

## **I. JURISDICTION**

Plaintiffs Salt Institute ("Salt") and The Chamber of Commerce of the United States ("The Chamber") (collectively "Plaintiffs") seek relief from a dismissal of their claims against the Secretary, Department of Health and Human Services, an agency of the United States, ("Defendant" or "HHS"), under Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedures. Final judgment was entered on November 15, 2004. See J.A.74. Plaintiffs filed a timely notice of appeal on January 11, 2005. See J.A.104. This Court has appellate jurisdiction under 28 U.S.C. § 1291. The district court's jurisdiction was alleged under 28 U.S.C. § 1331. The district court held that it had no subject matter jurisdiction over Plaintiffs' claims, therefore, subject matter jurisdiction is at issue in this appeal.

## **II. ISSUES PRESENTED**

This is the first case arising under the Information Quality Act ("IQA"), 44 U.S.C. § 3516 note, to be considered by a United States Court of Appeals. In deciding this case, the Court will determine whether Congress enacted the IQA to create meaningful and enforceable public rights or whether the IQA is a lesser breed of statute, merely admonishing agencies to ensure the validity of the scientific and technical information on which they rely but requiring nothing more. The questions presented are:

1. Do Plaintiffs have constitutional and prudential standing to challenge Defendant's denial of their request for relief under the IQA.
2. Is Defendant's refusal to grant IQA relief or even consider Plaintiffs' request for it, subject to judicial review under the standards prescribed in Section 10 of the Administrative Procedure Act("APA"), 5 U.S.C. §§ 701-706; as supplemented by the IQA and Guidelines for IQA review promulgated by the Office of Management and Budget ("OMB"), the Department

of Health and Human Services (“HHS”), and the National Institutes of Health (“NIH”).

### III. STATEMENT OF THE CASE

#### A. Statutory And Regulatory Background

The IQA was enacted by Congress in December 2000 and was codified in Paperwork Reduction Act. Pub. L. No. 106-554 § 1 (a)(3), 114 Stat. 2763 (2000).

It provides:

- 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 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.

Codified at 44 U.S.C. § 3516 note.

Following notice and comment, OMB's final Guidelines were published in the Federal Register on February 22, 2002. 67 Fed. Reg. 8452 (Feb. 22, 2002). The OMB Guidelines instruct each covered agency (which includes Defendant) to publish their own "information quality guidelines ensuring and maximizing the quality, objectively, utility and integrity of information, including statistical information disseminated by the agency..." and to "Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines." 67 Fed. Reg. at 8458, §§ II (1),(2).

In particular:

As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has

disseminated through documentation or other means appropriate to the information.

To facilitate public review, agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines. These administrative mechanisms shall be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into agency information resources management and administrative practices.

Id. at 8459.

Agencies are required to specify deadlines for their own decisions on "whether and how to correct" information that does not meet the applicable criteria, and to establish an "appellate" process with time limits, for the review or reconsideration of the agency's decisions in response to a correction request. Id. The quality criteria to be applied in adjudicating a request for correction are extensively detailed and defined. With a view toward maximizing the quality of information disseminated to the public, the OMB Guidelines exhaustively define the terms "quality", "utility", "objectively", "integrity", "information", "dissemination", and reproducibility", among other things. Id. at 8459-60. For example, each agency must, when asked,

"identify the sources of disseminated information...and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation and error sources affecting data quality should be identified and disclosed to users."

Id. at 8459 § V(3)(a). The OMB Guidelines suggest no exemptions, nor do they authorize any agency to opt out of the program if they want to do so.

