sup>56</sup> Yet, as discussed *infra*, there is very little evidence that poor-quality science has been used to support regulation.

Thus, the goal of the IQA and the intent of its drafters was not the benign purpose of providing a mechanism for correcting typographical errors, numerical transcription problems, or inaccurate weblinks; after all, there are existing mechanisms within the agencies to deal with such problems. Rather, the statute was designed as a back door tool for disputing assumptions about acting in the face of uncertainty and challenging unfavorable policy judgments and decisions made pursuant to environmental, health, and safety statutes. The IQA's suspicious industry-based origins and its true deregulatory purposes constitute Exhibit 1 in the case for repeal.

## **A Solution in Search of a Problem**

At the time of its enactment, there was not, by any stretch, a consensus that the IQA was necessary. There was no evidence that existing mechanisms for the correction of information were inadequate, nor was there any extensive evidence that agency information was flawed and in need of correction. In addition, the lack of any debate, hearings, or discussion regarding the legislation make it impossible to suggest that members of Congress had reached any type of consensus that the legislation was necessary. The use of the best available data and analysis by the federal government is crucial, especially when the government is disseminating information to the public. However, a statute that purports to achieve such a goal when there is no proven need and where existing mechanisms are in place to ensure reliable information is, at best, redundant and, at worst, another tool to limit public access to critical information and to stymie efforts to protect health, safety, and the environment.

Opponents of the IQA have long argued that federal agencies have ample existing mechanisms in place to ensure the quality of information they disseminate and to provide the public with a vehicle for seeking the correction of information that is in error. Indeed, the OMB guidelines acknowledge that “in accordance with OMB Circular A-130, agencies already have in place well-established information

quality standards and administrative mechanisms that allow persons to seek and obtain correction of information that is maintained and disseminated by the agency.”<sup>57</sup> The Guidelines state further that “agencies may rely on their implementation of the Federal Government’s computer security laws . . . to establish appropriate security safeguards for ensuring the ‘integrity’ of the information that the agencies disseminate.”<sup>58</sup>

In its own IQA Guidelines, EPA described the extensive pre-existing procedures it had in place to ensure information quality. EPA’s eight-step Agency-wide Quality System “helps ensure that EPA organizations maximize the quality of environmental information, including information disseminated by the Agency.”<sup>59</sup> This system extends to EPA contractors and other government agencies receiving assistance from EPA through interagency agreements.<sup>60</sup> Furthermore, to ensure that their scientific assessments are competent, EPA and other agencies already had mechanisms in place for both internal and external peer review.<sup>61</sup> For example, science advisory boards are commissioned under the Clean Air Act to conduct reviews of the science underlying clean air standards and under the Federal Insecticide, Fungicide, and Rodenticide Act to review the science behind pesticide registrations, and as CPR Scholar Wendy Wagner (a professor at the University of Texas School of Law) explains, this involvement by scientific advisers “generally reinforces the agencies’ scientific competency.”<sup>62</sup> EPA also has an established mechanism for error correction. Through this mechanism, called the Integrated Error Correction Process, members of the public can notify EPA of potential errors in data disseminated by the agency, including data on EPA’s website.<sup>63</sup> This process appears to be working well, and has received few reported errors in agency information.<sup>64</sup>

Other federal agencies also had pre-existing mechanisms to ensure the accuracy of information they disseminate. For example, officials from the Department of Health and Human Services (HHS) and the Federal Aviation Administration discussed their respective agencies’ existing, extensive data quality mechanisms at a National Academy of Sciences workshop on Data Quality held in April, 2002,<sup>65</sup> and HHS IQA guidelines describe the agency’s pre-existing peer review processes, adherence to existing quality control procedures and standards, and reviews by agency experts as vehicles for ensuring the quality and accuracy of the information the agency disseminates.<sup>66</sup>

In addition to the fact that there existing mechanisms in place for the correction of information, there is very little evidence that poor-quality science has been used to support regulation.<sup>67</sup> According to Professor Wagner, “despite the

thousands of public health and safety regulations promulgated annually, there are surprisingly few examples of EPA using unreliable science or using science inappropriately to support a final regulation.<sup>68</sup> Studies commissioned by the EPA over the last decade including *Strengthening Science at the U.S. Environmental Protection Agency*, have identified very few problems with the quality of agency science.<sup>69</sup> These conclusions also extend to the use of science at other agencies including the Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA).<sup>70</sup> In addition, in proposing to mandate that federal agencies conduct extensive peer review of information they disseminate under the auspices of the IQA in the fall of 2003, OMB failed to articulate examples of current regulations that are flawed because they did not undergo peer review.<sup>71</sup> Indeed, Wagner's analysis reveals that any "bad science" problem that does exist involves information produced by regulated industry and not by the agencies themselves.<sup>72</sup> Moreover, even the critics of agency science tend to argue not with the science itself but with the protective and precautionary use of science within the existing statutory framework.<sup>73</sup>

As noted previously, there was no legislative debate, hearing, or discussion regarding the IQA and there is little evidence that anyone in Congress other than its sponsors even knew of the Act's existence.<sup>74</sup> Thus, there was absolutely no legislative consensus that this statute was necessary. Moreover, the fact that the legislation was contained in an appropriations rider sandwiched between two unrelated provisions is further evidence that it was not a piece of legislation that had the support of Congress.

Finally, agency decision-making with respect to rulemaking has since 1946 been governed by procedures set in place by the Administrative Procedure Act (APA). Under the APA, agencies are required to provide the basis for proposed rules, including any scientific basis, to provide notice and an opportunity for comment, and to respond to those comments when a final rule is adopted. The involvement of the courts in reviewing rulemakings and ensuring that the public has an opportunity to comment adds an additional layer of oversight of agency dissemination of information.<sup>75</sup> As CPR Scholar Sidney Shapiro (a professor

at Wake Forest University School of Law) explains, with these protections in place for regulatory information used in the rulemaking process, the IQA is redundant.<sup>76</sup>

Thus, before any guidelines were issued or the first challenge under the new law had been filed with a federal agency, there was little reason to think the statute was needed.

The lack of proven need for the statute given existing mechanisms for ensuring data quality, the evidence that agency science is of generally good quality, and the lack of Congressional consensus in support of the Act combine to form Exhibit 2 in the case for repeal of the IQA. The law's industry-based, anti-regulatory origins and vague language coupled with the lack of proven need for the Act gave environmental and public health advocates every reason to think that the IQA would be used to stifle essential protections, and they braced themselves for the

perils implementation might bring.

### **OMB's Grand Implementation Scheme**

In the two years since IQA petitions began to stream into federal agencies, industry and trade organizations have expansively interpreted the rider, arguing that it provides an open-ended remedy to them for government information that they believe to be of insufficient quality. Indeed, industry groups have used the new procedures in a strategic manner to slow, or even stop, the release of information that is embarrassing or politically inconvenient to them. The vague nature of the legislation and OMB's efforts to fill that void with its guidelines invite such challenges. As a result, the Act has become a vehicle for industry and their allies to circumvent the mandates set forth in our substantive environmental, health, and safety laws and to challenge basic assumptions about protection and precaution that are established in those statutes. Rather than seeking the correction of factual information, the majority of petitioners are seeking to challenge policy decisions and judgments.

The law has forced agencies to devote considerable time, effort, and resources to responding to these petitions. The only way an agency can avoid these burdens is to decline to make public information about the environmental and health and safety risks, and agency responses to some petitions indicate that the law has made agencies much more cautious

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about claiming responsibility for the dissemination of certain information.

The vague wording and lack of definitions in the IQA invited OMB to interpret the Act to serve its own deregulatory agenda. Prior to joining the Bush Administration, OIRA Administrator Dr. John Graham founded and led the Harvard Center for Risk Analysis,<sup>77</sup> an industry-funded think tank that continues to produce much of the anti-regulatory data and analysis upon which the Bush Administration relies.

The guidelines issued by OMB under the IQA in February 2002 are much broader than the language of the statute allows. Even more disturbing, the guidelines create mandates on federal agencies that are found nowhere in the language of the Act, nor could they be found in

the non-existent legislative history for the Act. Moreover, OMB has used the IQA as the basis for mandating government-wide peer review procedures, despite the fact that the IQA makes no mention of peer review. Indeed, Congress has explicitly rejected attempts to pass legislation mandating government-wide peer review. The OMB guidelines and its rogue peer review proposal are Exhibit 3 in support of the case for repeal of the Act.

### ***Broad Definitions***

The OMB guidelines set out to define many of the terms that are used, but not defined, in the Act itself. The Guidelines define “information” in a way that includes almost anything disseminated by the agency except for “someone’s opinion[s],” thus taking a broad interpretation that extends well beyond data and facts.<sup>78</sup> As will be evidenced by a review of some of the petitions filed to date, petitioners have taken full advantage of this broad definition to take issue with government management decisions and standards, risk assessments, and assumptions in models predicting harmful effects.

### ***Borrowing Restrictive Language***

In its guidelines, OMB established additional data quality requirements for information determined by the agency to be “influential,” meaning that the information “will have or does have a clear and substantial impact on important public policies or important private sector decisions.”<sup>79</sup> With respect to this “influential” category of information, the guidelines require that the information be presented with sufficient

transparency to ensure that qualified third parties can reproduce it.<sup>80</sup> In addition, OMB established more onerous and detailed requirements for analyses of risks to human health, safety and the environment maintained or disseminated by agencies.<sup>81</sup> With respect to this category of risk information, the OMB guidelines require that agencies “adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the

Safe Drinking Water Act Amendments of 1996.”<sup>82</sup> Nowhere does the IQA suggest or require that such separate categories of information be established, or that such categories be subjected to more rigorous data quality requirements. Nevertheless, this requirement for risk information had been on John Graham’s agenda since the beginning of his tenure with the Bush Administration, and the IQA

became the vehicle that Graham could eventually use to impose such a requirement. In a September 20, 2001 Memorandum from Graham to the President’s Management Council, Graham recommended “that each agency consider adopting or adapting [SDWA] standards for judging the quality of scientific information about risk it uses and disseminates.”<sup>83</sup> Graham ultimately used the IQA guidelines as the vehicle for making this recommendation mandatory despite the lack of Congressional authority for such a requirement in the IQA itself.

The SDWA standards that OMB seeks to impose more broadly on all agencies’ risk information under any statutory framework apply specifically to national drinking water regulations for public water systems. In particular, the standards establish the minimum quality of scientific data on which EPA can rely in setting maximum contaminant level goals and maximum contaminant levels by requiring that “in carrying out this section, and, to the degree that an Agency action is based on science,” EPA “use the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices” and “use data collected by accepted methods or best available methods . . .”<sup>84</sup> In addition, the SDWA standards indicate how EPA is to describe that data to the public by requiring that EPA provide specific information including information about populations addressed in risk estimates, significant uncertainties identified in the studies, and identification of studies relevant to estimates of public health effects.<sup>85</sup> While the SDWA is narrowly drafted to cover “science and supporting studies” that EPA relies upon when an “action is

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*The guidelines issued by OMB under the IQA in February 2002 are much broader than the language of the statute allows. Even more disturbing, the guidelines create mandates on federal agencies that are found nowhere in the language of the Act, nor could they be found in the non-existent legislative history for the Act.*

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based on science,” the IQA is addressed to “information (including statistical information) disseminated by Federal agencies.” The term “information” encompasses more than “science and supporting studies,” and the practices and methods that govern the accuracy and reliability of scientific information may or may not be equivalent to the practices and methods that ensure accurate and reliable information that is not strictly scientific in nature. As the Natural Resources Defense Council (NRDC) has explained, “[b]y refusing to acknowledge the uncertainties that make risk assessment more of an art than a science, OMB uses the Information Quality Act to advance its agenda of pushing agencies to perform *quantitative* risk assessment, not mere *qualitative* analysis, creating the unfortunate illusion that decision-makers can make judgments on how to apply the precautionary principle and other statutory mandates on the basis of precise, ‘factual,’ numerically-based data.”<sup>86</sup> Forcing such a requirement on agencies for all risk information they disseminate would “effectively repeal[] crucial provisions of the Clean Air Act, Clean Water Act, and other EPA authorizing statutes, which deal with scientific uncertainty in a very different manner.”<sup>87</sup> Specifically, because of the large gaps in data on the quantity, chemical characteristics, and toxicology of even the most common pollutants, Congress passed statutes ensuring that both qualitative and quantitative information be used to inform the regulatory process.<sup>88</sup>

There is absolutely no indication from the text of the SDWA or its legislative history that Congress “adopted a basic standard of quality for the use of science in agency decisionmaking” when it enacted the SDWA, as OMB claims.<sup>89</sup> To the contrary, Congress indicated the nature of the evidence on which an agency can rely in its own substantive mandates, and these mandates are different, and less prescriptive, than the one Congress used under the SDWA. The Occupational Safety and Health Act, for example, only requires the Occupational Safety and Health Administration (OSHA) to use the “best available” scientific evidence in promulgating workplace standards for toxic materials or harmful physical agents.<sup>90</sup> Similarly, the Clean Air Act does not stipulate any specific scientific methodology for estimating risks, but instead simply requires EPA to use the “latest scientific knowledge,” as reflected in air quality criteria documents, in setting the National Ambient Air Quality Standards.<sup>91</sup> In fact, in *Whitman v. American Trucking Assns.*, industry parties asked the Supreme Court to announce that the Clean Air Act requires a quantitative risk assessment when EPA sets National Ambient Air Quality Standards under the Act. The Court declined to impose such a requirement.<sup>92</sup> Likewise, science-based decisions under the Clean Water Act, the Toxic Substances Control Act, and the Endangered Species Act do not embody the highly prescriptive risk

assessment principles announced in the Safe Drinking Water Act Amendments.<sup>93</sup> Even in the absence of an explicitly less prescriptive mandate in the statute they administer, agencies are not bound by the prescription for the quality of scientific data set forth in the SDWA, one subject-specific statute.

While most agencies including those that conduct the majority of risk assessments including the EPA, Department of Health and Human Services, OSHA, FDA, and Centers for Disease Control, have determined to “adapt” these SDWA principles rather than to “adopt” them in their entirety, OMB’s decision to include these provisions goes beyond any colorable interpretation of the mandate set forth in the IQA and demonstrates its interest in attempting to raise the burden of proof for agencies beyond that set forth in their substantive mandates. Indeed, several agencies have acknowledged that the SDWA standards may not apply in the context of certain information they disseminate, and these agencies have attempted to adapt their guidelines accordingly. For example, the guidelines of the Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry state that “[m]any of our actions are based on scientific experts’ judgments using available data, are essentially qualitative and do not lend themselves to the types of quantitative risk assessments contemplated by the SDWA principles. As a result, we have adapted the general principles for risk assessments from the SDWA to fit these situations.”<sup>94</sup> Similar language is found in the Food and Drug Administration’s guidelines.<sup>95</sup> EPA’s Guidelines make clear that the agency’s adaptation of SDWA principles must be “consistent with Agency statutes and existing legislative regulations.”<sup>96</sup>

In incorporating the provisions of the SDWA into the IQA guidelines, OMB is subtly attempting to force onto regulatory agencies a narrow view of regulation that Congress has written into one, arguably unique, statute. This requirement could lead to substantial harm to public health and the environment if it causes agencies to ignore the less prescriptive and more protective requirements of our environmental, health, and safety laws.

Predictably, industry is actively enlisting in OMB’s drive to force agencies into adopting the risk principles set forth in the outlier SDWA. Willfully ignoring the fact that: 1.) OMB’s guidelines direct agencies to “adopt or adapt” the SDWA principles; and 2.) EPA adapted, rather than adopted, the principles, industry advocates demand application of SDWA standards in their Requests for Correction. For example, a recent petition filed by the U.S. Chamber of Commerce seeking the correction of allegedly erroneous physical and chemical property information in EPA databases stated that “[t]he Guidelines require that influential

information concerning an analysis of risks to human health, safety, or the environment must meet the standard for risk assessments adopted by Congress in the Safe Drinking Water Act Amendments of 1996 (SDWA) that has been adopted governmentwide by OMB and adopted by EPA.”<sup>97</sup> While the statement is clearly erroneous, it demonstrates the pressures placed on EPA by industry to comply with such standards and the danger that agencies will begin to apply such standards in place of the more protective principles set forth in the substantive mandates governing the application of the particular information in question.

Other Requests for Correction have also chosen to blatantly disregard the clear language of OMB’s and EPA’s Information Quality Guidelines. A petition filed by nickel producers challenging the National Institutes of Health, National Toxicology Program’s 10<sup>th</sup> Report on Carcinogens listings of Nickel Compounds and Metallic Nickels made similar arguments that the listing fails to comply with the principles established in the SDWA, and should thus be corrected or withdrawn.<sup>98</sup> Another petition, filed by law firm representing a company made up of numerous petroleum and chemical companies opposed to the addition of a PCB-contaminated lake in Louisiana to the Superfund National Priorities List, demanded that EPA retract the proposed listing of the lake on the ground that EPA had not demonstrated that the analyses underlying its action comply with the SDWA principles.<sup>99</sup> These examples are a clear indication that petitioners will continue to force this interpretation upon federal agencies despite its lack of applicability outside of the context of the SDWA.

### *Peer Review*

The OMB Guidelines also provide a rebuttable presumption that information that has been subjected to formal, independent, external peer review will “generally be presumed to be of acceptable objectivity.”<sup>100</sup> Using its IQA Guidelines, OMB issued in September 2003 a set of prescriptive procedures for the conduct of peer review by federal agencies that would require an additional layer of review for a broad range of scientific information and assessments. The proposal was revised in April 2004 in response to criticism by environmental and public health advocates as well as scientific organizations. The *Final Information Quality Bulletin for Peer Review*, issued in December 2004, remains a concern because of its breadth and potential to delay the regulatory process.<sup>101</sup> The IQA says nothing about peer review, and efforts to impose such broad requirements across federal agencies have repeatedly failed in Congress throughout the last decade. Nonetheless, through its IQA Guidelines and associated bulletins, OMB has created this additional and potentially onerous burden

for broad categories of scientific information disseminated by federal agencies. While peer review of scientific and technical information supporting regulation is a part of our regulatory process in certain circumstances, including for example, EPA’s Clean Air Scientific Advisory Committee which reviews EPA’s National Ambient Air Quality Standards under the Clean Air Act, OMB’s broad mandate would seek to impose these processes in a manner that could result in delays for efforts to protect health and the environment.

Several petitions have already sought to invoke the peer review guidelines recently proposed by OMB. CRE’s recent petition challenging the proposed listing of diisononyl phthalate, a chemical used in plastics, on the Toxics Release Inventory (TRI) invokes the peer review guidelines and requests external peer review of the technical review underlying the proposal.<sup>102</sup> In response, EPA indicated that as part of an ongoing revision of the hazard assessment process (initiated before receipt of the petition), it had conducted an internal peer review and planned to subject the revised hazard risk assessment for the chemical to external peer review in accordance with its peer review policy and the Information Quality Guidelines.<sup>103</sup> Similarly, a recent petition filed by a law firm representing the National Paint and Coatings Association and Sherwin-Williams challenging information underlying a Model Rule for Volatile Organic Compounds (VOCs) in industrial coatings was accompanied by a separate request that the Model Rule be subjected to the specific peer review process prescribed in OMB’s recent bulletin.<sup>104</sup>

These recent requests indicate that the peer review procedures in OMB’s Bulletin will be invoked by industry to seek further delays in regulatory actions that affect them. While peer review may enhance agency evaluations in some cases, it is neither necessary nor appropriate in every case and should be restricted to those instances where it is already mandated as part of the regulatory process.

### *IQA Case Studies: Recipes for Delay*

With OMB’s Guidelines in hand, industry, trade organizations, and their allies (including Jim Tozzi, the self-described drafter of the Act) began to chart their strategy for filing petitions under the Act. A review of the petitions filed in the first two years reveals several disturbing trends. Not only has the Act been used by well-funded industry interests and their allies in an attempt to slow or halt the process of information dissemination by federal agencies in support of health, environmental, and consumer protections, as evidenced by the number of positions seeking complete withdrawal of information, but it has also been used to: 1.) challenge agency policy decisions and judgments rather than

the technical merit of information; 2.) circumvent essential protections set forth in our existing environmental, health, and safety laws; 3.) challenge the treatment of uncertainty; 4.) seek underlying data and analysis rather than the correction of information thereby causing delay by forcing agencies to respond multiple times to industry demands; and 5.) evade court processes for the introduction of evidence in litigation over environmental and health risks. These trends comprise Exhibit 4 in the case for repeal of the IQA.

The IQA has been used largely by industry groups and has resulted in delays in decision-making and consumption of agency resources that are needed to achieve substantive mandates. OMB's annual report on the first year of IQA implementation points to the fact that the IQA has not only been used by industry and their advocates, but also by private citizens and public interest organizations. However, while it is technically accurate that environmental groups such as the Sierra Club, Public Employees for Environmental Responsibility (PEER), and the Environmental Working Group have filed IQA petitions, industry, trade organizations, and conservative groups have filed the large majority of the petitions. For example, a July 2004 report by OMBWatch, *The Reality of Information Quality Act's First Year: A Correction of OMB's Report to Congress*, concluded that 72 percent of all requests for correction were filed by industry, and a majority of those requests challenged information relating to safety and the environment and were far more substantive and required much longer response times than petitions filed by individuals.<sup>105</sup> It is clear from a review of the petitions that those that are most vested in the outcome of the decisions associated with the challenged information, and those with the most resources to either file lengthy and complex challenges themselves or to engage sophisticated law firms to file their challenges, have been the ones to use the IQA most often. Public interest groups have largely been opposed to using the statute, even when its use may have been warranted, because of its potential to delay and impede the regulatory process.

The Act's ability to stall decision-making and consume resources is clear from a look at the first two years of implementation. While OMB states in its first Report to Congress on the IQA that the number of "substantive correction requests that were responded to was relatively small,"<sup>106</sup> a look at the numbers reveals a different picture.

OMB reported that the agencies had only received 35 correction requests "that appear to be stimulated by the Information Quality Act."<sup>107</sup> However, a recent analysis by OMBWatch revealed that there were actually 98 IQA petitions filed in fiscal year 2003,<sup>108</sup> and at least thirteen petitions have been filed with EPA alone between October 2003 and December 2004.<sup>109</sup> In addition, as OMBWatch has determined, there have been at least 16 requests for reconsideration filed by petitioners, in which petitioners often cite to new evidence and new issues not previously presented to the agency.<sup>110</sup> This number of requests might appear manageable if it were divided evenly among the agencies and if the requests merely involved the correction of information on an agency website.

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However, the bulk of these petitions have been aimed at a few agencies with regulatory powers, such as EPA, DHHS, and DOI. Furthermore, a majority of these requests are lengthy, substantive complaints about scientific judgments and policy that take the agency months to answer, as demonstrated below.

The IQA itself says nothing about the timing of agency responses to requests for correction. The Act leaves it to the agencies to establish administrative mechanisms for seeking correction of information. The OMB Guidelines similarly do not establish timeframes for review of correction requests. Rather, the Guidelines suggest that the agency "shall respond to complaints in a manner appropriate to the nature and extent of the complaint."<sup>111</sup> The EPA Guidelines state that it is EPA's "goal to respond to requests within 90 days of receipt" by either providing a response, or by notifying the petitioner that more time will be required.<sup>112</sup> In practice, a review of the correction requests reveals that initial responses to requests have taken anywhere from 1 ½ to 8 ½ months to complete.<sup>113</sup> The request that took the shortest time to answer, a request from an employee of the Ohio EPA, involved formatting problems with the electronic versions of two EPA documents. At the other end of the spectrum, it has taken EPA over 8 months to answer some requests, not including the appeal phase.<sup>114</sup> While some of these time-consuming requests have been answered with decisions not to correct or change information, as for example, where EPA denied a request for correction claiming that EPA was inaccurate in characterizing bromate as a likely human carcinogen,<sup>115</sup> the petition took nearly nine months to answer, confirming that the process is consuming significant agency time and resources. That petitioner then

filed a Request for Reconsideration, which remains unanswered more than three months later.<sup>116</sup> A request from the Perchlorate Study Group filed on December 22, 2003 was not answered until September 15, 2004, nearly nine months after the petition was filed.<sup>117</sup>

Moreover, in addition to requiring federal agencies to develop administrative mechanisms to allow “affected persons” to petition agencies for the correction of information, the Guidelines require agencies to establish an administrative appeals process.<sup>118</sup> While the IQA requires OMB to establish guidelines requiring agencies to establish correction mechanisms, the statute says nothing about an appeals process. This additional layer of process provides an added mechanism for delay. EPA’s stated goal is to respond to requests for reconsideration of adverse decisions on the request for correction within 90 days of receipt.<sup>119</sup> There have been at least five requests for reconsideration submitted to EPA. Two of these petitions took well over a year to resolve, while one took over seven months, and the other two remain to be answered.<sup>120</sup> The appeals process, not authorized by the IQA but invented by OMB, places an added drain on agency resources beyond that necessary to respond to the initial petitions.

While OMB recommends in its first report that timeliness of agency responses be improved, it is hard to see how that can happen given the nature of the requests. Moreover, this recommendation is at odds with OMB’s recommendation that the agencies consult with them at an earlier stage (which OMB suggests will streamline the process), as well as OMB’s suggestion that petitions should be directed at the inadequate treatment of uncertainty, a suggestion that screams for delay and commandeering of resources that could better be devoted to programs to protect the health and safety. While OMB suggests that the IQA has not affected the pace or length of rulemakings (without referencing any data to support this conclusion),<sup>121</sup> OMB acknowledges that it is taking agencies longer than expected to respond to requests and appeals, taking longer to find the correct personnel to handle the request, and is difficult to ensure that personnel have sufficient time to give “priority” to the request.<sup>122</sup> OMB further recommends in its Report that agency scientific and technical staff be increasingly engaged in the IQA process.<sup>123</sup> This increased involvement with responding to IQA petitions will undoubtedly come at the expense of agency scientific and technical involvement in other necessary projects. For example, despite the fact that we lack basic data about toxic pollutants in the air and chemicals in commerce,<sup>124</sup> limited agency resources will be devoted to responding to data quality petitions that challenge particular pieces of information that certain stakeholders do

not like, rather than devoting those resources to filling the enormous data gaps that currently plague our regulatory system.

Adding to the delay is the fact that many of the petitions challenge documents that were drafted years before the IQA was passed. A petition filed by asbestos industry lawyers challenges a guidance document for brake workers that was issued in 1986, and a petition by logging interests sought withdrawal of management documents for the northern goshawk that are nearly 13 years old, and have been the basis for numerous management decisions since the documents were issued. As similar attempts continue, agency resources will continue to be drained. In addition, there are no sanctions or costs for the filing of meritless complaints, nor is there any limit to the number or size of the petitions. Therefore, the costs of processing and the time necessary to respond to frivolous requests or those that are outside of the scope of the Act will be borne by the agency.

In terms of agency resources, there is very little information available to help the public determine how many agency resources are consumed responding to IQA requests. As OMBWatch pointed out in its report, the agencies’ annual reports to OMB, which follow a template developed by OMB, fail to include information on staff or other agency resources.<sup>125</sup> Direct requests to obtain such information from EPA failed to illicit any further information. In July, 2004, a member of EPA’s Office of Environmental Information’s Quality Staff responded to a request for resource information by explaining that “[a]t this time, I am not able to provide you with a report on the financial resources or personnel-hours dedicated to responding to the public’s request and overall management of the EPA’s Information Quality Guidelines (IQG) program.”<sup>126</sup> As further discussed in the *IQA Costs and Benefits* section of this report, the fact that the costs associated with implementing the IQA are unknown means that the IQA’s opportunity cost is also unknown – that is the extent to which other agency programs and initiatives are languishing while resources are diverted to respond to IQA petitions.