On October 1, 2002, Defendant published its own IQA guidelines. The HHS Guidelines include sub-agency-specific guidelines for the NIH, which apply in this case (see S.R.34; <http://www.hhs.gov/infoquality/NIH.info2.html>). HHS' Guidelines set forth agency IQA policy, specify the administrative procedure for seeking a correction of publicly disseminated information, and create an appellate procedure. They also set time lines for agency action and make the Administrative Procedure Act's public comment and rule-making process including "established procedural safeguards" applicable "to information quality complaints that arise." See S.R.25-37 at Part I(E) Overview of HHS Agency Complaint Procedure; <http://aspe.hhs.gov/infoquality/Guidelines/part1.shtml>)

The NIH Guidelines generally cross-reference the OMB and HHS Guidelines and specify that the "burden of proof", "with respect to the necessity for correction, as well as with respect to the type of correction they seek" rests with the party seeking a correction. *Id.* NIH Guidelines ¶ VI; S.R.53-57. NIH details the various methods it will employ to respond to a complaint. The remedies include the referral of complainants to the underlying data supporting the dissemination and making arrangements for a re-analysis of that data at the complainant's expense. *Id.* at ¶ 3; S.R.54-55. NIH emphasizes its obligation to disclose sufficient data, assumptions, analytical methods and statistical procedures "making the analysis sufficiently transparent so as to be capable of being reproduced."

B. The Plaintiffs' IQA Request

The National Heart, Lung and Blood Institute (NHLBI), a component of NIH, has for many years funded research concerning the relationship between sodium consumption (mostly from salt usage), high blood pressure and the potentially serious consequences of high blood pressure on human health. A 1997 research study called Dietary Approaches to Stop Hypertension ("DASH Study") published in the New England Journal of Medicine ("NEJM") reported findings

that a healthy low-fat, high fiber diet can reduce blood pressure ("Dash Diet"). The Dash Diet did not restrict salt consumption. See L.J. Appel et al., A Clinical Trial of the Effects of Dietary Patterns on Blood Pressure, 336 New Eng. J. Med. 1117 (1997).

A follow up study conducted by the DASH-Sodium Collaborative Research Group and funded by NHLBI was designed to investigate the effect of dietary sodium consumption at three different levels<sup>1</sup> on a variety of population subgroups (the "Sodium Trial"). The overall group was divided between persons eating a Dash-type diet and persons eating a normal diet. The Sodium Trial was designed to determine whether modifying the Dash Diet by severely restricting salt intake would have a further beneficial effect on blood pressure. Compl. ¶ 18, J.A.10.

The Sodium Trial results also were published in the NEJM. Frank M. Sachs, M.D. et al., Effects of Blood Pressure on Reduced Dietary Sodium and the Dietary Approaches to Stop Hypertension Diet, 344 New Eng. J. Med 3, (Jan. 4, 2001). A follow-up reanalysis of the data across various subgroups was published later. Frank M. Sachs, M.D. et al., Effects of Diet and Sodium Intake on Blood Pressure: Subgroup Analysis of the DASH-Sodium Trial, 135 Annals of Internal Medicine 1019, 1025-26 (Dec. 18, 2001). Both articles concluded generally that a reduction in dietary sodium below normal consumption levels would result in "clinically relevant decreases in blood pressure in all subgroups of test subjects." Compl. ¶¶ 18-28, J.A.10-12.

These articles stirred controversy and were criticized within the relevant scientific community for methodological flaws, and for inadequate disclosure of underlying data. The absence of such data effectively precluded third parties from

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<sup>1</sup> The levels were 1500 mg/day, 2400 mg/day and 3300 mg/day.

testing the accuracy, objectivity, and reproducibility of the study results. Id.<sup>2</sup> Plaintiffs believe that the underlying data, when fully disclosed and analyzed according to accepted scientific and statistical methods, will not support the generalized proposition that a reduction in dietary sodium consumption<sup>3</sup> below normal levels has a beneficial effect across all or even most population subgroups, aligned by age, sex, race, ethnicity, body mass, family history, education and other factors.