### *Official Censorship*

Numerous IQA petitions have called for the *exclusion or withdrawal* of studies or information entirely, rather than the *correction* of information. The use of the Act in this manner is contrary to the plain language of the IQA, which provides a process to seek correction of information, not for exclusion or withdrawal of information that petitioners do not like.

Moreover, petitions have sought complete withdrawal of information that is essential and critical to informing consumers and workers about risks to which they may be

exposed. For example, a petition filed by a law firm representing the asbestos industry sought the withdrawal of an EPA document known as the “Gold Book,” which warns auto mechanics of the risks associated with exposure to asbestos in brake material.<sup>127</sup> In its response to the asbestos petition, EPA indicated that it “is embarking on an overall effort to update and revise, as appropriate, various information materials associated with the Agency’s Asbestos program,” including the Gold Book.<sup>128</sup> EPA further stated that, in the meantime, both the hard and electronic copies of the Gold Book would indicate that the information it contains is in the process of being updated.<sup>129</sup>

Another example of industry’s attempted use of the IQA to muffle information critical to consumer safety is seen in the petition submitted to the Consumer Products Safety Commission (CPSC) by the Association of Home Appliance Manufacturers, which sought retraction of CPSC’s Final Report on Electric Clothes Dryers and Lint Ignition Characteristics.<sup>130</sup> The information the petition sought to withdraw could be used to prevent dryer fires and improve products and product standards. The CPSC denied the petition, concluding that the information in the report adhered to IQA Guidelines.

The National Legal and Policy Center asked the National Institute on Aging (NIA) to remove language in one of NIA’s *Age Pages* (documents aimed at a middle school reading level)<sup>131</sup> that stated that smokeless tobacco products are not safer than cigarettes.<sup>132</sup> The nine-page letter asked NIA not only to omit any references to the lack of safety of smokeless tobacco products, but also to include a paragraph entitled, “Smokeless Tobacco is Significantly Less Hazardous than Smoking,” to be followed by text that would state:

The use of smokeless tobacco available in the United States today involves *significantly less risk of adverse health effects* than cigarette smoking. Those who do not or cannot quit smoking, and for whom nicotine replacement therapy is not a satisfactory solution, should consider switching completely from smoking cigarettes to using smokeless tobacco as a *harm reduction alternative*.<sup>133</sup>

Though NIA’s response fell far short of granting the enthusiastic endorsement of smokeless tobacco sought by the petition, the phrase “not safer” in the offending paragraph

heading was replaced with “not safe,” thereby removing the direct comment on the relative risk inherent in using smokeless tobacco products as compared to smoking. However, the paragraph following the heading explains that while some people think smokeless tobacco products are safe, “they are not,” and proceeds to detail the myriad of health risks (including cancer) associated with use of smokeless tobacco products.<sup>134</sup>

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In addition to seeking the withdrawal of information that is critical to public health and safety, petitions have been filed seeking the withdrawal of information that could support regulatory action to protect the environment. For example, the Competitive Enterprise Institute (CEI), an industry think tank “that has received more than \$1 million in donations since 1998 from . . . Exxon,”<sup>135</sup> filed petitions with

EPA, the National Oceanic and Atmospheric Administration (NOAA), and the Office of Science and Technology Policy (OSTP) challenging climate change models used in the *National Assessment on Climate Change* and seeking withdrawal or exclusion of the models.<sup>136</sup> CEI filed the challenges notwithstanding the fact that the final report had been the subject of hundreds of public comments, and, significantly, had also been subjected to exhaustive peer review.<sup>137</sup> Specifically, 300 scientific and technical experts provided detailed comments on drafts of the report.<sup>138</sup> The agencies denied the requests on the ground that an advisory committee chartered under the Federal Advisory Committee Act produced the information,<sup>139</sup> and, in the case of EPA, on the basis that the information was not disseminated by that agency, but rather by the Department of State.<sup>140</sup>

Following the denials, CEI filed suit against OSTP in the United States District Court for the District of Columbia.<sup>141</sup> The parties eventually settled the suit, with the OSTP agreeing to post language on the web explaining that the document was produced by a FACA advisory committee and was “not subjected to OSTP’s Information Quality Guidelines.”<sup>142</sup> While the *Climate Action Report 2002*, a document containing information from the National Assessment, remains on the web, EPA in its response to CRE’s request for correction explained its position that the Climate Action Report 2002 is a State Department report “to assure that the web site does not suggest that the document supports or represents EPA’s viewpoint or that EPA endorses or agrees with it . . .”<sup>143</sup> This overly cautious language signals EPA’s concern about

dissemination of information that has been challenged, and provides support for the argument that the IQA may chill agency disseminations. EPA explained its intent to include similar language in response to a petition seeking correction of minutes from an EPA Science Advisory Board (SAB). While denying the petition because the information was not considered an agency dissemination, the agency indicated its intent to add explanatory notices to the SAB website to ensure that SAB documents or meeting minutes were not attributed to EPA.<sup>144</sup>

In other petitions, the Center for Regulatory Effectiveness (CRE) sought withdrawal of a technical review document used to support a proposal to add diisononyl phthalate, a chemical used in plastics, to the Toxics Release Inventory (TRI), because it allegedly did not comport with statutory requirements for listing, and relied on lab studies on rats and mice to extrapolate to effects in humans.<sup>145</sup> EPA responded by explaining that the agency was already conducting a review of the risk assessment and would consider CRE's request as part of those comments.<sup>146</sup> CRE also requested that EPA ignore comments filed by the Natural Resources Defense Council on the risks associated with dioxin and threatened an IQA petition.<sup>147</sup> In addition, a petition filed by the Chemical Products Corporation, a barium-producing corporation, requested that EPA replace the existing Integrated Risk Information System (IRIS) profile for barium with a profile compiled by scientists funded by the corporation itself.<sup>148</sup>

These attempts to exclude information from consideration by agencies could directly conflict with an agency's mandate, as for example when the Food Quality Protection Act requires an agency to consider all "available information" when determining whether to pass a protective standard.<sup>149</sup> Moreover, these attempts to seek withdrawal or exclusion of individual pieces of information directly conflict with the long-used and universally-employed weight of the evidence approach to evaluating environmental problems that is consistent with the statutory mandates set by Congress for the regulation of air, water, waste, pesticides, and chemicals. EPA's Information Quality guidelines explain that "[c]onsistent with EPA's current practices, application of these principles involves a 'weight-of-evidence' approach that considers all relevant information and its quality, consistent with the level of effort and complexity of detail appropriate to a particular risk assessment."<sup>150</sup>

The weight of the evidence approach necessarily acknowledges that some studies may be more reliable than others, but considers the totality of the information in making judgments rather than eliminating certain studies or pieces of information entirely to the point that there is nothing left upon which to make a decision.<sup>151</sup> By using the IQA to

break apart this information into small parts rather than allowing it to be analyzed collectively, the fundamental approach to determining risks to the environment is undermined. Frequent users of the IQA such as Jim Tozzi have acknowledged that they plan to use the IQA to challenge decisions, risk assessments, and other information by picking apart particular studies to find flaws. According to Tozzi, "[t]he Center believes that the thrust of the IQA was aimed at a win at the agency strategy, to pick out bullet point pieces of information, and go to the agency to deal with those particular matters of concern."<sup>152</sup> A petition filed on June 2, 2004 by a law firm representing the National Paint and Coatings Association (NPCA) takes exactly this approach. The NPCA filed a petition arguing that a because a single document (a Spreadsheet that projects reductions in volatile organic compounds (VOCs)) in the voluminous records assembled by states that have adopted a Model Rule allegedly violates the IQA, EPA must reject any state implementation plan (SIP) under the Clean Air Act that incorporates such a rule.<sup>153</sup> This is yet another example of the lengths to which industry will take the IQA to challenge substantive agency decisions by seeking the withdrawal or exclusion of individual pieces of information used to support regulatory action.

### *'Correcting' Policy, Not Information*

Many of the IQA petitions filed challenge agency policy decisions and precautionary policies rather than technical or scientific information.<sup>154</sup> This is despite the fact that the Act only applies to "information." OMB's broad Guidelines have invited these challenges by broadly defining "information" to include almost anything disseminated by the agency,<sup>155</sup> and OMB confirmed this broad interpretation in its first report to Congress on the Act, stating that "the Information Quality Act has been used to address complex issues and analyses that go beyond correcting errors entered into a spreadsheet."<sup>156</sup> This broad interpretation of the Act has become a harsh reality as the petitions discussed below indicate, despite the fact that some proponents of the IQA have acknowledged that even the support that did exist for a corrective mechanism for agency information prior to passage of the Act extended only to factual errors, and not to the correction of the quality of information and the policy judgments that underlie it.<sup>157</sup>

A petition filed by Tozzi's Center for Regulatory Effectiveness (CRE) and the makers of the most widely used herbicide in the United States, atrazine, sought to exclude studies on the hormonal effects of the herbicide from EPA's decision regarding its reregistration because those studies were not subject to EPA-approved testing protocols.<sup>158</sup> Rather than challenging an error in technical information, this argument endorsed a policy position that new, cutting edge

information cannot be considered by an agency until the underlying testing methods have been formally adopted by the agency – a position found nowhere in FIFRA, the statute providing for the registration of pesticides and herbicides.<sup>159</sup> EPA responded to the petition by making changes to documents required under FIFRA pertaining to the reregistration of the herbicide. While EPA has not entirely rejected the possibility that atrazine could cause hormonal effects in frogs, the agency has concluded in existing documents that due to “existing data uncertainties, the chemical should be subject to more definitive testing once the appropriate testing protocols have been established.”<sup>160</sup> EPA apparently intends to seek additional data to reduce these uncertainties. If the agency delays needed action while this is done, the petitioners will have succeeded in doing what they sought out to do – to derail the regulatory process and push the agency to establish protocols and obtain data that the underlying statutory framework does not compel. In addition, if agencies begin to become concerned about attacks on new or cutting edge studies, they may decide to forgo the use of these studies altogether, thus shrinking the number of studies used to support regulation and eliminating research that may be essential to the discovery of additional information on health and environmental effects.

This petition was not the end of the use of the IQA to challenge policy judgments and decisions with respect to atrazine. On June 28, 2004, CRE, the Kansas Corn Growers Association, the Missouri Corn Growers Association and two other agricultural interests filed a joint IQA petition with the National Toxicology Program of the Department of Health and Human Services seeking withdrawal of a notice that announces the Program’s intent to review 21 substances including atrazine for possible listing as a known or reasonably anticipated human carcinogen in its annual Report on Carcinogens.<sup>161</sup> The petition also asks that the nominations be withheld until the review procedures are clarified. The violation of the IQA alleged in the petition is that the Notice presents two conflicting procedures for review of the substances, one of which would not allow a substance to be dismissed from the list until the end of the process if it is determined that there is insufficient information to support the listing. The petitioners’ challenge to the purportedly conflicting “procedures” is merely a cloak for their real purpose – to delay the scientific inquiry into whether atrazine can cause cancer while battles are fought over procedure, and to challenge the listing proposal itself. Despite the fact that the Notice itself provides an opportunity for comment, providing the petitioners with an avenue to challenge the proposed list, they are nonetheless using the IQA as a means to challenge policy decisions and to delay further action with respect to atrazine.

Other petitions have similarly challenged policy judgments rather than technical information. For example, a barium producer’s challenge to EPA’s barium risk assessment was based on its disagreement with EPA’s conservative assumptions in the assessment.<sup>162</sup> A petition filed with the U.S. Fish and Wildlife Service (FWS) by an employee of the U.S. Air Force challenged information underlying the FWS’ proposed rule to list slickspot peppergrass, a rare plant found in Idaho, as an endangered species, arguing that there was a lack of scientific data to support a listing decision.<sup>163</sup> Air Force training operations in Idaho occur in areas where slickspot peppergrass is located. Despite the fact that the public comment period for the notice had closed, FWS reopened the comment period and extended the deadline for its final listing determination, acknowledging that its decision to reopen the process was based in part on the IQA petition filed by the Air Force.<sup>164</sup> In January, 2004, FWS filed a notice in the Federal Register announcing its withdrawal of the proposed rule to list the plant on the endangered species list, explaining that it had changed its previous decision about the risks to the species as a result of additional analysis and advancements in conservation efforts.<sup>165</sup> However, the withdrawal notice provides little documentation about what evidence and analysis had changed since the initial decision to list the species, suggesting that the Air Force objections in its IQA request may have contributed to the change in position.<sup>166</sup>

In addition, petitions filed by logging interests with the U.S. Forest Service also challenged agency management decisions rather than technical or scientific information. In the petitions, logging interests sought the complete withdrawal of several documents that made management recommendations for the northern goshawk, a hawk listed as a sensitive species, in forested areas.<sup>167</sup> In particular, the petitions challenged documents that have formed the basis for restrictions on forest and rangeland activities in order to protect goshawk habitat over the past decade. In rejecting the initial petitions as well as the petitioners’ request for reconsideration after a year of “extensive scientific review,”<sup>168</sup> the Forest Service determined that “the request was based upon a directed policy outcome rather than identifying a clear informational deficiency” and, as such, was an inappropriate use of the IQA. The Forest Service also noted in its response that “policy-makers must rely upon the whole of scientific and public input in a coordinated and concerted effort.”<sup>169</sup> While the agency correctly denied the petition, it conducted nearly a year of extensive review to come to its decision, and the process became an unnecessary burden on the agency rather than an effort to correct erroneous information.

Other petitions have been even more direct and explicit in requesting that agencies amend policy and legal determinations. A petition filed by an individual who works for a water treatment company requested that the “limitation against bromate should be relaxed by two orders of magnitude” and challenged references on EPA’s website that refer to bromate as a likely human carcinogen.<sup>170</sup> Rather than seeking the correction of information, the petition sought a relaxation of the bromate standard. EPA ultimately denied the petition, but it took the agency nine months to do so. The agency is now considering the appeal of that denial, a process that will ultimately consume at least six months, by EPA’s estimation.<sup>171</sup> Similarly, one of two petitions brought by a private citizen affiliated with Friends of the Massachusetts Military Reservation requested that EPA adopt a uniform standard for perchlorate, a chemical component of rocket fuel, citing differences in the advisory levels set by EPA headquarters and a regional office.<sup>172</sup> The petition was denied because it failed to reference any information disseminated by the agency.<sup>173</sup> A petition by BMW Manufacturing Corporation challenged EPA’s legal determination that the company was in significant non-compliance with the Resource Conservation and Recovery Act (RCRA) after EPA had conducted inspections at a BMW facility and had found violations involving disposal of hazardous wastes.<sup>174</sup> Because the company later came into compliance with RCRA, it sought to have its historical record of violations erased using the IQA. After its petition was denied, BMW sought reconsideration of its petition, and specifically set forth 17 “legal questions” for the appeals panel to review regarding the company’s compliance status.<sup>175</sup> The EPA appeals panel agreed with the denial of the original petition and concluded that EPA’s decision on the compliance status of a facility was outside the scope of the IQA.<sup>176</sup> While the EPA reached the appropriate result, the petition took one year and three months and considerable time and resources on the part of EPA to resolve.

Despite the fact that challenges to agency policy positions, judgments, and legal determinations are entirely outside of the scope of the IQA, OMB and industry petitioners have expanded the reach of the Act to challenge such petitions in a way that consumes untold agency resources, delays crucial action and circumvents existing statutory processes for regulatory decisionmaking.

### *End Run around Health and Safety Laws*

In the course of challenging management and policy decisions rather than seeking the correction of information errors, petitioners have sought to bypass existing statutory procedures with respect to health, safety, and the environment.

For example, the petitions filed with the U.S. Forest Service, which challenged management decisions made to benefit the Northern goshawk, sought to ignore the established process for vetting management decisions regarding the species under existing environmental laws. The documents challenged were part of the ongoing documentation required under the National Environmental Policy Act (NEPA), which requires federal agencies to assess the impacts of their actions before moving forward with those actions. Because petitioners had ample opportunities to participate in this existing process, the IQA petition process unnecessarily increased the administrative burden on the agency, resulting in added delay.<sup>177</sup> In a similar petition, aquaculture interests filed a challenge to data used by the U.S. Fish and Wildlife Service and the National Marine Fisheries Service in support of a draft Biological Opinion on atlantic salmon drafted pursuant to the Endangered Species Act (ESA).<sup>178</sup> The draft Biological Opinion sought to impose conditions on permits for the installation and maintenance of fish pens in Maine. The agencies denied the petition, concluding that the Biological Opinion was developed according to the processes set forth under the Endangered Species Act and its implementing regulations, and making clear that the IQA does not amend or repeal any of the agencies substantive mandates under the ESA. Again, while the agencies reached a conclusion that rejected any attempts by petitioners to evade the ESA process, the added delay resulting from the IQA petition added an unnecessary burden on the agency.

Another petition filed by Tozzi’s CRE challenged the technical review underlying EPA’s proposal to list diisononyl phthalate, a chemical used in plastic, on the Toxics Release Inventory (TRI).<sup>179</sup> CRE argued in the petition that the conclusions in the review are not consistent with the Emergency Planning and Community Right-to-Know Act (EPCRA), the statute governing the listing of chemicals on the TRI. The petition made legal arguments in support of its position that the challenged information was insufficient to support a TRI listing. In addition, the petition challenged 1994 EPA guidance interpreting the EPCRA provisions because it allegedly did not sufficiently describe the dose/response relationships, and suggested that a new rulemaking be initiated.<sup>180</sup> Similarly, other petitions have challenged information underlying State Implementation Plans required under the Clean Air Act, and the proposed listing of a contaminated site on the Superfund National Priorities List. Congress has even entered the mix by proposing in recent “Clear Skies” legislation that the Clean Air Act be amended to provide that a decision whether to establish standards for sources of sulfur dioxide, nitrogen oxides, and mercury be

based on “information satisfying the criteria of the Information Quality Act.”<sup>181</sup>

### *Coping with Uncertainty*

One of the clearest indications of OMB’s desire to ensure that the IQA is used to further a deregulatory agenda can be found in its report on the first year of the IQA, *Information Quality, A Report to Congress, Fiscal Year 2003*. In providing a general evaluation of the first year of implementation, OMB proffered that the IQA should be used to challenge “the inadequate treatment of uncertainty,” and not merely errors in information. The Report states:

OMB has also learned that improving the quality of information may involve multiple judgments. Often correction requests hinge on the interpretations of science or analyses. When dealing with uncertain scientific issues, it is possible to draw several reasonable inferences depending on the perspective of the reviewer. Thus, more than one plausible answer or methodology may exist. We are learning that it is possible for neither the agency nor the requestor to be incorrect. Thus far, the majority of non-frivolous correction requests have been denied, usually on the basis that a reasonable scientist could interpret the available information in the way that the agency had. Such correction requests might have been better focused if they had addressed the inadequate treatment of uncertainty rather than the accuracy of the information.<sup>182</sup>

OMB’s statement is a clear indication of its view that petitioners should be concerned less with the quality of data, and more with the completeness of the information that exists to support protective actions, and many of the petitions have followed OMB’s lead in this regard. As Professor Shapiro explains, when an agency lacks definitive or complete information, there is a policy choice that must be made regarding what actions the agency should take, based on the assumptions about precaution set forth in our environmental, health, and safety laws.<sup>183</sup> According to Shapiro, industry seeks not to challenge the quality of data, but rather the policy choices made by agencies pursuant to their substantive mandates, which require them to act before definitive proof of harm can be established.<sup>184</sup> If challenges filed on these grounds are successful, industry will have a tool for undermining the environmental and public health protections

that have been in place for over 30 years. OMB’s statement indicates that in the second Bush Administration, industry will have an advocate in the White House to ensure that this occurs.

Indeed, this is not the first time OMB has made this view known. In its 2002 Report to Congress on the Costs and Benefits of federal regulation, OMB stated that “[t]he key terms objectivity, utility and integrity – key dimensions of quality – convey an interest in information quality that goes beyond prevention and correction of factual errors.”<sup>185</sup> OMB’s statement also evinces OMB’s position about the requests themselves – that it wants more requests to be affirmed, perhaps to validate its claims that agency science is flawed.

Nothing in the language, structure, or history of the IQA evidences any considered congressional judgment to alter any agency’s substantive mandates with respect to the treatment of uncertainty. Environmental, health, and safety laws passed since the 1970s were specifically designed to allow regulators to regulate in the face of limited scientific evidence, because earlier approaches based on principles of tort law had proven ineffective at dealing with harms emanating from diffuse sources where irreparable damage could occur before the source of the harm was identified.<sup>186</sup> For example, under both the Clean Air Act and the Clean Water Act, Congress specified the hundreds of hazardous pollutants in need of regulation so that EPA would not need to develop scientific evidence of the harms from these chemicals prior to regulating them.<sup>187</sup> Even those statutes that do require some scientific evidence, such as the laws that regulate the generation, transport and disposal of hazardous wastes, do not require complete or definitive proof before regulatory action is justified.<sup>188</sup> Thus, these environmental and public health statutes traded unworkable and heavy burdens of proof for standards that allow agencies to consider all available evidence when making regulatory decisions.

Notwithstanding these statutory mandates, several IQA petitions have been used to suggest that the science used by federal agencies is not of sufficient quantity or quality to justify regulation under the IQA even though it satisfies the standards under the agencies’ substantive mandate. These challenges, if successful, could provide an end-run around our environmental laws and could gut protective measures and ensure that new measures are never enacted.

For example, a petition filed by the Chemical Products Corporation, a corporation which produces barium, requested that EPA replace the existing Integrated Risk Information System (IRIS) profile for barium with a profile compiled by scientists funded by the corporation itself because the petitioners were unhappy with the conservative assumptions used by EPA in the IRIS profile regarding doses of barium and effects.<sup>189</sup> While EPA denied the initial request for correction by defending the IRIS profile and the peer review thereof and explaining that the petition merely “expressed disagreement over issues of scientific judgment,”<sup>190</sup> the agency later determined that the IRIS summary should be revised and subject to additional peer review after receiving additional information from the petitioner in a request for reconsideration.<sup>191</sup> The letter specifically outlined EPA’s plans to request that the peer reviewers “examine whether the application of specific uncertainty factors is scientifically appropriate and supported by the analysis of the cited studies.”<sup>192</sup>

This additional layer of review of the EPA’s risk assessment assumptions is not mandated by the existing statutory framework, nor is it mandated by the IQA, which seeks the correction of information, and not assumptions about uncertainty. The characterization of risk is a difficult and controversial process in part because it involves difficult subjective judgments and is not merely a review of factual information. Because it is often difficult to say that a risk characterization is clearly “wrong,” given the degree to which assumptions, policy choices, and judgments are embedded into every step of the risk assessment process, this use of the IQA has become an effort to bog down risk assessments with procedural challenges, even though there is no realistic way to verify the objectivity of such information. OMB’s position that assumptions in risk assessments should be subject to the IQA, and recent challenges to risk assessments filed by petitioners demonstrate the lengths to which the IQA can be taken to challenge preventative assumptions that allow agencies to make progress towards reducing environmental risks.

Furthermore, there is a crucial distinction between incomplete data and poor quality data. For example, an excellent study of the adverse health effects of heightened blood lead levels can be *incomplete* with respect to the hazards of heightened levels of lead in the air if the rates of transfer between airborne lead and blood lead are poorly understood. Some may interpret the absence of knowledge about air-to-blood transfer rates to mean that the scientific evidence about the hazards of airborne lead to human health is of poor *quality*. If the quality requirements of the data quality rider are interpreted to make it harder to take protective action

when data is incomplete, this will mark a huge shift in American environmental policy, which since the 1970s has relied upon the principle that we should base policy on the best available evidence. In fact, one of the most successful protective actions ever taken was EPA’s 1973 decision to phase out the lead content in gasoline, when the air-to-blood transfer rate was not completely understood. Policy decisions should take into account the quality of the evidence as part of the process of deciding what to do, but it is often wise to act before all the answers are in.

### *Fishing Expeditions*

Several petitions have sought to obtain underlying data rather than requesting the correction of information. The IQA explicitly provides that agencies issue guidelines that establish administrative mechanisms allowing affected persons to seek and obtain *correction of information*, but the Act says nothing about providing access to the underlying data. Nevertheless, relying on the “reproducibility” standard set forth in the guidelines for “influential” information, the Perchlorate Study Group, an alliance of manufacturers and users of perchlorate, a component of rocket fuel that has contaminated water supplies throughout the country, sent a request for correction to EPA seeking disclosure of information underlying documents sent to the National Research Council Committee to Assess the Health Implications of Perchlorate Ingestion.<sup>193</sup> The petition, which sought information through the IQA that should be sought under the Freedom of Information Act (FOIA), consumed agency resources and burdened EPA with an unnecessary additional layer of review.

Indeed, the petition was filed in December 2003, but EPA did not issue its response until September 2004.<sup>194</sup> Noting that the document challenged by the petitioner was a draft and currently under active review, the agency stated that it did not consider associated documents as disseminations within the purview of its Information Quality Guidelines.<sup>195</sup> EPA responded to the petition’s fishing expedition by spending a full page detailing the whereabouts of information requested.<sup>196</sup> Such an effort on the part of Information Quality Guidelines staff is redundant and wasteful in view of the agency’s FOIA office, to which the petition’s request for information should have been directed.

In addition, a recent IQA challenge filed by the U.S. Chamber of Commerce and the Salt Institute seeks to have the Department of Health and Human Services, National Institute of Health, National Heart, Lung and Blood Institute (NHLBI) disclose data from a grant-funded trial concerning the effects of salt intake on blood pressure. The petition specifically challenges information “that directly states and

otherwise suggests that reduced sodium consumption will result in lower blood pressure in *all* individuals.<sup>2197</sup> The agency denied the request for correction, explaining that because the petitioners sought copies of data and not the correction of information, they should use the FOIA process for obtaining the requested information. While concluding that FOIA was the proper mechanism for obtaining the information sought, the NHLBI also concluded that the documents cited by the Petitioners were of sufficient quality under the IQA because the information was subject to rigorous peer review.<sup>198</sup>

After an appeal by the Petitioners was denied, the Chamber filed suit under the IQA and the Shelby Amendment requesting that the agency comply with the IQA and release the requested information. The government filed a motion to dismiss the case on grounds that the Petitioners lacked standing and the IQA provides no private right of action allowing enforcement of the law in federal court.<sup>199</sup> The government also argued that judicial review is not available under the Administrative Procedure Act (APA) because the petitioners failed to challenge a final agency action and because the agency decisions were committed to agency discretion by law.<sup>200</sup> Oral arguments in the case were held in September 2004, and at that time the Judge overseeing the case indicated his skepticism with respect to the argument that the IQA provides for judicial review.<sup>201</sup> At the hearing, the Judge also “expressed concern that allowing courts to review agency actions would have the effect of limiting scientific discourse.”