Notwithstanding the unresolved controversy over the scientific and statistical accuracy of the conclusions drawn from the Sodium Trial research, NHLBI disseminated substantial and influential information to the public based upon the Sodium Trial, including:

- An October 15, 2002 NHLBI news release stating "limiting daily dietary sodium intake to less than 2400 mg of sodium (about 1 teaspoon of salt) per day helps lower or control blood pressure."
- An October 16, 2002 NEJM article contributed by the National High Blood Pressure Education Program citing the DASH-Sodium trial findings in support of the conclusion that reducing dietary sodium intake to no more than 1000 milligrams per day is a proper

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<sup>2</sup> In its opinion, the district court went far outside the pleadings to consider a number of articles addressing the effects of dietary sodium consumption on blood pressure. J.A.92. There has been no expert evaluation of whether this litany of authorities supports or detracts from Plaintiffs' basic premise that the Sodium Trial is of insufficient scientific rigor to justify agency reliance on it for the dissemination of important health information to the public. The agency claimed no reliance on these other articles and their content is simply not relevant to the issues presented in this case, nor is it appropriately considered. See Mylan Labs Inc. v. Matkari, 7 F.3d 1130, 1134 (4th Cir. 1993).

<sup>3</sup> Plaintiffs believe that a one-size-fits-all link between salt consumption and blood pressure outcomes is simply wrong.

lifestyle modification for "primary prevention" of hypertension even in persons with normal blood pressure.

- A December 17, 2001 NHLBI news release stating "reduced dietary sodium lowers blood pressure for all persons." In this release, NHLBI Director, Dr. Claude Lenfant is quoted stating "we can say that cutting back on dietary sodium will benefit Americans generally and not just those with high blood pressure."
- An agency website publication citing the DASH-Sodium trials in support of the statement "that reducing dietary sodium lowered blood pressure... at each sodium level."
- A second website publication entitled "Facts About Lowering Blood Pressure" citing the DASH-Sodium trials as support for the statements, "the less sodium consumed, the lower the blood pressure, and [that], the effects of sodium reduction were seen in cell study participants..." and;
- NHLBI's "Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure released on May 14, 2003 and published on the agency's website, recommending that "everyone" limit dietary sodium to no more than 2400 milligrams per day. Both the NEJM and Annals articles are cited.

Compl. ¶ 29, J.A.12-14

C. Plaintiffs' Exhaustion Of Administrative Remedies

On May 14, 2003, Plaintiffs filed an IQA complaint containing an extensively detailed request for "corrective action" to address scientific inaccuracies in disseminated information advising the public concerning the risks of high blood pressure related to salt consumption. J.A.24-40. Plaintiffs first explained that they were "affected" parties within the meaning of 515 (b)(2)(B) of the IQA. Salt identified itself as an association of members that produce and market sodium chloride (salt). It is asserted further that "the public's use of salt and salted products is ...heavily influenced by scientific findings of the federal



government." The Chamber identified itself as a business federation including "a substantial number of companies that use and/or market salt and salt products, including food manufacturers, grocers, restaurants, and the Salt Institute" among others. The Chamber thus claimed that its members are "affected by NHLBI's information concerning the relationships between sodium and blood pressure."

Salt and The Chamber asserted that disseminated information most likely did not comply with the quality criteria of the IQA or meet its standards of presentation, objectivity, transparency, and reproducibility. J.A.24-40. (Application For Correction, May 14, 2003). In support of these allegations, Salt and The Chamber quoted a letter authored by Dr. John H. Laragh described as "one of the Nation's foremost experts on hypertension." Id. at 12, J.A.36. Dr. Laragh stated,

In neither of the publications of the DASH-Sodium Trial was I able to identify a complete and objective presentation of the data that communications would allow an appropriate independent expert or entity to determine the validity of NHLBI's interpretation. Specifically only a full presentation of the mean blood pressures, their [standard deviations] and sample size for each of the subgroups that NHLBI stated in the NEJM paper the study was 'powered' to test for, would suffice to confirm independently the validity of their public statements.... [O]nly a complete table of the blood pressures on the various combinations of the DASH Diet and dietary sodium level will allow interested parties to determine independently the validity of NHLBI's public posture on this important policy issue.

J.A. 36-37. In light of these concerns, the Application concluded "the agency is not in compliance with the Data Quality Act and its implementing guidelines, and the enumerated statements must be corrected."