In its opinion, issued in November 2004, the court agreed with the government on all counts and dismissed the suit in its entirety.<sup>202</sup> With regard to plaintiffs’ IQA challenge, the court stated that “[n]either the Act itself nor its very limited legislative history provide a mechanism for judicial review of information quality or any avenue for judicial relief.”<sup>2203</sup> The court further reasoned that the language of the IQA reflects Congress’s intent that challenges to information quality disseminated by federal agencies be handled in administrative proceedings before the agencies, *not* in the courts.<sup>204</sup> Notably, plaintiffs’ APA claim was rejected because (among other reasons), the IQA commits the decision on whether to correct a prior communication to agency discretion.<sup>205</sup> Specifically, the court noted that OMB’s guidelines insulate the agency’s determinations of when correction of information is warranted, providing that:

Agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved.<sup>206</sup>

Following the ruling, on January 11, 2005 the Salt Institute and U.S. Chamber of Commerce filed a petition seeking appellate review of the lower court’s decision in the United States Court of Appeals for the Fourth Circuit.<sup>207</sup>

A recent IQA petition filed by a law firm representing NPC Services, Inc. (the petrochemical processors who seek to avoid the clean-up of a site heavily contaminated by PCBs under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)) also improperly seeks the disclosure of underlying data and methods used to support the decision to list the site on the National Priorities List.<sup>208</sup> This is despite its acknowledgement that “[c]orrection is the congressionally-mandated remedy for dissemination of information that does not meet quality standards.”<sup>2209</sup> EPA’s response to the petition indicated that the agency would treat the IQA petition as an addendum to comments filed by

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*The IQA may also have the potential to impact decision making under our environmental laws with respect to burdens borne by minority and low income populations, both by challenging decisions that could improve conditions where they live, and by making it increasingly difficult to access information about contamination in their neighborhoods.*

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NPC on the substantive rule, that is, the listing of the lake on the National Priorities list.<sup>210</sup> With regard to the improperly directed FOIA request contained within the IQA petition, EPA directed NPC to EPA’s Region VI docket, which EPA had specifically referenced as the repository for such underlying reference documents in the Federal Register notice proposing the lake to the NPL.<sup>211</sup>

NPC’s petition is of particular concern, because the area in question is in the middle of a poor, rural, African American community that still uses the area for subsistence fishing. EPA’s decision to consider NPC’s IQA petition as a comment on the original rule rather than denying it outright, gives undue consideration to the concerns of a well-funded conglomerate of industry giants, since the IQA petition was submitted to EPA almost four months *after* the close of the comment period.<sup>212</sup> Thus, the IQA may also have the potential to impact decision making under our environmental laws with respect to burdens borne by minority and low income populations, both by challenging decisions that could improve conditions where they live, and by making it increasingly difficult to access information about contamination in their neighborhoods.<sup>213</sup>

## *Sidestepping the Courts*

The IQA has also been used to deal with information used in litigation that industry does not like. For example, the asbestos industry's IQA challenge to the "Gold Book," a document providing information to auto mechanics about the risks of exposure to brakes containing asbestos was brought because lawyers for the asbestos industry had failed to have the document excluded as evidence at trial in tort cases brought by auto mechanics seeking damages for their injuries allegedly caused by asbestos exposure.<sup>214</sup> During repair and replacement of brakes containing asbestos, auto mechanics and shop workers are at risk for heavy exposure to the material. It is well documented that exposure can lead to severe and often fatal diseases including mesothelioma, a fatal cancer of the lining of the lung and chest cavity, and asbestosis, a lung disease that may become so severe that the lungs cease to function. In the face of a clear need to provide brake workers with information about the known risks of exposure to asbestos that remain in their workplaces, a Philadelphia law firm that has refused to identify its client recently sent a IQA petition to EPA seeking to have a 1986 EPA guidance document to brake workers about the harms of asbestos corrected or removed from the public domain.

The Gold Book, titled "Guidance for Preventing Disease Among Auto Mechanics," warns of the dangers of asbestos exposure during brake work and provides guidelines for reducing exposure to asbestos during brake repair work. The document is an important tool for spreading the word about the dangers of asbestos and has taken on an increased role in the face of lax enforcement and resistance to a ban on asbestos products. As an alternative to litigating its case in court where the firm was apparently having difficulty having the document excluded, the firm sought to circumvent that process by bringing an IQA challenge, requesting that EPA withdraw a document that serves as a needed warning to brake workers and make a determination that the document is insufficient to demonstrate that exposure to asbestos can cause disease among brake workers, an inquiry that should appropriately be in the courts. While the manual was meant to serve as a warning to auto mechanics and not as a definitive statement of causation, the IQA has been used to subject the document to a level of scrutiny that does not match the document's intended purpose. It remains to be seen whether the revised document will provide adequate warnings to brake workers.

Similarly, a law firm representing the Dow Chemical Company filed a recent challenge to a quality assurance project plan and work plan involving groundwater flow and contaminant fate and transport in Louisiana.<sup>215</sup> The petition suggests that the information challenged should be

characterized as "influential" and thus subject to the more prescriptive IQA requirements because "potential groundwater flow and contaminant fate and transport, are issues in major litigation."<sup>216</sup> In addition, the petitioners seek the "influential" categorization because they are concerned that the plan and the model that may be developed based on that plan, could be used in enforcement or other administrative actions.

The petition suggests that the plan fails to conform with EPA guidance for such plans, lacks detail, was not subject to external peer review, and does not account for uncertainty, and should therefore EPA should be prohibited from disseminating any model based on that plan until the petition has been considered. Dow complains that the alleged errors may cause it to "expend significant resources to demonstrate the fallibility of the model, and may very well be prejudiced in defense of the cases against it if a faulty model is used in litigation or in enforcement or other administrative actions."<sup>217</sup> Not only does the petition challenge a model that does not yet exist, it seeks to expend agency resources on its own behalf rather than using its own resources to challenge the model in court. The petition does not seek the correction of information, rather it seeks to strike fear in EPA by challenging a model before it has been created, particularly because of its concerns that EPA apparently indicated that it does not plan to rely on data collected by Dow in the model.<sup>218</sup> EPA appropriately denied Dow's request, noting that the model is only a planning tool for internal agency use, was never disseminated to the public.<sup>219</sup> Counsel for Dow has since filed a Request for Reconsideration, asserting that EPA's denial of the IQA request was an "arbitrary and capricious exercise of discretion" by EPA, language that threatens the agency with litigation.<sup>220</sup>

In yet another example, a challenge by a law firm representing the paint and coatings industry to information underlying a state model rule on volatile organic compounds in paint is attempting to use the IQA process to circumvent court challenges to the rule that have largely been rejected.<sup>221</sup>

## *IQA Costs and Benefits*

Oft-repeated refrains among those who advocate "regulatory reform" are that the costs of many regulations exceed their benefits. Without an understanding of regulatory costs and benefits, critics charge, government is unable to engage in sensible priority setting and must engage in a sort of "fly by the seat of one's pants" approach to choosing among alternative actions.<sup>222</sup> Cost-benefit analysis, "sets out to do for government what the market does for business: add up the benefits of a public policy and compare them to

the costs.”<sup>223</sup> As CPR Scholars Frank Ackerman and Lisa Heinzerling point out, however, there is no ledger to readily provide the values of regulatory costs and benefits. Rather, cost-benefit analyses must create that ledger, and calculations of costs and benefits involve a multitude of challenging questions.<sup>224</sup> Nonetheless, cost-benefit analysis has become an increasingly prevalent tool since the legislation accompanying the 104<sup>th</sup> Congress’s Contract With America,<sup>225</sup> and particularly under the Bush Administration.

In marked contrast to its usual enthusiasm for and insistence on cost-benefit analyses, however, OMB imposed its IQA Guidelines without any explicit discussion or analysis concerning the costs and attendant benefits associated with implementation of the Guidelines or the Act. OMB did not attempt to compare the benefits of improved data quality with the cost to the public in terms of potential lives lost, health effects, and environmental effects attributable to diverted agency resources, delayed access to information, and delayed implementation of rules.

When criticized for the fact that it had not given cost-benefit consideration to its information quality requirements, OMB stated in its 2002 Report to Congress on the costs and benefits of federal regulation that its guidelines “do reflect cost-benefit considerations . . . .”<sup>226</sup> The Guidelines include the following passage regarding the costs and benefits of the IQA:

the guidelines recognize, however, that information quality comes at a cost. Accordingly, the agencies should weigh the costs (for example, including costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality) and the benefits of higher information quality in the development of information, and the level of quality to which the information disseminated will be held.<sup>227</sup>

Nowhere in this vague narrative does OMB consider the potential costs to health, safety, and the environment that could arise as a result of implementation and use of the IQA.

Moreover, any suggestion in the narrative that might caution agencies to ensure that the costs of responding to the deluge of IQA requests they receive do not exceed the benefits associated with whatever increase in information quality might result is muffled by such directives as those recently issued by Dr. John Graham and Representative Joe

Barton (R-TX). Based on the fact that the National Institutes of Health’s (NIH) National Toxicology Program (NTP) had received six IQA requests, in November 2004 Dr. Graham issued a prompt letter to NIH’s Director suggesting three additional procedural hurdles that NTP should undertake before issuing its Report on Carcinogens or finalizing the NTP review process for individual substances.<sup>228</sup> In January 2005, Representative Barton sent a letter to fifteen federal agencies including EPA, DHHS, NIH, EPA and the CPSC that requests the agencies to respond to nine specific inquiries regarding their IQA practices.<sup>229</sup>

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*Without even a quantification of costs, let alone corresponding benefits, it is impossible to know the true opportunity costs of the IQA – what programs, initiatives and actions are being foregone in order to devote resources to responding to IQA petitions.*

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Representative Barton seeks the information in order to better understand agency activity related to the IQA, in response to “Congress’s concern that agencies were not complying fully” with the IQA, as expressed in the November 2003 report that prompted OMB’s own report to Congress on the IQA. In short,

the weak suggestion in OMB’s IQA Guidelines that agencies consider relative costs and benefits associated with implementing the IQA is effectively drowned out by subsequent insistence that agencies are not doing enough and must do more in order to comply with the IQA.

Finally, as detailed in this Report, there is little evidence that there is a widespread information dissemination problem at the agencies or that an aggressive administration mechanism is the best solution, even if there is a problem. Thus, the supposed “benefits” from the IQA have little support and are highly overstated. The Bush Administration’s departure from the usual canons of cost-benefit analysis it regularly promotes in other contexts belies the supposedly objective insistence that such analysis is necessary to ensure that only those public actions that will produce benefits in excess of their costs are pursued, and thus that the public interest is being helped, not harmed. The costs associated with requiring already under-funded federal agencies to respond to legions of IQA requests, often lengthy and complex challenges generated by wealthy corporations (or their legal counsel) with an interest in undermining bases for regulation, have never been analyzed in any systematic way. Without even a quantification of costs, let alone corresponding benefits, it is impossible to know the true opportunity costs of the IQA – what programs, initiatives and actions are being foregone in order to devote resources to responding to IQA petitions. The failure to subject the IQA and implementation procedures to any form of cost-benefit consideration provides Exhibit 5 in the case for repeal of the IQA.

## Conclusion

The above analysis collectively provides the case against the IQA. The statute's suspicious and industry-based origins, the lack of proven need for the statute, and the abounding examples of the misuse of the Act in just two years demonstrate that the Act must be repealed. While there may be a need for a mechanism to address correction of factual errors, the agencies already have processes for correction of this type of information in place, and the expansive IQA is not the correct vehicle for this, in light of the ways it has

been used thus far to challenge the underpinnings of regulations to protect health, safety, and the environment. If Congress fails to repeal the IQA, the public interest community must continue to aggressively monitor and critique the most egregious petitions to encourage agencies to reject these challenges to our environment and our health and safety and to continue to build the case against the IQA.

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## Appendix A: Text of the Information Quality Act

The Information Quality Act amends the Paperwork Reduction Act:

(a) In General.—The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, issue guidelines under sections 3504(d)(1) and 3516 of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.

(b) Content of Guidelines.—The guidelines under subsection (a) shall—

(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

(2) require that each Federal agency to which the guidelines apply—

(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

(C) report periodically to the Director—(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency and; (ii) how such complaints were handled by the agency.

## About the Authors

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## Endnotes

- <sup>1</sup> Section 515 of the FY 2001 Appropriations Act, P.L. 106-554, 114 Stat. 2763A-153-154 (December 21, 2000).
- <sup>2</sup> *Id.*
- <sup>3</sup> *Id.*
- <sup>4</sup> OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*; Republication, 67 FR 8452 (February 22, 2002) [hereinafter “OMB Guidelines”].
- <sup>5</sup> OMB Watch has completed an informative comparative analysis of the various agency guidelines at <http://www.ombwatch.org/rtk/dqcomparison-entirecharts.pdf>.
- <sup>6</sup> Thomas Riehle, “PEOPLE: Washington’s Movers and Shakers,” *National Journal*, May 21, 1983, Vol. 15, No. 21, at 1085.
- <sup>7</sup> “Group Asks Bush To Issue Executive Order; Harmonizing Of Guidelines, Practices Sought, Bureau of National Affairs,” *Environment Reporter*, July 12, 1991, Vol. 22, No. 11; at 605.
- <sup>8</sup> *Id.*
- <sup>9</sup> *Id.*
- <sup>10</sup> Letter to Marc Firestone from Jim Tozzi, dated May 7, 1996, Bates No. 2061693747.
- <sup>11</sup> An internal company document reported that “OSHA will delay any decision on initiating regulatory steps until EPA has completed its work.” Memorandum to James W. Johnston from M.B. Oglesby, Jr. re: Weekly Status Report—Government Relations, Dated November 30, 1990.
- <sup>12</sup> Federal Focus, Inc., Grant-in-aid request, dated March 15, 1991 and April 1, 1991. This was signed by Stephen C. Parrish, Vice-President, Philip Morris, Inc. on April 1, 1991.
- <sup>13</sup> No author, Environmental Tobacco Smoke Update, dated February 3, 1992 [Bates No. 2023004316].
- <sup>14</sup> Office of Atmospheric and Indoor Air Programs, U.S. Environmental Protection Agency, Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders (December, 1992).
- <sup>15</sup> No Author, IAQ Goals, January 25, 1993, Bates No. 2023206195, at 2.
- <sup>16</sup> 44 U.S.C. § 3501(4).
- <sup>17</sup> 44 U.S.C. § 3504(d).
- <sup>18</sup> 44 U.S.C. § 3506(c).
- <sup>19</sup> 44 U.S.C. § 3506(d).
- <sup>20</sup> Federal Focus, Inc., Federal Focus Outreach Program on Data Integrity: A Proposal (Working Draft dated December 14, 1998), Bates No. 2065230955, at 3.
- <sup>21</sup> Center for Regulatory Effectiveness, Draft Outline for Legislation on Integrity and Dissemination of Federal Information, dated November 12, 1997, at 1, [http://www.thecre.com/pdf/20020107\\_data.pdf](http://www.thecre.com/pdf/20020107_data.pdf).
- <sup>22</sup> *Id.*
- <sup>23</sup> *Id.* at 2.
- <sup>24</sup> *Id.*
- <sup>25</sup> *Id.*
- <sup>26</sup> *Id.*
- <sup>27</sup> *Id.*
- <sup>28</sup> Memorandum to Matthew Winokur from Jim Tozzi, re: Language on Data Access in Treasury Appropriations Bill for FY ‘99 (H.R. 4104), dated October 12, 1998. Bates No. 2065231124, at 2.
- <sup>29</sup> *Id.* at Attachment 2, Bates No. 2065231130.
- <sup>30</sup> *Id.*
- <sup>31</sup> Multinational Business Services, Inc., Federal Data Access and Information Quality Directives in the FY ‘99 Omnibus Appropriations Act and Conference Report, October 19, 1998. Bates No. 2065231093, at 1.
- <sup>32</sup> Fax to Matt Winokur from Jim Tozzi, dated December 11, 1998, Bates No. 2065253923.
- <sup>33</sup> No Author, MBS Proposed Work Agenda CY ‘99, undated ca: December 11, 1998, Bates No. 2065253924.
- <sup>34</sup> Letter to Matthew Winokur from Jim Tozzi, dated December 16, 1998, Bates No. 2065230945.
- <sup>35</sup> Philip Morris, WRA Contract Request Form, dated December 24, 1998, Bates No. 2064779000.
- <sup>36</sup> Myron Levin, “Stealth Lobbying Kills Secondary Smoke Proposal,” *Los Angeles Times*, August 17, 1995, Part A; Page 1. According to the *Los Angeles Times*, MBS “spearheaded” the ICD-9 effort, during which it “even orchestrated comments from a medical group that OMB later cited as support for its decision.”
- <sup>37</sup> See Memorandum from Jim Tozzi to NTP Working Group on ETS, re: Paper on Opportunities for Scientific Cooperation with Federal Agencies on the ETS Issue, dated April 16, 1999, Bates No. 2074593804.

<sup>38</sup> Multinational Business Services, Inc., Opportunities for Scientific Cooperation with Federal Agencies on the ETS Issue, Working Draft, dated May 6, 1999, Bates No. 2505590250, at 20.

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> Draft Letter to John T. Spotila from Jim Tozzi, dated January 17, 2000, Bates No. 2072826846, Attachment 1.

<sup>43</sup> Letter to Robert Elves from Jim Tozzi, dated January 24, 2000, Bates No. 2072826845.

<sup>44</sup> “Industry Group Develops Plan for New Administration Data Quality Rules,” *Inside EPA*, February 4, 2000, at 4.

<sup>45</sup> Email to Comments@thecre.com from Roger A. Walk, dated June 26, 2000, Bates No. 2078738342A.

<sup>46</sup> Letter to Robert Elves from Jim J. Tozzi, dated February 29, 2000, Bates No. 2072826830.

<sup>47</sup> *Id.* at 2.

<sup>48</sup> Consolidated Appropriations Act of 2001, Pub. L. No. 106-554 § 515, 114 Stat. 2763, 2763A-153-154 (December 21, 2000). *See also* Jim Stimson, “Budget Bill Provision On Data Accuracy Could Open Rules To Industry Challenges, Bureau of National Affairs,” *Chemical Regulation Reporter*, January 8, 2001, Vol. 25, No. 2, at 145.

<sup>49</sup> Jim Stimson, “Budget Bill Provision On Data Accuracy Could Open Rules To Industry Challenges, Bureau of National Affairs,” *Chemical Regulation Reporter*, January 8, 2001, Vol. 25, No. 2, at 145.

<sup>50</sup> Wendy E. Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, 12 J. OF LAW & POL’Y 589, 612 (2003).

<sup>51</sup> Center for Regulatory Effectiveness website, [www.thecre.com/quality/Background.html](http://www.thecre.com/quality/Background.html); *see also* Frederick R. Anderson, Information Quality Act, *National Law Journal*, October 14, 2004, at B9 (“The widely accepted explanation is that corporate interests slipped the Information Quality Act through Congress to counter indiscriminate ‘data dumps’ of corporate information into federal Internet websites.”).

<sup>52</sup> CRE Legislative Working Papers on Data Quality, “Ensuring the Integrity of Information Disseminated to the Public by Federal Agencies, at 1, [http://www.thecre.com/pdf/20020107\\_data.pdf](http://www.thecre.com/pdf/20020107_data.pdf).

<sup>53</sup> Jim Tozzi, The Federal Information Triangle, Guest Perspective, *Risk Policy Report*, September 18, 2001, [http://www.thecre.com/quality/20010924\\_fedinfortriangle.html](http://www.thecre.com/quality/20010924_fedinfortriangle.html).

<sup>54</sup> CRE Legislative Working Papers on Data Quality, “Ensuring the Integrity of Information Disseminated to the Public by Federal Agencies, at 1-2, [http://www.thecre.com/pdf/20020107\\_data.pdf](http://www.thecre.com/pdf/20020107_data.pdf); *see also* [Insert Cite to page above where principles are outlined].

<sup>55</sup> *See, e.g.*, Job Creation and Wage Enhancement Act of 1995, H.R. 9, 104<sup>th</sup> Congress, S. 981, 105<sup>th</sup> Cong. § 625 (1998).

<sup>56</sup> Comments of Paul Noe, Counselor to John Graham, OIRA, *Learning to Live With the Information Quality Act*, 33 ENVIRONMENTAL LAW REPORTER 10224, 10224 (2003).

<sup>57</sup> OMB Guidelines, 67 Fed. Reg. at 8453 (referencing OMB Circular A-130).

<sup>58</sup> OMB Guidelines, 67 Fed. Reg. at 8453.

<sup>59</sup> EPA’s *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, October 2002, EPA/260R-02-008, 10-11, <http://www.epa.gov/oei/qualityguidelines/> [hereinafter “EPA Guidelines”].

<sup>60</sup> EPA Guidelines at 11.

<sup>61</sup> *Id.*

<sup>62</sup> Wendy E. Wagner, *The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 LAW AND CONTEMPORARY PROBLEMS 63, 79-80 (2003).

<sup>63</sup> EPA Guidelines at 12.

<sup>64</sup> John D. Echeverria & Julie B. Kaplan, “Poisonous Procedural “Reform”: In Defense of Environmental Right-to-Know” 12 KAN. J. OF LAW & PUB. POL’Y 579, 598 (2003) (citing Integrated Error Correction: Setting the Record Straight, EPA Annual Report 2001 at 22).

<sup>65</sup> Wagner, *The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, *supra* n. 62 at 83, n. 80 (highlighting examples from the Department of Health and Human Services and the Federal Aviation Administration presented at the National Academy of Sciences workshop on Data Quality of existing correction mechanisms).

<sup>66</sup> The Department of Health and Human Services, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information

Disseminated to the Public, Part I, D.4.e., <http://www.hhs.gov/infoquality/part1.html#d4d>.

<sup>67</sup> Wagner, *The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, *supra* n. 62 at 72-73, 76-79.

<sup>68</sup> *Id.* at 72.

<sup>69</sup> Wagner, *Importing Daubert to Administrative Agencies through the Information Quality Act*, *supra*, n. 50 at 593-94 (citing Strengthening Science at the U.S. Environmental Protection Agency – National Research Council (NRC) Findings: Hearing Before the House Subcomm. On Energy and Env’t, 106<sup>th</sup> Cong. 106-97 (2000)); Wagner, *The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, *supra*, n. 62 at 76-79.

<sup>70</sup> Wagner, *The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, *supra*, n. 62 at 75 (citing Ted Greenwood, Knowledge and Discretion in Governmental Regulation 15 (1984); Sheila Jasanoff, The Fifth Branch: Science Advisers as Policymakers 246 (1990); Bruce L.R. Smith, The Advisors: Scientists in the Policy Process 100 (1992)).

<sup>71</sup> Statement by David Michaels, PhD, MPH, November 18, 2003, NAS Peer Review Workshop, November 18, 2003, available at [http://www7.nationalacademies.org/stl/Michaels\\_Presentation.pdf](http://www7.nationalacademies.org/stl/Michaels_Presentation.pdf).

<sup>72</sup> Wagner, *The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, *supra*, n. 62 at 73.

<sup>73</sup> *Id.* at 77-78, n. 60 (2003).

<sup>74</sup> Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, *supra*, n. 50 at n. 23 (citing Nat’l Acad. Of Sci., Ensuring the Quality of Data Disseminated by the Federal Government: Workshop #1, at 32 (April 21, 2002), available at [http://www7.nationalacademies.org/stl/4-21-02\\_Transcript.doc](http://www7.nationalacademies.org/stl/4-21-02_Transcript.doc)).

<sup>75</sup> Wagner, *The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, *supra*, n. 62.

<sup>76</sup> Sidney A. Shapiro, OMB’s *Dubious Peer Review Procedures*, 34 ENVIRONMENTAL LAW REPORTER 10064, 10065 (2004).

<sup>77</sup> Office of Information and Regulatory Affairs, Biography of John D. Graham, <http://www.whitehouse.gov/omb/inforeg/bio.html>.

<sup>78</sup> OMB Guidelines, 67 FR at 8460, § V.5.; *see also* Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, *supra*, n. 50 at 595.

<sup>79</sup> OMB Guidelines 67 FR at 8460, § V.9.

<sup>80</sup> OMB Guidelines, 67 FR at 8460, V.3.a.ii.

<sup>81</sup> OMB Guidelines, 67 FR at 8760, §V.3.b.ii.C.

<sup>82</sup> OMB Guidelines, 67 FR at 8460, V..3.b.ii.C. *See also* SDWA Amendments of 1996 (SDWA), 42 U.S.C. § 300g-1(b)(3)(A) & (B)).

<sup>83</sup> Memorandum from John Graham to the President’s Management Council, Presidential Review of Agency Rulemaking by OIRA, September 20, 2001, [http://www.whitehouse.gov/omb/inforeg/oira\\_review-process.html](http://www.whitehouse.gov/omb/inforeg/oira_review-process.html).

<sup>84</sup> The SDWA provides:

(A) Use of science in decisionmaking  
*In carrying out this section*, and, to the degree that an Agency action is based on science, the Administrator shall use—  
(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

42 U.S.C. § 300g-1(b)(3)(A) (emphasis added).

<sup>85</sup> The SDWA provides:

(B) Public information  
*In carrying out this section*, the Administrator shall ensure that the presentation of information on public health effects is comprehensive, informative, and understandable. The Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable— (i) each population addressed by any estimate of public health effects; (ii) the expected risk or central estimate of risk for the specific populations; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.

42 U.S.C. § 300g-1(b)(3)(B) (emphasis added).

<sup>86</sup> Comments of the Natural Resources Defense Council regarding EPA Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, May 31, 2002, at 22. [hereinafter “NRDC Comments”].

<sup>87</sup> *Id.* at 23.

<sup>88</sup> *Id.* at 25.

<sup>89</sup> OMB Guidelines, 67 Fed. Reg. at 8457 (OMB’s claim of universal applicability).

<sup>90</sup> 29 U.S.C. § 655(b)(5).

<sup>91</sup> 42 U.S.C. § 7408(a)(2).

<sup>92</sup> *Whitman v. American Trucking Assns.*, 121 S.Ct. 901 (2001).

<sup>93</sup> *See, e.g.*, Clean Water Act, 26 U.S.C. § 1314(a)(1) (requiring EPA recommendations on science-based water quality criteria to be based on “latest scientific knowledge”); Toxic Substances Control Act, 15 U.S.C. § 2626(a) (providing general authority to develop testing protocols for evaluating risks from toxic substances); Endangered Species Act, 16 U.S.C. §1533(b)(1)(A) (requiring the Secretaries of the Interior and Commerce to make decisions based on “the best scientific and commercial data available”).

<sup>94</sup> Guidelines for Ensuring the Quality of Information Disseminated to the Public, Centers for Disease Control and Agency for Toxic Substances and Disease Registry, Section VII., <http://www.hhs.gov/infoquality/cdcinfo2.htm#vb>.

<sup>95</sup> Guidelines for Ensuring the Quality of Information Disseminated to the Public, Food and Drug Administration, VII.C., <http://www.hhs.gov/infoquality/fda.html#viic>.

<sup>96</sup> EPA Guidelines at 6.4, p. 22 (emphasis added).

<sup>97</sup> Request for Correction by U.S. Chamber of Commerce to EPA, filed May 26, 2004, at 7, <http://www.epa.gov/quality/informationguidelines/documents/04019.pdf>.

<sup>98</sup> OMB Information Quality Act Report at 48-49.

<sup>99</sup> Petition for Disclosure and Correction to EPA, Greenberg Traurig on behalf of NPC Services, Inc., August 30, 2004, <http://www.epa.gov/quality/informationguidelines/documents/04023.pdf>.

<sup>100</sup> OMB Guidelines, 67 FR at 8459, V.3.b.i.