The corrective process mandated by the IQA contemplates an investigative sequence of disclosure, testing, and verification, leading to more accurate information. Therefore, Salt and The Chamber proposed a procedure for testing

their belief that the information required correction or removal from the public domain, suggesting that NHLBI make the missing data available for analysis, while reserving the right to seek correction or removal if appropriate. J.A. 38-39. This approach is specifically authorized by the HHS/NIH guidelines as a logical and scientifically sound way of dealing with probable analytic errors in the agency's public communications.

The NIH Guidelines contain a lengthy and detailed treatise on the agency's commitment to information quality, transparency and research meeting the highest standards of scientific integrity. For example, NIH Guidelines § I stated:

It is NIH policy to make available to the public the results and accomplishments derived from the activities that it funds. Therefore, NIH-funded intramural and extramural investigators are expected to make the results and accomplishments of their activities available to the research community and to the public at large, and to effect their timely transfer to industry for commercialization.

See S.R. 36. Section V (1) stated:

NIH recognizes the scientific need for replication of findings, and encourages data sharing as appropriate. After publication, the research data, and unique reagents, and any supporting data that form the basis of the communication in question should be made available promptly and completely to all responsible scientists seeking further information.

See S.R. 43.

The NIH Guidelines invite persons requesting a correction to propose "corrective actions," reflecting an openness to a flexible menu of remedies for defective information. See NIH Guidelines § VI(1)-(3), S.R.53-55. Among the remedies NIH identified were the referral of the "complainant to the underlying data" if available, or to "arrange for an independent reanalysis of the data by NIH

or a mutually acceptable third party if the data are not publicly available, and the complaint involves 'influential' scientific or statistical information." Id. § VI(3).

The Defendant, however, failed to live up to its promises, or to follow either the letter or the spirit of the IQA. Engaging none of the flexible options and openness to the best science promised in the Guidelines, on August 19, 2003. NIH informed Salt and The Chamber that their application was more like a request for information under the Freedom of Information Act ("FOIA") and that the NIH IQA Guidelines were inapplicable to it. NIH stated that even if IQA did apply, the application was of no moment because the disseminated information would meet NIH information quality standards, other research supported the disseminated information, and the DASH research had, in any case, been fairly extensively reviewed by scientists. J.A.42-47. Furthermore, NIH denied that the challenged information was "influential," and consequently determined that it is exempt from the IQA's reproducibility standards. Id. at J.A.44. NIH, however, did not explain why governmental advice recommending a reduction in consumption of a substance used by every American every day, and used extensively in the food manufacturing industry, is not "influential."

As a result of NIH's action, HHS's promise of APA rulemaking type rights and safeguards also was broken.

On September 3, 2003, NIH supplemented its IQA denial by denying the FOIA request Salt and The Chamber never made. J.A. 49-50. In this denial, NIH opined that the data requested were not subject to FOIA disclosure. Id.

On September 22, 2003, Salt and The Chamber filed a timely appeal of NHLBI's IQA denial. J.A. 52-67. Each of the reasons for the denial was addressed and disputed. NHLBI was asked to correct the disputed information and cease disseminating it. The appeal pointed out, in particular, that the efforts made to obtain and validate missing data to insure objectivity and reproducibility

did not convert the IQA request into a FOIA request. The appeal argued generally that NHLBI's approach to the application, and indifference to the scientific and statistical shortcomings alleged, paid little respect to the principles embodied in, and requirements of, the IQA statute and guidelines, frustrating Congress' objectives and violating the law. Id.

The appeal was denied on February 11, 2004. The denial asserted that adequate standards of reproducibility, which did not in any event apply, had been met. The agency also suggested that a request for the missing data be submitted directly to the third party researchers. J.A. 69-73.

D. Judicial Proceedings

On March 31, 2004, Salt and The Chamber filed suit in the U.S. District for the Eastern District of Virginia seeking review of Defendant's refusal to follow the IQA.<sup>4</sup> Defendant filed a Motion to Dismiss under Rules 12 (b)(1) and (6) of the

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<sup>4</sup> Plaintiffs also alleged a violation of their rights to the full disclosure of federally-funded research data under the Shelby Amendment, Pub. L. No. 105-277, 112 Stat. 2681 (1998). The Shelby Amendment requires OMB to amend § .36 of OMB Circular A-110 to require Federal agencies to ensure that all data produced under research awards will be made available to the public through the procedures established under the Freedom of Information Act. H.R. Conf. Rep. No. 105-789 at 17 (1999). Post-Shelby, all federal agencies must treat federally funded research data as available for FOIA disclosure. Nevertheless, the district court held that NHLBI's refusal to disclose the requested data under FOIA was not subject to judicial review because: "As with their claims under the IQA, Plaintiffs lack standing because they have not alleged an injury that is sufficiently particularized and concrete to satisfy the constitutional requirements for standing." J.A. 101. Here, the district court departed from an unbroken line of Supreme Court decisions holding that no more is required to establish Article III standing under FOIA than a request for information and a denial of that request. Public Citizen v. United States Dep't of Justice, 491 U.S. 440, 459 (1989). Plaintiffs have not appealed this aspect of the district court's holding because the amendment to A-110 to incorporate the requirements of Shelby applies only to grants awarded after April 17, 2000, thus excluding the grants awarded for the DASH-Sodium trials, and to data or research supporting agency action with the force and effect of law. See 64 Fed. Reg. 54526

Federal Rules of Civil Procedure. The Rule 12(b)(6) motion was granted by the district court on November 15, 2004. It held:

1. Plaintiffs lack Article III or constitutional standing to enforce a denial of disclosure and correction rights under the IQA because:
  - (a) Plaintiffs suffered no specific injury and allege no injuries other than the agency's refusal to disclose or correct;
  - (b) Plaintiffs' injury is neither actual nor imminent because any economic consequences flowing from disseminated information disparaging salt consumption are hypothetical and the result of actions of third parties, and in any event no such economic injury was alleged;
  - (c) Plaintiffs' injury is not fairly traceable to NHLBI's actions because "numerous other scientific studies [none of which are in the record] have reached the conclusion that reducing sodium intake reduces blood pressure [citation omitted]";<sup>5</sup>
  - (d) Plaintiff's injuries are not redressable by the court, because the other non-record articles would remain in circulation whether or not NHLBI changed its public information and thus would do the same harm to plaintiffs that would flow from the NHLBI publications and website information.<sup>6</sup>

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(Oct. 8, 1999). Plaintiffs argued below that OMB's rules so limiting Shelby's scope are not authorized; however, they have chosen not to pursue the line of argument in this appeal because there is no clear statutory mandate to apply Shelby retroactively.

<sup>5</sup> Curiously, the court offers its opinion that the Sodium Trial data, if correctly reported, would do more harm to Plaintiffs than a non-disclosure. J.A.90.

<sup>6</sup> Organizational standing was denied as well on the theory that no member of Salt or The Chamber would have standing to sue and accordingly their organizations have no standing.

2. Plaintiffs had no right to judicial review even if they had standing because:
  - (a) The IQA did not expressly include a right to review and the plain language of the IQA evidences Congressional intent to preclude judicial review and constrain the rights of a party making a request under the IQA to "administrative proceedings before federal agencies and not in the courts." (The Court cited no language in the IQA evidencing an intent by Congress to preclude judicial review once the administrative process had been completed);
  - (b) The Administrative Procedure Act did not authorize review because an agency's advisory recommendations are not final agency action. (The court did not consider the central issue actually raised by Salt and the Chamber - whether the final denial of an application for access to data or a correction is or is not APA final agency action.); and
  - (c) Agency IQA action was "committed to agency discretion by law" and thus is not subject to review under the APA, for "neither the IQA nor the OMB Guidelines provide judicially manageable standards that would allow meaningful judicial review to determine whether an agency properly exercised discretion in deciding a request to correct a prior communication." The court characterized NHLBI's decision to grant or deny a correction as "discretionary" and concluded the IQA and OMB Guidelines at issue insulate the agency's determination of when a correction of information contained in informal agency statements is warranted.