<sup>101</sup> *See* OMB, *Final Information Quality Bulletin for Peer Review*, December 16, 2004, available at: <http://>

[www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf](http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf).

<sup>102</sup> CRE Petition filed with EPA re: Diisononyl Phthalate, October 16, 2003 at 2-3, <http://www.epa.gov/quality/informationguidelines/documents/13166rfc.pdf>.

<sup>103</sup> EPA Response to Diisononyl Phthalate petition, March 15, 2004, <http://www.epa.gov/quality/informationguidelines/documents/13166Response.pdf>.

<sup>104</sup> Letter from Wilkie, Farr, & Gallagher, LLP to Jeffery Holmstead, EPA, Re: Request for Peer Review of the Ozone Transport Commission Model Rule for Volatile Organic Compounds for AIM Coatings as a Highly Influential Scientific Assessment Under OMB’s Information Quality Bulletin for Peer Review, June 2, 2004, <http://www.epa.gov/quality/informationguidelines/documents/04020.pdf>.

<sup>105</sup> OMBWatch, *The Reality of the Information Quality Act’s First Year: A Correction of OMB’s Report to Congress*, July 24, 2004, at 7, <http://www.ombwatch.org/info/dataqualityreport.pdf> [hereinafter “OMBWatch Report”].

<sup>106</sup> OMB, *Information Quality: A Report to Congress, Fiscal Year 2003* at 5, available at: [http://www.whitehouse.gov/omb/inforeg/fy03\\_info\\_quality\\_rpt.pdf](http://www.whitehouse.gov/omb/inforeg/fy03_info_quality_rpt.pdf) [hereinafter “OMB Information Quality Act Report”].

<sup>107</sup> OMB Information Quality Act Report at 8.

<sup>108</sup> OMBWatch Report at D-6.

<sup>109</sup> EPA website, *Information Quality Guidelines – Requests for Correction (RFC) and Requests for Reconsideration (RFR) Submitted to EPA*, <http://www.epa.gov/quality/informationguidelines/iqg-list.html>.

<sup>110</sup> OMBWatch Report at DQ-6.

<sup>111</sup> OMB Guidelines at IV.2.

<sup>112</sup> EPA Guidelines at 31.

<sup>113</sup> EPA website, *Information Quality Guidelines – Requests for Correction (RFC) and Requests for Reconsideration (RFR) Submitted to EPA*, <http://www.epa.gov/quality/informationguidelines/iqg-list.html>.

<sup>114</sup> Request for Correction from David A. Smith, Ozone Industry, <http://www.epa.gov/quality/informationguidelines/documents/12029.pdf>, July 21, 2003; EPA Response to Petition, April 28, 2004, <http://www.epa.gov/quality/informationguidelines/documents/12385-response.pdf>.

<sup>115</sup> *Id.*

<sup>116</sup> Request for Reconsideration from David A. Smith, Ozone Industry, September 23, 2004, <http://www.epa.gov/quality/informationguidelines/documents/12385A.pdf>.

<sup>117</sup> Petition Filed by the Perchlorate Study Group with EPA, December 22, 2003, <http://www.epa.gov/quality/informationguidelines/documents/13679.pdf>; EPA Response to Petition, September 15, 2004, <http://www.epa.gov/quality/informationguidelines/documents/13679-response.pdf>.

<sup>118</sup> OMB Guidelines, 67 FR at 8459, III.3.ii.

<sup>119</sup> EPA Guidelines at 35.

<sup>120</sup> EPA website, *Information Quality Guidelines – Requests for Correction (RFC) and Requests for Reconsideration (RFR) Submitted to EPA*, <http://www.epa.gov/quality/informationguidelines/iqg-list.html>.

<sup>121</sup> OMB Information Quality Act Report at 9.

<sup>122</sup> OMB Information Quality Act Report at 10.

<sup>123</sup> OMB Information Quality Act Report at 5.

<sup>124</sup> See, e.g., Wendy Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L. J. 1619, 1625, n. 10 (2004).

<sup>125</sup> OMBWatch Report at DQ-4.

<sup>126</sup> E-mail from Vincia C. Francis-Holloman, EPA, Office of Environmental Information Quality Staff to Matthew Shudtz, Research Assistant to Professor Rena Steinzor, University of Maryland School of Law, July 1, 2004 (on file with CPR).

<sup>127</sup> Information Quality Act Request for Correction of Information, filed with EPA by Morgan Lewis, August 19, 2003, <http://www.epa.gov/quality/informationguidelines/documents/12467.pdf>.

<sup>128</sup> EPA Response to Morgan Lewis Request for Correction, November 24, 2003, <http://www.epa.gov/quality/informationguidelines/documents/12467response-morgan-lewis.pdf>.

<sup>129</sup> *Id.*

<sup>130</sup> OMB Information Quality Act Report at 89-90.

<sup>131</sup> NIA Response to National Legal and Policy Center Request for Correction, June 29, 2004, <http://aspe.hhs.gov/infoquality/request&response/13b.shtml>.

<sup>132</sup> Information Quality Act Request for Correction of Erroneous Information, filed with NIA by the National

Legal and Policy Center, March 16, 2004, <http://aspe.hhs.gov/infoquality/request&response/13a.pdf>.

<sup>133</sup> *Id.* at 7.

<sup>134</sup> NIA Response to National Legal and Policy Center Request for Correction, June 29, 2004, <http://aspe.hhs.gov/infoquality/request&response/13b.shtml>.

<sup>135</sup> Sidney A. Shapiro, *The Information Quality Act and Environmental Protection: The Perils of Reform by Appropriations Rider*, 28 Wm. & Mary Env'tl. L. Pol'y Rev. 339, 359 (2004) (citing Paul Harris, *Bush Covers Up Climate Research: White House Officials Play Down Its Own Scientists' Evidence of Global Warming*, GUARDIAN UNLIMITED, Sept. 21, 2003).

<sup>136</sup> See, e.g., CEI Petition to EPA, Request for Response to/ Renewal of Federal Information Quality Act Petition Against Further Dissemination of 'Climate Action Report 2002', February 10, 2003, <http://www.epa.gov/quality/informationguidelines/documents/7428.pdf>. Similar petitions were filed with NOAA and the Office of Science and Technology Policy.

<sup>137</sup> Shapiro, *The Information Quality Act and Environmental Protection: The Perils of Reform by Appropriations Rider*, *supra*, n. 135 at 359, n. 114 (citing Nat'l Assessments Synthesis Team, US Global Change Research Program, *Climate Change Impacts on the United States: The Potential Consequences of Climate Variability and Change* (2000)). See also, Thomas O. McGarity, *Our Science is Sound Science and Their Science is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 U. Kan. L. Rev. 897, 925 (2004) (noting that the National Assessment on Climate Change had "received extensive peer review and public vetting").

<sup>138</sup> Shapiro, *The Information Quality Act and Environmental Protection: The Perils of Reform by Appropriations Rider*, *supra*, n. 135 at 359, n. 114 (citing Nat'l Assessments Synthesis Team, US Global Change Research Program, *Climate Change Impacts on the United States: The Potential Consequences of Climate Variability and Change* (2000)).

<sup>139</sup> OMB's Information Quality Act Report at 30, 119.

<sup>140</sup> EPA Letter to CEI re: Information Quality Guidelines Request for Reconsideration #7428A, September 23, 2003, <http://www.epa.gov/quality/informationguidelines/documents/7428AresponseetoCEI.pdf>.

<sup>141</sup> OMB Watch, The OMB Watcher, First Data Quality Lawsuit Filed, August 11, 2003, <http://www.ombwatch.org/article/articleview/1733/1/185/>.

<sup>142</sup> See U.S. National Assessment of the Potential Consequences of Climate Variability and Change, <http://>

[www.usgcrp.gov/usgcrp/nacc/](http://www.usgcrp.gov/usgcrp/nacc/); see also OMB Watch, The OMB Watcher, First Data Quality Lawsuit Filed, August 11, 2003, <http://www.ombwatch.org/article/articleview/1733/1/185/>.

<sup>143</sup> EPA's Response to CEI's Request for Reconsideration, September 23, 2003, 3, <http://www.epa.gov/quality/informationguidelines/documents/7428AresponsetoCEI.pdf>.

<sup>144</sup> EPA Response to Correction of Science Advisory Panel (SAB) Meeting Minutes, March 5, 2003, at 2, <http://www.epa.gov/quality/informationguidelines/documents/4301Response.pdf>.

<sup>145</sup> Center for Regulatory Effectiveness Request for Correction regarding Technical Review of Diisononyl Phthalate, October 16, 2003, <http://www.epa.gov/quality/informationguidelines/documents/13166rfc.pdf>.

<sup>146</sup> U.S. EPA Letter to American Chemistry Council Phthalate Esters Panel, March 15, 2004, <http://www.epa.gov/quality/informationguidelines/documents/13166Response.pdf>.

<sup>147</sup> Letter from William G. Kelly, Center for Regulatory Effectiveness (CRE) to EPA Water Docket (February 27, 2003), [http://www.thecre.com/pdf/20030310\\_biosolids.pdf](http://www.thecre.com/pdf/20030310_biosolids.pdf).

<sup>148</sup> Chemical Products Corporation Request for Correction of the IRIS Barium and Compounds Substance File, October 29, 2002, at 2, <http://www.epa.gov/quality/informationguidelines/documents/2293.pdf>. See also Request for Correction of Information: Petition to Cease Dissemination of the Biological Reference Points for Northeast Multispecies (New England Groundfish) contained in Draft Multispecies FMP, October 16, 2003, filed with NOAA, [http://www.ombwatch.org/info/dataquality/Commerce\\_NOAA\\_GroundfishRequest.pdf](http://www.ombwatch.org/info/dataquality/Commerce_NOAA_GroundfishRequest.pdf) (requesting that the agency "immediately" cease dissemination of reference points for groundfish).

<sup>149</sup> Wagner, *The "Bad Science" Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, *supra*, n. 62 at 100, n. 165 (citing Thomas O. McGarity, *Politics by Other Means: Law, Science, and Policy in EPA's Implementation of the Food Quality Protection Act*, 53 ADMIN L. REV. 103, 146 (2001)).

<sup>150</sup> EPA Guidelines at 21.

<sup>151</sup> See Thomas O. McGarity, *On the Prospect of 'Daubertizing' Judicial Review of Risk Assessment*, 66 LAW AND CONTEMPORARY PROBLEMS 155, 175 (2003).

<sup>152</sup> Noe, *supra*, n. 56, *Learning to Live With the Information Quality Act*, at 10231.

<sup>153</sup> Request for Correction of Information and to Prevent EPA's Approval of Air Credits and State Implementation Plan Amendments that Violate EPA's Data Quality Guidelines, filed with EPA by Willkie Farr & Gallagher, June 2, 2004, <http://www.epa.gov/quality/informationguidelines/documents/04020.pdf>.

<sup>154</sup> Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, *supra*, n. 50, at 601; Wagner, *The "Bad Science" Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, *supra*, n. 62 at n. 187.

<sup>155</sup> See OMB Guidelines, 67 FR 8452, 8460, §V.5, see also Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, *supra*, n. 50 at 595.

<sup>156</sup> OMB Information Quality Act Report, at 11.

<sup>157</sup> See, e.g., James W. Conrad, Jr., *The Information Quality Act – Antiregulatory Costs of Mythic Proportions?*, 12 KAN. J. OF LAW & PUB. POL'Y 521, 534-35 (2003) (pointing out GAO and ABA recommendations that error correction processes be implemented, but acknowledging that these recommendations extended to correction of factual errors, and not to the correction of the quality of information).

<sup>158</sup> Center for Regulatory Effectiveness Information Quality Act Request for Correction regarding atrazine, November 25, 2002, <http://www.epa.gov/quality/informationguidelines/documents/2807.pdf>.

<sup>159</sup> Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, *supra*, n. 50 at 601.

<sup>160</sup> U.S. EPA Response to Comments from Syngenta and its Contractors, March 26, 2003, 19, [http://www.epa.gov/quality/informationguidelines/documents/2807Response\\_03\\_27\\_03.pdf](http://www.epa.gov/quality/informationguidelines/documents/2807Response_03_27_03.pdf).

<sup>161</sup> Center for Regulatory Effectiveness, et. al., Information Quality Act Request for Correction of Information re: RoC Procedures, June 28, 2004, [http://thecre.com/pdf/20040630\\_IQA\\_petition.pdf](http://thecre.com/pdf/20040630_IQA_petition.pdf); see also "Industry Files Data Challenge to Block Cancer Review of Widely Used Herbicide," *Inside EPA*, July 6, 2004, [http://www.thecre.com/quality/20040706\\_insideepa.html](http://www.thecre.com/quality/20040706_insideepa.html).

<sup>162</sup> Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, *supra*, n. 50, at 602.

<sup>163</sup> OMB Information Quality Act Report at 54; OMB Watch, The Watcher, August 9, 2004, "Data Quality Challenge Helps Bump Species from Consideration for

Endangered Species List,” <http://www.ombwatch.org/article/articleprint/2328/-1/259/>.

<sup>164</sup> OMB Watch, The Watcher, August 9, 2004, “Data Quality Challenge Helps Bump Species from Consideration for Endangered Species List,” <http://www.ombwatch.org/article/articleprint/2328/-1/259/>; see also U.S. Department of the Interior, U.S. Fish and Wildlife Service, Endangered and Threatened Wildlife and Plants; Withdrawal of Proposed Rule to List *Lepidium papilliferum* (Slickspot Peppergrass) as Endangered, 69 FR 3094, 3100 (January 22, 2004).

<sup>165</sup> U.S. Department of the Interior, U.S. Fish and Wildlife Service, Endangered and Threatened Wildlife and Plants; Withdrawal of Proposed Rule to List *Lepidium papilliferum* (Slickspot Peppergrass) as Endangered, 69 FR 3094, 3116 (January 22, 2004); OMB Watch, The Watcher, August 9, 2004, “Data Quality Challenge Helps Bump Species from Consideration for Endangered Species List,” <http://www.ombwatch.org/article/articleprint/2328/-1/259/>.