This timely appeal followed.

#### IV. STATEMENT OF FACTS

All of the facts relevant to the proceedings below are set forth in the foregoing statement of the case. Legislative facts arguably relevant to the court's understanding of the text and the IQA's context are set forth below.

The enactment of the APA followed many years of Congressional concern that the business of government was compromised by a lack of uniform procedures, the exclusion of meaningful public rights to participate in agency lawmaking and a lack of uniform public remedies to address agency indifference to public rights and concerns. These deficits in the behavior of agencies not only harmed the public, they undermined the Constitutional authority of Congress as well and the Constitutional mandate of legislative supremacy. See Richard B. Stewart & Cass R. Sunstein, Public Programs and Private Rights, 95 Harv. L. Rev. 1193, 1200 (1982); see also generally Administrative Procedure Act, Legislative History, 79th Cong. 1944-46 (1946).

As the APA was evolving and for many years thereafter, agencies influenced public behavior principally by rulemaking and formal adjudication. Adherence to the standards of uniformity, fairness, public openness, as well as the principles of good science were enforced by the centerpiece of the APA, which was readily available judicial review of agency action. Stewart, et al., supra at 1200. The public dissemination of information by agencies outside of rulemaking and administrative adjudication was not addressed in these early days and, of course, the public dissemination of information intended to influence the public on matters of interest to it was not nearly so pervasive as it is today. See Ernest Gelhorn, Adverse Publicity by Administrative Agencies, 86 Harv. L. Rev. 1380, 1426-27 (1973).

By the 1990s, Congress and others had become concerned by the bureaucracy's growing practice of using science generated by third-party

researchers to make policy,<sup>7</sup> and its reliance on the Internet, and non-regulatory methods of communicating rather than on formal APA rulemaking or adjudication, to announce policy and influence private behavior.<sup>8</sup> This "regulation by information" allowed agencies, for the most part, to evade judicial review, and effectively sidestep the APA.

In 1995, Congress enacted the Paperwork Reduction Act ("PRA"). 44 U.S.C. § 3501 et seq. The PRA directed the Office of Management and Budget ("OMB") to implement "policies, principles, standards, and guidelines" to ensure the quality of the information used and disseminated by federal agencies, and to promote public access to that information. See 44 U.S.C. § 3504(d).

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<sup>7</sup> For example, in 1997, a U.S. Senator asked the Environmental Protection Agency ("EPA") Administrator to produce scientific data used to formulate a controversial policy. EPA advised it did not have the data, had never independently reviewed the underlying research, and had formulated policy based on summary findings reported in "peer-reviewed" studies. EPA further advised that the data was FOIA-exempt because it was in the possession of third party researchers, not the agency. See Sen. Richard Shelby, Accountability and Transparency: Public Access to Federally Funded Research Data, 37 Harv. J. on Legis., 369, 373-75 (2000) (citations omitted); see also General Accounting Office, Pub No. GAO/RCED-98-245, Environmental Information: Agencywide Policies And Procedure Are Needed For Epa's Information Dissemination, at 19 (Sept. 1998); ABA House of Delegates 2001 Annual Meeting, Daily J. of the AM. Bar Assoc., Report No. 107c, at 17, 20 (Aug. 6-7, 2001) ("Recommendation concerning significantly agency information dissemination activities intended to promote policy goals,"); see generally James W. Conrad, The Information Quality Act-Antiregulatory Costs of Mythic Proportions?, 12 Kan. J.L. & Pub. Pol'y, 521, 526 (2003) (citations omitted).

<sup>8</sup> See, e.g., Environmental Law Institute, The Environmental Forum 36 (July/August 1998) (former EPA General Counsel noted information dissemination can be a supplement or alternative to formal regulation); 67 Fed. Reg. at 8452 (the Internet "increases the potential harm that can result from information that does not meet basic quality principles.")