<sup>166</sup> OMB Watch, The Watcher, August 9, 2004, “Data Quality Challenge Helps Bump Species from Consideration for Endangered Species List,” <http://www.ombwatch.org/article/articleprint/2328/-1/259/>.

<sup>167</sup> See Goshawk Petitions, <http://www.ombwatch.org/article/articleview/1419/1/170/#usda>.

<sup>168</sup> U.S. Department of Agriculture, Forest Service, Letter to William K. Olsen, re: Request for Reconsideration, January 8, 2004, 1, <http://www.fs.fed.us/qoi/RequestforReconsideration/RFR030010/theresponse.pdf>.

<sup>169</sup> U.S. Department of Agriculture, Forest Service, Letter to William K. Olsen, re: Request for Reconsideration, January 8, 2004, 2, <http://www.fs.fed.us/qoi/RequestforReconsideration/RFR030010/theresponse.pdf>.

<sup>170</sup> Request for Correction from David A. Smith, re: bromate, <http://www.epa.gov/quality/informationguidelines/documents/12029.pdf>, Request for Correction from David A. Smith re: bromate, <http://www.epa.gov/quality/informationguidelines/documents/12385.pdf>.

<sup>171</sup> Request for Reconsideration from David A. Smith, September 23, 2004, <http://www.epa.gov/quality/informationguidelines/documents/12385A.pdf>; see also EPA Interim Response to Request for Reconsideration from David A. Smith, December 22, 2004, <http://www.epa.gov/quality/informationguidelines/documents/12385A-interim.pdf>.

<sup>172</sup> Request for Correction, Perchlorate Advisory Levels, July 5, 2003, <http://www.epa.gov/quality/informationguidelines/documents/11702.pdf>.

<sup>173</sup> EPA Response to Perchlorate Request for Correction, February 23, 2004, <http://www.epa.gov/quality/informationguidelines/documents/percRFC11702.pdf>.

<sup>174</sup> BMW Manufacturing Corp. Request for Correction to EPA, February 7, 2003, <http://www.epa.gov/quality/informationguidelines/documents/7421.pdf>.

<sup>175</sup> BMW Manufacturing Corp. Request for Reconsideration to EPA, November 25, 2003, <http://www.epa.gov/quality/informationguidelines/documents/7421A.pdf>.

<sup>176</sup> EPA Response to Request for Reconsideration (RFR) on BMW’s Designation of Significant Non-compliance (SNC), May 13, 2004, <http://www.epa.gov/quality/informationguidelines/documents/7421A-response.pdf>.

<sup>177</sup> See Request for Interested Party Status and Comments Submitted on Quality of Information Petitions Regarding Northern Goshawks on the Tongass National Forest, June 24, 2003, Center for Biological Diversity, et. al., 8-11, <http://www.biologicaldiversity.org/swcbd/species/goshawk/intervention2003.pdf>.

<sup>178</sup> OMB Information Quality Act Report at 27-29; 53-54.

<sup>179</sup> Center for Regulatory Effectiveness Request for Correction regarding Technical Review of Diisononyl Phthalate, October 16, 2003, <http://www.epa.gov/quality/informationguidelines/documents/13166rfc.pdf>.

<sup>180</sup> Center for Regulatory Effectiveness Request for Correction regarding Technical Review of Diisononyl Phthalate, October 16, 2003, <http://www.epa.gov/quality/informationguidelines/documents/13166rfc.pdf>.

<sup>181</sup> S. 1844, Clear Skies Act of 2003, Sec. 407(j).

<sup>182</sup> OMB Information Quality Act Report at 8.

<sup>183</sup> Shapiro, *The Information Quality Act and Environmental Protection: The Perils of Reform by Appropriations Rider*, *supra*, n. 135 at 350.

<sup>184</sup> *Id.*

<sup>185</sup> OMB, Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities, at 26, [http://www.whitehouse.gov/omb/inforeg/2002\\_report\\_to\\_congress.pdf](http://www.whitehouse.gov/omb/inforeg/2002_report_to_congress.pdf).

<sup>186</sup> Wagner, *The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental*

*Regulation*, *supra*, n. 62 at 85, n. 89 (citing Sidney A. Shapiro & Robert L. Glicksman, Risk Regulation at Risk: Restoring a Pragmatic Approach 15 (2003)).

<sup>187</sup> *Id.* at n. 93 (citing Clean Water Act, 33 U.S.C. §1311(b)(2)(C)-(D) (2000); Clean Air Act, 42 U.S.C. § 7412(b) (2000)).

<sup>188</sup> *Id.* at 86.

<sup>189</sup> Chemical Products Corporation Request for Correction of the IRIS Barium and Compounds Substance File, October 29, 2002, at 2, <http://www.epa.gov/quality/informationguidelines/documents/2293.pdf>. *See also* Request for Correction of Information: Petition to Cease Dissemination of the Biological Reference Points for Northeast Multispecies (New England Groundfish) contained in Draft Multispecies FMP, October 16, 2003, filed with NOAA, [http://www.ombwatch.org/info/dataquality/Commerce\\_NOAA\\_GroundfishRequest.pdf](http://www.ombwatch.org/info/dataquality/Commerce_NOAA_GroundfishRequest.pdf) (requesting that the agency “immediately” cease dissemination of reference points for groundfish).

<sup>190</sup> EPA Letter to Chemical Products Corporation re: Request for Correction of the IRIS Barium and Compounds Substance File, January 30, 2003, 4, <http://www.epa.gov/quality/informationguidelines/documents/2293Response.pdf>.

<sup>191</sup> EPA Letter to Chemical Products Corporation re: Request for Correction for Barium and Compounds, December 11, 2003, <http://www.epa.gov/quality/informationguidelines/documents/2293AResponse.pdf>.

<sup>192</sup> EPA Letter to Chemical Products Corporation re: Request for Correction for Barium and Compounds, December 11, 2003, 2, <http://www.epa.gov/quality/informationguidelines/documents/2293AResponse.pdf>.

<sup>193</sup> Perchlorate Study Group, Request for Correction, December 22, 2003, <http://www.epa.gov/quality/informationguidelines/documents/13679.pdf>.

<sup>194</sup> EPA, Response to Perchlorate Study Group’s Request for Correction, September 15, 2004, available at: <http://www.epa.gov/quality/informationguidelines/documents/13679-response.pdf>.

<sup>195</sup> *Id.* at 1.

<sup>196</sup> *Id.* at 2.

<sup>197</sup> OMB Information Quality Act Report at 51; U.S. Chamber of Commerce, Salt Institute Petition to National Heart, Lung, and Blood Institute, May 14, 2003, at 2, <http://www.uschamber.com/NR/rdonlyres/pjwabkg7qr2u7x7v64muvkhfei6jnvovvuxcljo3naowkz2a/DQPETITIONNHLBI.pdf>.

<sup>198</sup> OMB Information Quality Act Report at 51; HHS Response, August 19, 2003, [http://www.ombwatch.org/info/dataquality/HHS\\_SaltResponse.pdf](http://www.ombwatch.org/info/dataquality/HHS_SaltResponse.pdf).

<sup>199</sup> Salt Institute, et. al. v. Tommy Thompson, Secretary, U.S. Department of Health and Human Services, 04-CV-359 GBL, Memorandum in Support of Defendant’s Motion to Dismiss, June 25, 2004.

<sup>200</sup> Salt Institute, et. al. v. Tommy Thompson, Secretary, U.S. Department of Health and Human Services, 04-CV-359 GBL, Memorandum in Support of Defendant’s Motion to Dismiss, June 25, 2004.

<sup>201</sup> “Judge Questions Industry Effort to Have Courts Hear Data Law Complaints,” *Inside EPA*, September 3, 2004.

<sup>202</sup> *Salt Inst. v. Thompson*, 345 F. Supp.2d 589, 603 (E.D. Va. 2004); *accord In re: Operation of the Missouri River Sys. Litig.*, 2004 WL 1402563 (D. Minn. June 21, 2004) (slip op.).

<sup>203</sup> *Salt Inst. v. Thompson*, 345 F. Supp.2d at 593.

<sup>204</sup> *Id.* at 601.

<sup>205</sup> *Id.* at 602-03.

<sup>206</sup> *Id.* at 602.

<sup>207</sup> “Industry Could Face Tough Precedent in Appeal of Data Quality Case,” *InsideEPA*, January 21, 2005.

<sup>208</sup> Petition for Disclosure and Correction to EPA, Greenberg Traurig on behalf of NPC Services, Inc., August 30, 2004, <http://www.epa.gov/quality/informationguidelines/documents/04023.pdf>.

<sup>209</sup> *Id.*

<sup>210</sup> EPA Response to NPC Services, Inc. Petition, December 16, 2004, <http://www.epa.gov/quality/informationguidelines/documents/04023-response.pdf>.

<sup>211</sup> *Id.*; *See also* 69 Fed. Reg. 10646, 10649 (March 8, 2004).

<sup>212</sup> The comment period on the proposed listing closed on May 7, 2004. 69 Fed. Reg. 10646. NPC’s IQA Petition was submitted on August 30, 2004.

<sup>213</sup> Eileen Gauna, *An Essay on Environmental Justice: The Past, The Present, and Back to the Future*, 42 NAT. RES. J. 701, 713 (2002) (noting that the IQA may make it increasingly difficult to access information about contamination in minority neighborhoods).

<sup>214</sup> *See, e.g.*, Andrew Schneider, EPA Warning on Asbestos is Under Attack, *St. Louis Post-Dispatch*, Oct. 26, 2003, at A1.

<sup>215</sup> Request for Correction filed with EPA by Taylor, Porter, Brooks, and Phillips on behalf of Dow Chemical

Company, June 14, 2004, <http://www.epa.gov/quality/informationguidelines/documents/04021.pdf>.

<sup>216</sup> *Id.* at 4.

<sup>217</sup> *Id.* at 12.

<sup>218</sup> *Id.* at 8.

<sup>219</sup> EPA Response to Request for Correction filed by Taylor, Porter, Brooks and Phillips on behalf of Dow Chemical Company, October 6, 2004, <http://www.epa.gov/quality/informationguidelines/documents/04021-response.pdf>. EPA further noted that the concerns about the model raised by Dow are outside the purview of EPA's Information Quality Guidelines and fail to raise substantial technical concerns. *Id.*

<sup>220</sup> Request for Reconsideration filed with EPA by Taylor, Porter, Brooks and Phillips on behalf of Dow Chemical Company, January 3, 2005, <http://www.epa.gov/quality/informationguidelines/documents/04021A.pdf>.

<sup>221</sup> "EPA Approval of State Paint Emissions Rules Would Violate Information Quality Act, Industry Says," *BNA Environment Reporter*, June 25, 2004, at 1359.

<sup>222</sup> See, e.g., Lisa Heinzerling, *Reductionist Regulatory Reform*, 8 *FORDHAM ENVTL. L. J.* 459, 460 (1997).

<sup>223</sup> Frank Ackerman and Lisa Heinzerling, *Priceless: On Knowing the Price of Everything and the Value of Nothing* (New York: The New Press, 2004), 37.

<sup>224</sup> *Id.*

<sup>225</sup> Heinzerling, *supra*, n. 220 at 461.

<sup>226</sup> OMB, Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities, 27, December 2002, [http://www.whitehouse.gov/omb/inforeg/2002\\_report\\_to\\_congress.pdf](http://www.whitehouse.gov/omb/inforeg/2002_report_to_congress.pdf); see also Comments of Wendy Wagner, University of Texas School of Law on Draft 2002 Report, June 8, 2002, n. 5, <http://www.whitehouse.gov/omb/inforeg/comments/comment104.pdf>.

<sup>227</sup> OMB Guidelines, 67 FR at 8452-53.

<sup>228</sup> Letter from Dr. John Graham, Administrator, OIRA to Dr. Elias Zerhouni, Director, NIH (November 16, 2004), available at: [http://www.whitehouse.gov/omb/inforeg/prompt/nih\\_ntp111604.pdf](http://www.whitehouse.gov/omb/inforeg/prompt/nih_ntp111604.pdf).

<sup>229</sup> Letter from the Honorable Joe Barton, Chairman, House Energy and Commerce Committee to: U.S. Department of Energy; DHHS, NIH, Food and Drug Administration, Centers for Medicare & Medicaid Services; EPA; U.S. Department of Commerce; National Highway Traffic Safety Administration; Federal Trade Commission; Federal Communications Commission; CPSC; Federal Energy Regulatory Commission; National Transportation Safety Board; U.S. Chemical Safety and Hazard Investigation Board; and U.S. Nuclear Regulatory Commission (January 13, 2005), available at: [http://energycommerce.house.gov/108/News/01132005\\_1422.htm](http://energycommerce.house.gov/108/News/01132005_1422.htm).

### About the Center for Progressive Regulation

*Founded in 2002, the Center for Progressive Regulation is a nonprofit research and educational organization of university-affiliated academics with expertise in the legal, economic, and scientific issues related to regulation of health, safety, and the environment. CPR supports regulatory action to protect health, safety, and the environment, and rejects the conservative view that government's only function is to increase the economic efficiency of private markets. Through research and commentary, CPR seeks to inform policy debates, critique anti-regulatory research, enhance public understanding of the issues, and open the regulatory process to public scrutiny. Direct media inquiries to Matthew Freeman at [mfreeman@progressiveregulation.org](mailto:mfreeman@progressiveregulation.org). For general information, email [info@progressiveregulation.org](mailto:info@progressiveregulation.org). Visit CPR's website at [www.progressiveregulation.org](http://www.progressiveregulation.org). The Center for Progressive Regulation is grateful to the Deer Creek Foundation for its generous support of this project and CPR's work in general.*



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